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Dual-Use Science and Bioethics:
Governance of Biotechnology in Post-Soviet Russia

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Submitted for the Degree of
Doctor of Philosophy

Faculty of Social Sciences
University of Bradford

2015

Abstract

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Title: Dual-Use Science and Bioethics: Governance of Biotechnology in Post-Soviet Russia

Keywords: dual use, biotechnology, biosecurity, bioethics, Russia, governance

Throughout the world, systems of life science governance carry historical, cultural, and political legacies, which now confront the revolutionary and pervasive advances of twenty-first century biotechnology. Nations' adaptability to the twin challenges of attempting to secure the benefits while reducing the risks and threats is a large and still burgeoning governance challenge. The legacy of the Soviet Union is particularly important in this regard, since its history of prolonged authoritarian rule and intense development of biological weapons in combination with the continuing scientific and technological prowess of Russia is a governance challenge, unprecedented in its nature and scale. The aim of the dissertation therefore is to examine to what extent and by what means it is possible for Russia to reconcile its on-going expansion in biotechnology with the institutional and normative inertia arising from its Soviet past. The first part of the dissertation (Chapters 1-4) seeks to uncover and analyse both the growth and consolidation of the governance of biotechnology and the multifaceted governance challenges brought about by the rapid advancement of the life sciences in the twenty-first century. The second part (Chapters 5-8) examines the extent to which the Soviet institutional and infrastructural legacies in the culture of life science research still persist in Russia and impact the governance of biotechnology in that country. The concluding chapter offers an assessment of the current state of the governance of biotechnology in Russia and outlines a scope for further research.

Acknowledgement

Completing my dissertation has been by far the most exciting, enriching and intellectually stimulating journey I have ever experienced. I have been extremely lucky to work with an outstanding supervisory team. I am deeply indebted to my supervisor, Professor Jim Whitman for his excellent guidance throughout the project, especially in its early stages when finding a direction was nothing less than a challenge. His kind support and invaluable insights have proved indispensable for shaping my thoughts and finding my own voice during the process of writing. And his professionalism, wide-ranging scholarship, and deep commitment to academic excellence have been a constant source of inspiration, nurturing my perseverance and curiosity. I am absolutely grateful to my supervisor, Dr Simon Whitby for his always helpful interventions and feedback which have tremendously helped me refine my ideas but even more so, for bringing to my attention the issue of dual use in the life sciences during an Arms Control class in my second year as an undergraduate student. I owe a great debt of gratitude both to him and to Professor Malcolm Dando for getting me involved in and allowing me to work alongside them, first as an intern and subsequently as a doctoral candidate on various initiatives related to biosecurity education. This has been one of the most rewarding and enjoyable learning experiences I have had and I will always cherish deep appreciation for the opportunities I have been given over the past five years. Equally, I am grateful to the many colleagues and esteemed scholars whom I have met and had the pleasure of interacting with throughout the research. The list is too long to name each and every one of them but in particular thanks should go to Professor Graham Pearson, Dr Jo Husbands, Professor Maurizio Martellini and all wonderful individuals at the Landau Network-Centro Volta, Dr Karin Hjalmarsson and the staff of the United Office for Disarmament Affairs – Geneva Branch, and last but certainly not least, the numerous colleagues from Russia and other FSU countries who kindly agreed to take part in the project and found time to talk to me. Further thanks should go to the Wellcome Trust without whose generous support the research would have been impossible. Looking back

on my pre-Bradford days, I am grateful to my mid-school teacher, Mrs Diana Raykova who sparked in me a long-lasting interest in biology. First English Language School (Sofia) prepared me for the school of life. The classes of Mr Nikolay Nikolov, Ms Tonka Koleva, Mrs Antonia Kraeva and Mrs Mariana Iordanova tremendously broadened my horizons and helped me develop my critical thinking, love for reading, and attention to detail. My friends have been a constant source of support, positive energy and encouragement and I doubt that I would have made it through so smoothly had it not been for their re-assurance and persistent faith in me. Again, the list is way too long to name all of them but a few deserve an explicit mention: Cristina, who has been ‘mothering’ me over the past five years in Bradford; Katina, who is always there for me from any corner of the globe; Angie, whose motivation and hard-working nature will never cease to amaze me; Michi, whose will power and dedication to success have shown me the true meaning of being strong; Dari, whose big heart always reminds me how beautiful the world is; Tito, who is capable of making me laugh even when I barely feel like smiling; Dom, Zaf, Ellie, Mirek, Rebecca, Silvia, Andrew, Nikoela, Marina, Masa, Maria, Tedi, Paul, Botev, Alex, Mihaela, Miro and all the lovely people, both back in Bulgaria and around the world who make me feel the richest person on the planet. Finally, words cannot express how deeply indebted I am to my family for everything they have done and continue to do for me. The dissertation is dedicated to them: to my mum, Victoria; my dad, Andrey; my nana, Vania; my granddad, Valentin; to the loving memory of my grandmother, Associate Professor Tatiana I. Novoselova, whom I never had the chance of meeting but whose example has been guiding me; and to the loving memory of my granddad, Ivan, who always had my back no matter what.

Table of Contents

Abstract	i
Acknowledgement	ii
Table of Abbreviations	v
Introduction	ix
Chapter 1: Culture and Governance	1
Man's Second Nature	1
Cultures within Culture: the 'Matryoshka Principle'	9
The Social Homeostasis.....	17
Engineering Governance	23
Chapter 2: Governance of Science before 1945	27
Science as an 'Aristocratic Endeavour'	27
Science as a Vocational Pursuit	33
Harnessing the Power of Science.....	40
Toward a Permanent Mobilisation	55
Chapter 3: Governance and Cultures of Life Science Research during the Cold War	61
The Life Sciences as a Professional Domain	61
Life Science Research in the East and West.....	80
Chapter 4: 21st Century Governance Challenges in the Life Sciences	121
Biotechnology Advancement in the 21 st Century.....	121
Trends in Biotechnology Governance	126
Engines that Drive Biotechnology Momentum.....	145
Runaway Biotechnology?	163
Chapter 5: Biotechnology Governance: The Case of Russia	167
The Governance of Biotechnology as Shaped by History, Politics, and Culture	167
The Challenges Posed by 21 st Century Biotechnology	170
Inertia and Resistance to Change: The Case of Russia	175
Research Hypotheses and Research Question	177
Methodology.....	178
Chapter 6: Organisation and Governance of Soviet Biotechnology	182
Science in the Soviet Union.....	182
Growth and Consolidation of Biotechnology Research in the Soviet Union	190
Features of Soviet Biotechnology Governance	200
Chapter 7: Post-Cold War Institutional and Infrastructural Legacies	226
The Collapse of the USSR and Its Impact on the Life Sciences.....	226
Persistence of Soviet Inertia.....	235
Chapter 8: Life Science Policy and Practice in Present-Day Russia	268
Current State of Biotechnology in Russia.....	268
Mapping Russia's Life Science Policy	272
Life Science Professional Practice	292
Soviet Inertia Revisited.....	303
Conclusion and Research Implications	306
Bibliography	312
Appendix 1	376

Table of Abbreviations

AAAS	American Association for the Advancement of Science
ABSA	American Biological Safety Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
AEA	Atomic Energy Agency
AGITPROP	Department of Propaganda and Agitation
AMA	American Medical Association
AMN	Academy of Medical Sciences of the USSR
AP	Anti-Plague
ASM	American Society for Microbiology
ARC	Agricultural Research Council
ASPET	American Society for Pharmacology and Experimental Therapeutics
ASTA	American Seed Trade Association
BIO	Biotechnology Industry Organisation
BIRPI	United International Bureaux for the Protection of Intellectual Property
BRICS	Brazil, Russia, India, China and South Africa Alliance
BTWC	Biological and Toxin Weapons Convention
BVL	Biochemistry and Virus Laboratory
CBMs	Confidence-Building Measures
CDC	Centre for Disease Control and Prevention
CEN	European Committee for Standardisation
CIOMS	Council for International Organisations of Medical Sciences
CMR	Committee on Medical Research
COTIF	Convention Concerning International Carriage by Rail
CRDF	Civilian Research and Development Foundation
CRT	Cooperative Threat Reduction
CWC	Chemical Weapons Convention
DARPA	Defence Advanced Research Projects Agency
DHS	Department of Homeland Security
DIY	Do-It-Yourself Biology
DNA	Deoxyribose Nucleic Acid
DoD	Department of Defence
DSP	For Internal Use Only
DTRA	Defence Threat Reduction Agency
ECOSOC	United Nations Economic and Social Council
EPC	European Patent Convention
EU	European Union
EURIMAGES	European Cinema Support Fund of the Council of Europe
FANO	Federal Agency of Scientific Organisations
FAO	United Nations Food and Agriculture Organisation
FBI	Federal Bureau of Investigation
FGM	Female Genital Mutilation
FMBA	Federal Medical and Biological Agency
FMD	Foot-and-Mouth Disease
FPI	Foundation for Advanced Research

FRP	Fund for Industrial Development
FSB	Ministry of Federal Services
FSTEK	Federal Service Technical and Export Control
FSU	Former Soviet Union
FTsP	Federal Target Programme
GAO	Government Accountability Office
GDP	Gross Domestic Product
GEC	General Electric Company
GINZ	Pasteur State Institute of Healthcare
GKNT	State Committee of Science and Technology
GLAVLIT	Main Directorate for Literary and Publishing Affairs (later) Main Directorate for the Protection of State Secrets in the Press
GLAVMIKROBIOPROM	Main Directorate of Biotechnology Industry
GMOs	Genetically Modified Organisms
GOF	Gain-of-Function
GOSPATENT	USSR State Patent Agency
GOSPLAN	State Planning Committee
GSA	Genetics Society of America
GSEU	Main Sanitary Epidemiological Directorate
GUKI	Directorate of Quarantine Infections
GUMS	Main Scientific Medical Council
HGP	Human Genome Project
HUAC	House Committee on Un-American Activities
IAEA	International Atomic Energy Agency
IATA	International Air Transport Association
ICAO	International Civil Aviation Organisation
ICBMs	Intercontinental Ballistic Missiles
ICCPR	International Covenant on Civil and Political Rights
IFESCCO	Intergovernmental Foundation for Educational, Scientific and Cultural Cooperation
iGEM	International Genetically Engineered Machine Competition
IHR	International Health Regulations
IMO	International Maritime Organisation
INTAS	International Association for the Promotion of Cooperation with Scientists from the Independent States of the former Soviet Union
IP	Intellectual Property
IREX	International Research and Exchanges Board
ISF	International Science Foundation
ISTC	International Science and Technology Centre
KEPS	Commission for the Study of Natural Resources
KGB	Committee of State Security
KOMOChUM	State Anti-Plague Commission
LMOs	Living Modified Organisms
MChS	Ministry of Emergency Situations
MGU	Moscow State University
MIAC	Military-Industrial-Academic Complex

MINEKONOMRAZVITIYA	Ministry of Economic Development
MINMEDPROM	Ministry of Medical Industry
MINOBRANAUKI	Ministry of Education and Science
MINZDRAV	Ministry of Healthcare
MIT	Massachusetts Institute of Technology
MO	Ministry of Defence, Russia
MRC	Medical Research Council
NARKOMPROS	People's Commissariat of Enlightenment
NARKOMZDRAV	People's Commissariat of Public Health
NARKOMZEM	People's Commissariat of Agriculture
NAS	US National Academy of Sciences
NATO	North Atlantic Treaty Organisation
NBIC	Nanotechnology, Biotechnology, Information Technology, and Cognitive Science
NC	Natural Conservancy
NDRC	National Defence Research Committee
NEP	New Economic Policy
NGO	Non-Governmental Organisations
NGU	Novosibirsk State University
NIH	National Institutes of Health
NIIEG	Scientific Research Institute of Epidemiology and Hygiene
NKVD	People's Commissariat of Internal Affairs
NONT	Scientific Management of Scientific Labour
NRC	National Research Council
NSF	National Science Foundation
NTO	New Technology Opportunities
OJSC	Open Joint-Stock Companies
OOI	Highly Dangerous Infections
ONR	Office of Naval Research
OPBW	Organisation for the Prohibition of Biological Weapons
OPCW	Organisation for the Prohibition of Chemical Weapons
OSRD	Office of Scientific Research and Development
OTIF	Organisation for International Carriage by Rail
PhARMA	Pharmaceutical Research and Manufacturers of America
PPE	Personal Protective Equipment
PVPA	Plant Variety Protection Act
RAMN	Russian Academy of Medical Sciences
RAN	Russian Academy of Sciences
RASKhN	Russian Academy of Agricultural Sciences
RCBP	Radiation, Chemical, and Biological Protection
R&D	Research and Development
RES	Russian Eugenics Society
RFFI	Russian Foundation for Basic Research
RFTR	Russian Fund for Technological Development
RID	Regulation Concerning the International Carriage of Dangerous Goods

RKB	Russian Bioethics Committee
RKKA	Red Army
RNF	Russian Science Foundation
ROSPATENT	State Patent Agency – Russia
ROSPOTREBNADZOR	Federal Service for Surveillance in Consumer Rights Protection and Welfare
ROSPRIRODNADZOR	Federal Service for Surveillance on Natural Resources Management
ROSSELKHOZNADZOR	Federal Service for Veterinary and Phytosanitary Surveillance
ROSZDRAVNADZOR	Federal Service for Surveillance in Healthcare
RRL	Roderplaat Research Laboratories
RSFSR	Russian Soviet Federative Socialist Republic
SISS	Senate Internal Security Subcommittee
SNK	Council of People's Commissars
SOLAS	International Convention for the Safety of Life at Sea
SOVMIN	Council of Ministers
SPEBiy	Specialised Anti-Epidemic Brigades
STCU	Science and Technology Centre in Ukraine
TMV	Tobacco Mosaic Virus
TNCs	Transnational Corporations
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
TsK	Communist Party's Central Committee
UN	United Nations
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organisation
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organisation
UNMOVIC	United Nations Monitoring, Verification and Inspection Commission
UNSCOM	United Nations Special Commission on Iraq
UNSCR 1540	United Nations Security Council Resolution 1540
UPOV	International Convention for the Protection of New Varieties of Plants
USSR	Union of Soviet Socialist Republics
VAK	Highest Central Attestation Commission for Scientific Degrees and Titles
VASKhNIL	Lenin All-Union Academy of Agricultural Sciences
VIEM	All-Union Institute of Experimental Medicine
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WMA	World Medical Association
WMD	Weapons of Mass Destruction
WPB	War Production Board
WTO	World Trade Organisation

Introduction

The present research seeks to examine the state of the culture of life science practice in post-Soviet Russia. As such, it constitutes an empirical investigation into the formal and intangible attributes and artefacts of biotechnology policy and practice in that country. The research advances two hypotheses:

(i) It is argued that throughout the world, systems of science governance carry historical, cultural, and political legacies, which now confront the revolutionary and pervasive advances of the twenty-first century biotechnology. Nations' adaptability to the twin challenges of attempting to secure the benefits while reducing the risks and threats is a large and still burgeoning governance challenge.

(ii) It is argued that the legacy of the Soviet Union is particularly important in this regard, since the history of a prolonged authoritarian rule and intense development of biological weapons in combination with the continuing scientific and technological prowess of Russia is a governance challenge, unprecedented in its nature and scale.

The primary research question that the dissertation seeks to examine is:

- To what extent and by what means is it possible for Russia to reconcile its on-going expansion in biotechnology with the institutional and normative inertia, arising from its Soviet past?

The dissertation cuts across several sets of literature, bringing together elements of the anthropological study of culture; history of science and technology; management and international governance; and Soviet history and politics. A key concept utilised for the purposes of analysing change and continuities in the culture of life science research in present-day Russia is structural inertia. Originally developed in the field of organisational management, the concept of inertia is used in the context of the current research to elucidate the persistence of Soviet-style governance relations,

mentality, and power distribution among stakeholders involved in the biotechnology enterprise in Russia after 1990.

In terms of structure, the dissertation takes the shape of an hourglass formed by two triangles. Chapter 1 introduces the concept of culture and examines the inter-connectedness between culture and governance. By demonstrating the ways in which culture impacts, and indeed underpins, governance, it underscores the limits of total and technocratic approaches to governance. Chapter 2 looks into the governance of science and technology until 1945. It focuses on the evolution of science as a professional sphere of activity and the ways in which it has been shaped by cultural, historical, political, and socio-economic contingencies. Chapter 3, then, delves into and examines the formation and governance of life science professional practice throughout the Cold War. It maps out some of the key developments, dynamics, and trends in the relations between the scientific community and the state that have had bearing on the consolidation of life science culture. Chapter 4 narrows down the discussion the rapid advancement of biotechnology over the past few decades, outlining an array of factors that drive innovation and, at the same time, raise concerns of the extent to which the scope and pace of novel life science developments can be adequately governed.

The first four chapters form Part 1 of the dissertation, and as such, seek to provide a rationale for looking into the case of post-Soviet Russia, in order to examine the impact and quality of inertia in the culture and governance of life science practice. Chapter 5 introduces the research hypotheses and main research question, as well as giving an overview of the methodological approach adopted for the study. Chapter 6 analyses the organisation, culture and governance of life science research from the late Imperial period in Russia throughout the years of Soviet rule. Chapter 7 then identifies and elucidates those attributes and artefacts that have persisted despite the disintegration of the USSR and the establishment of Russia as a pro-democratic country with a market-oriented economy. In particular, it analyses the institutional and infrastructural legacies in power relations, practices, and socio-economic and political dynamics that shape life science policy and practice. Chapter 8 follows with an in-depth critical appraisal of life science

policy and practice in post-Soviet Russia. The concluding chapter offers an assessment of the current state of the governance of biotechnology in Russia and outlines a scope for further research.

Parts of Chapters 1 and 4 have already been published. Full references are available in the Bibliography section of the dissertation.

Chapter 1: Culture and Governance

Man's Second Nature

Arguably 'culture' is 'one of the two or three most complicated words in the English language'¹: a term shrouded in conceptual complexity and loaded with 'considerable intellectual baggage',² which has 'obstinately resisted final definition'.³ Much of the controversy surrounding the use of the concept stems from the fact that it has incessantly been employed in fundamentally differently ways⁴ and adapted in accordance with the dominant concerns of the day.⁵ Lamenting the mechanisation of human life under the pressures of the Industrial Revolution, nineteenth century authors, including Coleridge, Carlyle and Arnold, drew a Romantic picture of culture as 'the pursuit of total perfection',⁶ an ideal that must be 'safeguarded, preserved, aspired towards and worked for', which served as a counterforce in the face of the dehumanising influence of industrialisation.⁷ Hence the idea of the cultivated man, the intellectual, whose utter dedication to upholding the ideal of culture grants him a place within the social elite of the 'clerisy', or the intelligentsia. This usage of the word is closely linked with another, whereby culture is a collective category signifying the whole body of art and intellectual work within a society.⁸ In political terms, the concept of culture is often equated with the German idea of *Kultur*, which emphasises national differences and the particular identity of groups, and invoked in defence of indigenous styles of life and learning, distinct from those associated with the Western tradition.⁹

By design, the concept of culture has a central standing¹⁰ in the discipline of anthropology but even there its meaning and use continue to be vigorously contested, as the work of Kroeber and Kluckhohn has illustrated. In an

¹ Raymond Williams, *Keywords: A Vocabulary of Culture and Society*, Revised and Expanded Edition, (London: Fontana Press, 1988) p.87.

² Robert Borofsky et al. 'When: A Conversation about Culture', *American Anthropologist*, 103:2 (2001) p.434.

³ Tim Ingold (ed). *Companion Encyclopaedia of Anthropology: Humanity, Culture and Social Life*, (London: Routledge, 1994) p.329.

⁴ Elvin Hatch, *Theories of Man and Culture* (New York: Columbia University Press, 1973).

⁵ *Ibid.*

⁶ Matthew Arnold, *Culture and Anarchy*, (Ann Arbor: University of Michigan Press, 1965).

⁷ Chris Jenks, *Culture*, 2nd Ed. (London: Routledge, 2004), p.17;18.

⁸ *Ibid.*, p.11-12.

⁹ Robert Borofsky, 'When: A Conversation about Culture', p.433 *op cit.*

¹⁰ Richard Fox, 'Culture – A Second Chance?', *Current Anthropology*, vol.40:S1 (1999), pp.Si-Sii.

attempt to come up with an authoritative definition of the term, the authors conducted a detailed review of 150 definitions of culture, but their efforts have met with very little success.¹¹ Despite the lack of consensus on how the term should be best defined, by and large anthropologists agree on the value of the concept of culture,¹² not least because it provides them with a powerful tool with which to grasp the features of human existence.¹³ Language, belief systems, sacred rituals, routine activities, symbols, group ethos, spoken and unspoken rules guiding behaviour, styles of expression, art – virtually any aspect of the way of life of a given collective – are all elements of culture. Far from being an observable object or phenomenon, culture then is an abstraction, inferred from the observation of practices and artefacts perceived to be relatively common among the members of a certain group or population.¹⁴ As such, it is not merely a ‘complex whole’¹⁵ comprising single units but a system that is ‘highly patterned, cohesive, and coherent’¹⁶ and within which every sound, act, or object constitutes a sign bearing shared meaning.

Culture is exclusively a human attribute. Unlike people, animals ‘have neither culture, nor history’, not only because they lack language and exchange information primarily via the lowest grade of social transmission, that is without conscious deliberation by either party, but also, and even more fundamentally, because they lack the categorical distinctions which provide the foundations on which cultural belief depends.¹⁷ Further differences stem from the fact that most animals, including higher mammals, inhabit an unchanging milieu to which their specialised organ structure is adapted and within which equally specific, innate, instinctive behaviour is carried out.¹⁸ Man, by contrast, is characterised by morphological deficiency, insofar as he has practically no specialisations, his body is barely designed for attack and

¹¹ Alfred Kroeber and Clyde Kluckhohn, *Culture: A Critical Review of Concepts and Definitions*, (Cambridge MA: Harvard University Press, 1952); Robert Borofsky, p.432-433 *op cit*.

¹² For critique of the concept, see Edward Sapir, ‘Culture, Genuine and Spurious’, *The American Journal of Sociology*, vol.29:4 (1924), pp.401-429.

¹³ Clifford Geertz, *The Interpretation of Culture: Selected Essays*, (New York: Basic Books, 1973).

¹⁴ Mark Schaller, Lucian Gideon Conway III and Christian Crandall, ‘The Psychological Foundations of Culture: An Introduction’ in Mark Schaller and Christian Crandall (ed.), *The Psychological Foundations of Culture*, (Mahwah, New Jersey: Lawrence Erlbaum Associates, 2004), p.8.

¹⁵ Edward B. Taylor, *The Origins of Culture*, 2nd ed. (New York: Harper and Row, 1958 [1873]).

¹⁶ Clifford Geertz, *The Interpretation of Culture*, *op cit*.

¹⁷ *Ibid*, p.362; p.352; p.351

¹⁸ Arnold Gehlen, *Man, His Nature and Place in the World*, New York: Columbia University Press, 1988), p.27.

protection and his senses are significantly underdeveloped compared to those of other animals.¹⁹ Given his 'dangerous lack of true instincts', man is not bound to a particular habitat to ensure his survival but is 'world-open',²⁰ which in turn allows him to move constrained only by his physical capacities, and makes him capable of adapting to even hostile natural conditions. Still, in order to survive, man somehow has to overcome, or at least to compensate for his biological deficiencies. His innate vulnerability thus becomes the primary stimulus to his creativity driving him to concentrate his efforts and energy on transforming the environment to meet his needs and satisfy his urges. By combining skill and ingenuity, man builds a shelter, devises weapons, creates tools, finds food and raises his offspring. In the process of accomplishing these and other tasks man learns the importance of co-operating and communicating with others. The interplay between communication and cognition eventually gives rise to man's 'second nature' – culture.²¹

To man, culture is more than just a characteristic; rather, it is a necessity, for no human being can fully develop and fulfil his capacities outside the boundaries of culture. Since man is not associated with any particular natural habitat, he is required to create his own 'unnatural' environment²² in order to become truly human. The human world is thus the cultural world.²³ The reason for this primarily stems from the fact that human biological development is not completed at the moment of birth but continues afterwards in an interrelationship with an environment and under the influence of significant others.²⁴ An infant deprived of human presence would hardly resemble Kipling's famous character, Mowgli. On the contrary, his development would be irreversibly impaired not only in terms of language and speech, but also as far as skills, reasoning, and morality are concerned. This in turn implies that man's behaviour is neither just a sequence of responses to certain stimuli, nor a consequence of genetic programming.

¹⁹ Ibid, p.26.

²⁰ Ibid.

²¹ Ibid, p.29.

²² Ibid.

²³ Ibid.

²⁴ Peter Berger and Peter Ludwig, *The Social Construction of Reality: A treatise in the Sociology of Knowledge*, (London: Allen Lane/Penguin Books, 1967), p.66.

Rather, it is moulded under the influence of continuous social interaction upon which the human brain is inevitably reliant for building its 'own autonomous, ongoing pattern of activity'.²⁵ Hence, the process of becoming man inevitably takes place in an established socio-cultural setting in the context of order, stability and direction, and never in isolation.²⁶ Culture establishes the essential conditions for human existence, not least because without it man's experience would be little more than a shapeless amalgamation of pointless actions and exploding emotions,²⁷ and his ability to make sense of the outside world would be severely crippled. As such, it functions as a set of control mechanisms for the governing of human behaviour, effectively providing man with the templates, blueprints, moral codes and aesthetic judgements that he desperately requires in order to give form, point and direction to his life.²⁸

Culture grants man sanctuary from the tormenting pressures of chaos, which, if left untamed, threaten to engulf and eventually destroy him. By transforming human actions into habits and routines, it relieves man from the burden of constant decision-making and opens up a foreground for deliberation and innovation.²⁹ It cushions man's most severe anxieties thus offering him the comfort and tranquillity of living in a familiar setting. There is hardly a human fear more overwhelming than the terror of the 'uncanny', the unknown, the incomprehensible. Confronting what cannot be explained or interpreted horrifies man causing him mental paralysis and distress. Confusion, suffering and 'a sense of intractable ethical paradox' all mark a point beyond which the menace of chaos breaking in upon man appears vividly acute, not least because such states pose a radical challenge to the ability of man to grasp the intricacy of life.³⁰ And this ability is vital to him, for man:

must fulfil one condition of existence more than any other animal: man *must* from time to time believe he knows *why* he exists; his race cannot thrive

²⁵ Clifford Geertz, *The Interpretation of Culture*, p.83, *op cit*.

²⁶ *Ibid*, p.69.

²⁷ *Ibid* p.46.

²⁸ *Ibid*, p. 44, p.52

²⁹ Peter Berger and Peter Ludwig, *The Social Construction of Reality*, p.71, *op cit*.

³⁰ Clifford Geertz, *The Interpretation of Culture*, p.100, *op cit*.

without a periodic trust in life – without faith in the
*reason in life!*³¹

Satisfying man's desperate need for answers would be impossible without a stable frame of reference, one that provides him with the tools required to construe and rationalise the objects and phenomena he encounters, and within which his actions acquire both purpose and meaning. Hence the indispensable role that culture plays in the life of human beings. Through its 'public symbolic structures' culture suspends man in 'webs of significance' which simultaneously shape, guide and constrain his behaviour.³² With the aid of symbols and signs man succeeds in making sense of the surrounding world. Far from being mere mechanical expressions, his actions are goal-oriented and motive-driven. By reading other people's behaviour, he develops the ability to interact with his peers, giving verbal expression to his thoughts, intentions, and beliefs and wrapping his deeds in meaning. He reflects on and learns from his past experience, makes decisions about the present and envisions the future. This in turn allows him to utilise the power of his imagination and give shape to his dreams and desires by turning them into tangible reality; to plan his course of action according to external contingencies; and to creatively adapt the physical environment so as to satisfy his needs. The unfamiliar is conquered. Every phenomenon, object, gesture, sound has its place in the dominant cultural narrative reflected in myths, legends, sacred texts and folklore. Man can rest re-assured: he is no longer just a lone performer of random acts but finds himself in the midst of a cosmological drama, the beginning and the end of which remain forever shrouded in mystery but which nevertheless relates him to his predecessors and successors in a meaningful totality.³³

Culture constitutes man's primary source of order and stability, insofar as it acts as a symbolic universe that demarcates the borders of social reality and defines the rules for social interaction.³⁴ Any culture inevitably rests upon a

³¹ Friedrich Nietzsche, *The Gay Science*, (Cambridge: Cambridge University Press, 2001), p. 29 (emphasis as original).

³² Clifford Geertz, *The Interpretation of Culture*, p.83 *op cit*.

³³ Peter Berger and Peter Ludwig, *The Social Construction of Reality*, p.120 *op cit*.

³⁴ *Ibid*.

set of 'unquestioned and unverifiable beliefs',³⁵ which provide the basis for human action. Such beliefs are reinforced by the 'frequent repetition of petty acts'³⁶ and sustained by transmission across generations via 'appropriate social mechanisms.'³⁷ Through the process of transmission, they are permanently incorporated into the general stock of knowledge and accepted as fundamental truths. As a result, culture is no longer seen as a product of human activity but comes to resemble a 'societal force', one that is independent of 'human purpose and wit' and that exerts a strain on every person within its reach by dint of habit and custom.³⁸ It is firm and opaque which makes it both resilient to challenges and resistant to change. Above all, it signifies both the institutionalised 'way of how things are done' within the respective group and the established model of behaviour with which every member has to demonstrate compliance.

Man confronts culture as an objective reality: an external domain that is separate from his cognition and upon the elements of which he has little control. Under the influence of his peers, he is gradually 'programmed' to abide by cultural dogmas and behave in a way that is consistent with the prevalent normative order. Culture determines the standards on the basis of which man apprehends the world, relates to his milieu, acts and expresses himself.³⁹ In other words, it reflects the accepted group ethos and as such, serves as the chief mechanism for regulation of human relatedness. Indeed

[t]he most basic aspect of culture is its aptness for enabling a society to preserve reliable and acceptable *relations*, both internally between its members and externally with its milieu. If either fails, the society perishes.⁴⁰

It is worth noting that in performing its regulatory role culture is hardly dependent on enforcement tools. While such mechanisms do exist in the

³⁵ Geoffrey Vickers, Unpublished manuscript on culture p.8.

³⁶ William Sumner, *Folkways: A study of the Sociological Importance of Usage, Manners, Customs, Mores, and Morals*, (New York: Cosimo Inc. 2007 [1906]), p.3.

³⁷ David Premack and Ann James Premack, 'Why Animals Have neither Culture nor History', in Tim Ingold ed. *Companion Encyclopaedia of Anthropology*, p.352 *op cit*.

³⁸ William Sumner, *Folkways*, *op cit*.

³⁹ Geoffrey Vickers, Unpublished manuscript, *op cit*.

⁴⁰ *Ibid*, p.29. (emphasis as in original)

form of taboos, rules and laws, which envisage severe punishment for anyone daring to violate them, they are only occasionally invoked and enforced. This is not to say that individuals do not engage in practices such as murder, incest, or adultery solely on the grounds of fear of being reprimanded but because they view these activities as morally wicked and unacceptable, running counter to 'normal' human relations. Whereas compliance with cultural norms offers members of the collective certain benefits, including security and serenity, any attempt at defiance threatens to erode the status of the latter, effectively leading to their castigation. This subsequently raises the costs of nonconformity and facilitates the maintenance of the established order. Every aspect of this order is to a greater or lesser extent a manifestation of culture. Social roles, formal institutions, the distribution of power and regulatory architecture are all expressions of cultural forms. Even more importantly, they are reinforced and legitimated through culture.

All forms of human association within a particular community are shaped by culture. This includes the fundamentals: the accrual and exercise of power; the determination of accountability and authority; and the articulation, organisation and pursuit of common interests. Hence, whether governing officials accede to power based on hereditary right or as a result of election, whether members of the polity can hold their governors accountable through formal procedures or find themselves at the whim of the ruling elite, or whether a society is devoid of hierarchy or organised around a rigid class system are matters that are deeply rooted in the historical and cultural development of a given community and as such, reflect its shared values, beliefs, convictions and morals. Very simple societies, for example, are rarely hierarchical, with power being vested in councils of elders, heads of households, or spiritual leaders such as priests and shamans, and collaboration arising spontaneously from a shared understanding of what needs to be done.⁴¹ By contrast, more complex forms of social organisation are characterised by a vertical distribution of power and intricate structures of

⁴¹ Ibid, p.67.

interconnected positions. The differences notwithstanding, individuals within any collective are constantly engaged in role-playing, with the behaviour and actions of each role-holder being guided by tacit but more or less rigid shared standards of what is expected of them in any such position and of what they are in turn entitled to expect.⁴² What it means to be a husband, a wife, a ruler, or a servant is thus determined by the prevalent cultural values. Power relations at all levels from the social to private sphere are a function of culture. For instance, the status of and the attitude toward women in a society which asserts gender equality and promotes women's freedom of choice and expression are in sharp contrast with the standing of women and the way they are treated in a social setting which tolerates male dominance and emphasises female modesty. Needless to say, the variance in the conception of gender across different cultures is reflected in virtually every aspect of life from the family realm through interaction in public to political activity.

Yet it would be naïve to assume that the standards which shape social roles and serve as a precondition for social action are equally shared among all members of a given collective. On the contrary, cultures are never entirely uniform, even if their formal structures make them appear so.⁴³ Indeed, every culture is bound to accommodate a range of subcultures formed around common criteria that can be as general as sex or age, or more specific like class, social rank, or economic status. While those subcultures inevitably bear some of the features of dominant cultures, they also differ from the latter in important ways, which in turn ensures richness and diversity within the community. Such heterogeneity is vital to cultures, not least because it makes them vibrant, plastic and adaptable, allowing them to maintain stability through change. But diversity can also be a source of tension and conflict, especially in times of rapid alternation under the influence of external factors when social values and established morals – the chief modulators of human relations – are challenged, or utterly eroded. Hence, it is of primary importance for any society to preserve enough shared culture in order to

⁴² Ibid, p.66.

⁴³ See, for example, Valentina Lebedeva, 'Totalitarian and Mass Elements in Soviet Culture of the 1930s', *Russian Studies in History*, vol.42:2 (2003), pp.66-96.

sustain its internal relations and be able to act as a whole to the extent to which its survival requires.⁴⁴

Cultures within Culture: the ‘Matryoshka Principle’

It is possible to think of culture in terms of a multi-layered pattern. A useful analogy in this regard is the idea of a Matryoshka – a set of wooden dolls of decreasing size placed one inside the other. While all figures of a single Matryoshka are similar in form and designed around a shared concept, each of them differs from the rest as far as decoration is concerned. Despite the discrepancies in colour and style, the dolls belonging to a particular set still make up a coherent whole. Likewise, the subcultures found within a given society, by and large, resemble and/or are informed by the larger, dominant culture of the group.

Subcultures based on biological sex are indicative. As discussed in the previous section, the roles of both men and women within a collective are culturally constructed, that is, gender differences stem not so much from physiological differences but from a shared understanding of what an appropriate male and female behaviour encompasses. In other words, they are expressed by dint of symbols, hero images, rituals and values⁴⁵ with which individuals are expected to comply in every area of social activity. Thus, in communities where the position of women is accepted to be inferior *vis-à-vis* that of men, the principles asserted by the dominant culture are to a greater or lesser extent reflected in the various subcultures formed around gender. The same tendency is also valid for other types of subcultures, including those arising from differences in age and social class. What is generally perceived as a ‘gap between generations’ more often than not refers to values and practices that are attributes of age and, as such, repeat themselves for each successive pair of generations.⁴⁶ A sharp divergence from the ethos and established routines of the dominant culture manifested,

⁴⁴ Geoffrey Vickers, Unpublished manuscript, p.23 *op cit*.

⁴⁵ Geert Hofstede, *Cultures and Organisations: Software of the Mind, Intercultural Cooperation and Its Importance for Survival*, 3rd ed. (London: Mc Graw-Hill, 2010) p.16.

⁴⁶ *Ibid*, p.17.

say in the willingness of the youth to radically alter their lifestyle by abandoning the village and moving permanently to the city, is an anomaly which poses an existential threat to the survival of the larger culture in question. In a similar fashion, individuals belonging to a class subculture, for example the working class, middle class or the intelligentsia, share certain beliefs, manners of behaviour, symbols and values that distinguish them from those with a higher or lower social rank. Such differences usually stem from the education and occupation opportunities open to class members, the economic power of the class and its relative standing *vis-à-vis* other class subcultures within the social hierarchy. Nevertheless, the prevalent norms and practices associated with a given subculture (e.g. the working class) are inevitably influenced by the larger, dominant culture (e.g. state's national culture) within which the former is situated.

But there is another type of subculture to which individuals, far from being 'assigned' as a result of circumstances beyond their control, choose to belong in the course of their lives. Such elective subcultures are, by and large, present in every community and fulfil various purposes. Depending on their origins and function, their normative ethos, guiding principles and belief system can be loosely defined or formally codified in official documents and codes. In any event, members are expected to demonstrate conformity with the established rules, be they unspoken or formalised, and any departure from the norms is treated as a break with the group ethos. Informal subcultures often develop in opposition to aspects of the dominant culture and, as such, are viewed as odd or subversive, constituting a deviation from the prevalent social mores and enjoying a consciousness of 'otherness'.⁴⁷ They may be formed around a shared interest (e.g. music, art), hobby (e.g. sport), or a cause. The punk movement, 'Beatlemania', football fan clubs, the hippie movement, and environmental and AIDS activists all bear similar features, insofar as their members carry certain symbols (clothes, slang, impolite behaviour) aspire to certain hero images (pop stars, bands, sport players, political figures, spiritual leaders), engage in certain rituals (demonstrations, graffiti, use of recreational drugs) and cherish certain values

⁴⁷ Ken Gelder and Sarah Thorton, (ed.), *The Subcultures Reader*, (London: Routledge 1997), p.5.

(freedom, equality, justice, peace, concern for nature, health) which unequivocally distinguish them from the rest of society. The crucial role that those elements play in the functioning and sustaining of subcultures contravenes the popular myth that the latter are little more than 'lawless forms'.⁴⁸ On the contrary:

the internal structure of any particular subculture is characterised by an extreme orderliness: each part is organically related to other parts and it is through the fit between them that the subcultural member makes sense of the world.⁴⁹

But elective subcultures can also be institutionalised through formal practices and procedures. Such is the case with cultures of work and professional norms. Cultures of work derive from the diverse functional roles that individuals within a social grouping are expected to perform as a result of the division of labour. Whereas the choice of role is, by and large, in the hands of individuals, the question of a good performance is not. In other words, community members are invariably required to demonstrate sufficient proficiency in completing the tasks that particular roles encompass. To this end, individuals are expected to develop a certain set of skills and acquire knowledge as to how best to fulfil their work-related duties and thus contribute to the common good. The type and gamut of functional roles are bound to vary across different groups depending on the needs, traditions and lifestyle of their members. A pre-historic tribe with a relatively small size and simple structure, for instance, would require only a limited number of functional subgroups specialising in activities chiefly directed at providing food and shelter. By contrast, a mediaeval city-state or modern industrialised society characterised by the innate intricacy of its structures and dynamics would be capable of accommodating a considerably larger number of work subcultures formed around activities as diverse as curing, governing, teaching, ensuring territorial integrity and security, crafting, building, and engineering. What is important, however, is that irrespective of whether individuals choose to join the tribal hunting group, the guild of master craftsmen, or the Bar Association, they have to meet certain requirements,

⁴⁸ Dick Hebdige, 'Subculture: The Meaning of a Style [1979]', in *ibid.*, p.137.

⁴⁹ *Ibid.*

learn certain strategies, obtain certain skills, become familiar with and abide by established group ethos, engage in certain practices and rituals, and be able to pass the acquired knowledge and abilities to younger generations. In short, they need to undergo a process of cultural socialisation which not only would facilitate their personal development but also would allow them to excel and rise through the ranks of the functional group.

Yet to say that functional groups generally possess culture by no means implies that there are no significant differences in what their culture is like or how it is manifested. On the contrary, such discrepancies do exist and even play a crucial part in determining the status of a particular functional group within the social hierarchy. Accordingly, based on the 'thickness' of their culture, functional groups are classified as either 'professions', or 'occupations'. By design, this distinction is not a qualitative but a quantitative one, for nonprofessional occupations do possess most of the attributes of professions, including systematic body of theory, authority, community sanction and ethical code, but to a lesser degree.⁵⁰ So, instead of constituting two opposing camps, professions and occupations seem to be distributed along a continuum with well-recognised and undisputed professions (e.g. physician, scientist, accountant, lawyer) situated at one end, the least skilled and least attractive occupations (e.g. cleaner, driver, truckloader) at the other, with the rest distributed in-between in accordance with their level of required skill and prestige.⁵¹ The category of professions is a curious one, for while occupations have to develop into professions, not all occupations are destined to professionalise; that is, some activities are more likely to enjoy the status of becoming and being regarded as professions than others. The reason behind this trend in part can be traced in the historical development of professions.

Traditionally, professions were understood as those occupations that were 'suitable for a gentleman' in the sense that they were supposed neither to

⁵⁰ Ernest Greenwood, 'The Attributes of a Profession', *Social Work*, vol.2:3 (1957), p.46.

⁵¹ Ibid.

'dull the brain, like manual labour', nor to 'corrupt the soul, like commerce'.⁵² Since embarking on a professional career demanded utter dedication, extensive preparation and training, and substantial investment of time and resources, professions were the chief mark only of those members of society who could afford to live life as an end in itself relieved from the worry of securing their daily subsistence (e.g. the nobility). As a consequence, the practice of professions was virtually free of economic pressures⁵³ guided purely by an individual's interest in the subject matter of their choice and not subject to profit calculations. In conducting their activity, professionals were supposed, first and foremost, to be in service of society always working up to established standards and demonstrating expert proficiency without aiming or even expecting to earn a fortune. Being a professional was not a money-making business; rather it was a vocation. And even when those engaged in a professional endeavour enjoyed rewards for their service, this was not in response to commercial cravings but only a gesture confirming the unequivocal value of professions as social institutions:

We trust our health to the physician, our fortune and sometimes our life and reputation to the lawyer and attorney. Such confidence could not safely be reposed in people of a very mean or low condition. Their reward must be such, therefore, as may give them that rank in the society which so important a trust requires.⁵⁴

Along with their historical origins, there are additional nuance features that grant professions an air of superiority *vis-à-vis* occupations. One pertains to their *raison d'être*. By design, the idea of professions rests on the two-fold premise that first, there are such human problems that cannot remain unaddressed, and, secondly, that such human ills can be alleviated through the provision of expert service. While the range of problems that inevitably needs to be tackled tends to vary among different communities, virtually all cultures seem to give special attention to certain concerns including sickness, salvation, and protection of life, property and reputation, by

⁵² Thomas H. Marshall, 'The Recent History of Professionalism in Relation to Social Structure and Social Policy', *The Canadian Journal of Economics and Political Science*, vol.5:3 (1939) p.325.

⁵³ Ibid.

⁵⁴ Adam Smith quoted in *ibid*, p.326.

assigning their solution to a designated group of individuals which alone is in a position to assess the situation correctly and articulate expert advice. Authority is vested in those groups by dint of their monopoly on the knowledge and skill required to make informed decisions when it comes to curing the sick, preaching the words of god, administering one's money, defending one's dignity, teaching the youth and discovering the truth in the world. What makes the work of a professional utterly indispensable therefore is not merely its importance to public welfare but the fact that it can only be conducted by a representative of the respective professional guild. Given this 'asymmetry of expertise',⁵⁵ any relationship between professionals and those in need of their service is deemed to be an unequal one, with the latter being almost entirely dependent on the quality of advice offered by the former. Hence, in the professional realm, unlike in other occupations, trust between the parties involved is an essential requirement. The conduct of a lawyer is guided by an established code of ethics; the work of a market seller is not. Likewise, those requesting professional help are not customers but clients and, as such, they are not always right: they have to accept and comply with the conditions set by the experts, since it is the latter who know best what the former need.⁵⁶

Besides technical proficiency in their selected area of specialisation, professionals are also expected to demonstrate adherence to set of norms which shape their behaviour toward colleagues and professionals in other fields, as well as clients.⁵⁷ Far from being divorced from a moral duty, professional practice is bound to be devoted to a service ideal, often enshrined in a formal code of ethics, according to which quality should not be sacrificed, standards should not be compromised and personal or commercial profit should not be advanced at the expense of the client's interests.⁵⁸ It is the responsibility of any professional to work toward the

⁵⁵ Andrew Abbott *The System of Professions: An essay on the Division of Expert Labour* (Chicago: The University of Chicago Press, 1988), p.5.

⁵⁶ Thomas H. Marshall, 'The Recent History of Professionalism in Relation to Social Structure and Social Policy' p.330, *op cit*.

⁵⁷ Harold Wilensky, 'The Professionalisation of Everyone?', *The American Journal of Sociology*, vol.70:2 (1964), p.138.

⁵⁸ *Ibid*, p.140.

promotion and preservation of this ideal by exhibiting collegial respect, protecting clients, refraining from abusing their position of knowledge for personal gain, and exposing instances of incompetence and unscrupulous practice. Fostering dedication to professional ethos is thus a requisite element of the process of acquiring a professional role. The professional paradigm usually begins with a selection and passes through several stages including instruction, apprenticeship, sanctioning, certification and sponsorship.⁵⁹ Advancing from one stage to another, the prospective professional aims to acquire the knowledge, skills and attributes that would eventually both grant them a full membership in the 'quasi-sacred extra-mundane sphere' of professional communities and allow them to excel in their career.⁶⁰ Yet the process of professional socialisation is never finished until the individuals have entirely immersed themselves in the culture of the respective profession, that is, until they have not become familiar with the argot (e.g. jargon, abbreviations, slogans), values (e.g. rationality, impartiality, commitment to objectivity regarding theory and technique), symbols (e.g. dress, emblems, insignias, heritage, folklore, stereotypes, heroes and villains) etiquette (e.g. formal and unspoken rules for being admitted to a profession, making a career, attracting clients, applying for funds, relating to peers, superiors, or subordinates) and marketplace information (e.g. matrix of activities and opportunities salient to practice).⁶¹ As a result of the acculturation process, whereby the individual internalises the values, norms, and symbols of the occupational group, the acquired professional status becomes the dominant source of the individual's identity with other sources being voluntarily and, sometimes, forcibly subordinated.⁶²

Since professions do not exist in a vacuum but find themselves in a constant interaction with other social groups and structures, cultures of work are hardly sheltered from the influences of the dominant culture within which they

⁵⁹ Basil Sherlock and Richard Morris, 'The Evolution of the Professional: A Paradigm', *Sociological Inquiry*, vol.37:1 (1967) p.33, p.44.

⁶⁰ *Ibid.*

⁶¹ *Ibid.*; See also Ernest Greenwood, 'Attributes of a Profession', p.52, *op cit.*

⁶² See Basil Sherlock and Richard Morris, 'The Evolution of the Professional: A Paradigm', p.34, *op cit.*; Ernest Greenwood, p.53 *op cit.*; Robert Maclver, 'The Social Significance of Professional Ethics', *Annals of the American Academy of Political and Social Science*, vol.297 (1955), pp.118-124.

operate. That is, in their greatest part, professional norms reflect and are conditioned by the historical and cultural contingencies that have influenced social development. Almost any aspect of an individual's career path from occupational training through job selection to professional practice and building a reputation is subject to the mores and morals prevalent in a given community. Thus, whether a job is suitable for a male or female, whether it is prestigious or not, or whether it offers enough scope for career development inevitably depends on and is determined by society's shared beliefs, needs and priorities. In a similar fashion, both formal and informal aspects of cultures of work are a function of the modes of behaviour sanctioned by the larger culture. For instance, in societies where discrimination and harassment on the grounds of sex, race and age are generally viewed as unacceptable, powerful norms against such actions are expected to develop in the professional realm, as well. Likewise, in conservative societies with explicit social hierarchy, professions also tend to be hierarchical, which in turn predisposes individuals to act in accordance with their professional rank by, say, always referring to their superiors by title and surname. Occasionally, the dominant culture may impact on, interfere or even clash with certain technical aspects of professional cultures. The pressure put on doctors who conduct abortion and/or euthanasia in communities where a strong taboo against such practices exists; the opposition toward providing legal service to members of minority groups; and the negative opinion voiced by the Church regarding certain scientific advances including stem cell research are all indicative of the how public opinion and social norms may affect the activity of professional groups.

In modern industrialised states the penetrating influence that the dominant social culture exerts on the cultures of work is explicitly manifested in the way the former shapes and governs the latter. Virtually any culture of work is subject to some form of state regulation. Moreover, the type and extent of regulation that a professional culture requires is bound to vary from one occupation to another, as well as from a country to country. Depending on their standing within society and the value attached to the service they provide, certain occupations tend to be more strictly regulated compared to

others. For instance, the rules and guidelines with which medical doctors have to comply in their everyday practice are far more wide-ranging and sophisticated than the ones guiding the conduct of, say, cleaners. But there are other factors that are crucial for determining the degree of state control over a professional activity. Some pertain to the characteristics of the occupation in question. Those include its utility to the proper functioning of the state body; the level of expertise and skills, and the responsibilities it entails; and the conditions in which it has to be carried out. Hence, police officers enjoy the prerogative to carry a gun; prospective teachers are expected to hold formal qualifications and demonstrate competence in their area of specialisation; drivers are obliged not to exceed a set amount of working hours; and miners are required to use special work gear and equipment that ensures their safety. The kind and intensity of regulation is further dependent on country specificities.⁶³ In capitalist societies which foster and promote private ownership and enterprise, state control is generally limited and attempts by governments to interfere with the affairs of professional guilds are perceived as intrusive, even threatening. By contrast, in communist societies professional practice in almost any sphere is not only heavily regulated by the ruling elite, but very often it is also funded and directed at ends and objectives that are explicitly set and defined by the government.

The Social Homeostasis⁶⁴

Just as the human body has to maintain inner balance in order to perform its vital functions, virtually any social grouping requires a certain degree of internal stability to ensure that it can survive and flourish. As far as the body is concerned, balance is achieved via the process of homeostasis, which allows the body to keep its inner conditions, such as temperature and blood pressure, at constant rates, especially when reacting to changes. For social groups, order is established and maintained by dint of governance. The

⁶³ P. Sohl and H. A. Bassford, 'Codes of Medical Ethics: Traditional Foundations and Contemporary Practice', *Social Science and Medicine*, vol.22:11 (1986), p.1179.

⁶⁴ Parts of this section appear in Tatyana Novossiolova, 'Biosecurity as a Normative Challenge' in Jens Clausen and Neil Levy, (ed.), *Handbook of Neuroethics*, (Dordrecht: Springer, 2015), pp.1813-1825.

process of governance is a complex one happening on multiple levels, encompassing a multitude of actors and taking a variety of forms. Since one of the chief properties of social systems is communication, it is possible to view governance as a combination of steering and coordination,⁶⁵ both of which are communicative processes aimed at influencing actions and behaviour, and attaining desired goals. Among the most common modes of governance are hierarchies, the 'rationalised instrument of authority',⁶⁶ networks, defined as 'relatively institutionalised frameworks of negotiated interaction within which different actors struggle with each other, create opportunities for joint decisions and coordinate concrete actions',⁶⁷ and markets. What form of governance needs to be adopted within a particular community cannot be determined in abstract terms but has to be reconciled with historical and cultural contingencies. One of the main reasons behind this lies in the unique and highly specific nature of social order.

Social order is not static but finds itself in a constant flux under the influence of various internal and external factors impacting on the community and on its relations with other systems. In contrast to the common perception of order as fixed and visual, among the chief attributes of social order are functionality and plasticity, which allow it to adjust to and accommodate changes in the social and ecological circumstances, and to respond to novel challenges. Among the most fascinating features of social order is its informal character, which mirrors the vibrant spirit and multi-faceted complexity of human-to-human interaction, vigorous communication and mutual understanding. Social order is therefore entrenched in the underlying logic of everyday social life:

The sum of each casual, public contact at a local level (e.g. nodding hello, admiring a newborn baby, asking where someone's nice pears come from) – most of it fortuitous, most of it associated with errands, all of it mattered by the person concerned and not thrust upon him by anyone – is a feeling for the public identity of people, a web of public respect

⁶⁵ Anders Esmark, 'The Functional Differentiation of Governance: Public Governance beyond Hierarchy, Market and Networks', *Public Administration*, vol.87:2 (2009), p.356.

⁶⁶ Robbie Waters Robichau, 'The Mosaic of Governance: Creating a Picture with Definitions, Theories and Debates', *Policy Studies Journal*, vol.39:s1 (2011), p.123.

⁶⁷ *Ibid*, p.122.

and trust, and a resource in time of personal or neighbourhood need. The absence of this trust is a disaster to a city street. Its cultivation cannot be institutionalised.⁶⁸

One aspect of social order that merits special attention is its normative foundation. Contrary to the assumption that order within social systems stems from formally established rules and procedures, such as laws and the institutions responsible for their enforcement, there are sufficient grounds to treat the former as a product of the predominant social norms and the expectations for acceptable behaviour that they create. It suffices to mention that people seldom refrain from committing illegal acts, including theft and murder, merely out of fear of facing sanctions afterwards. Were this the case, crime rates would be ubiquitously high and the prisons would be permanently full. Rather, individuals themselves choose to follow agreed rules of common decency, for they are convinced it is in their interest to do so. The underlying logic of such behaviour is not difficult to grasp: by accepting certain constraints on their freedom individuals signal their inclination to cooperate with other members of society and contribute to the common good, thus enjoying benefits which otherwise will be unattainable. Not only does free-riding then become a costly option, but it also loses its attractiveness, as 'cheaters' are hardly tolerated and likely to be ostracised.⁶⁹ A powerful social stigma on certain actions will undoubtedly have direct implications for the establishment of social order. To be sure, the members of a society in which theft and murder are commonly viewed as unacceptable acts that merit denunciation are much more likely to enjoy a relative degree of safety than those living in a society utterly dependent on law enforcement for tackling such problems:

Social order is not the result of the architectural order created by T squares and slide rules. Nor is social order brought about by such professionals as policemen, nightwatchmen, and public officials. Instead, 'the public peace is – the sidewalk and street peace – of cities is ...kept by an intricate, almost unconscious network of voluntary controls

⁶⁸ Jane Jacob quoted in James Scott, *Seeing like a State: How Certain Schemes to Improve the Human Condition Have Failed*, (New Haven: Yale University Press, 1998), p.136.

⁶⁹ Gary Becker, *Accounting for Tastes*, (Cambridge MA: Harvard University Press, 1996).

and standards among the people themselves, and enforced by people themselves'.⁷⁰ (Emphasis as original)

Norms signify what a particular social group considers acceptable and unacceptable modes of behaviour. Unlike laws, they are not dependent on government for either promulgation or enforcement.⁷¹ Instead, norms arise from and crystallise in the emergence of gradual consensus⁷² as to what the members of a given group perceive as 'normal', and are sustained by a shared recognition of their importance. Norms carry significant regulatory weight, insofar as they reflect the ethos of the group, that is, the beliefs, values and morals shared by its members, and instances of non-compliance may have severe consequences. Thus, conformity with established norms both plays a paramount role in the maintenance of social order and constitutes an indispensable precondition for the functioning of law. As Tamanaha⁷³ has pointed out, the 'state legal system would not even exist, were it not for an already stable and effective baseline provided by the unarticulated substrate, shared norms, instrumental behaviour and consent'.

Norms are inevitably subject to cultural and historical contingencies and tend to vary across communities. As such, they resemble 'a living, negotiated tissue of practices which are continually being adapted to new ecological and social circumstances – including, of course, power relations'.⁷⁴ Far from being static, norms evolve and change in parallel with social processes and practices. For their part, laws by and large, follow the dynamics of social norms and adapt accordingly. Laws that guarantee women's rights have only emerged as a result of the persistent efforts of the emancipation movements over the past century that challenged the prevalent norms of male superiority. Similarly, the collapse of the apartheid regime in South Africa would not have

⁷⁰ Jane Jacob in James Scott, *Seeing like a State*, p.135, *op cit*.

⁷¹ Richard Posner and Eric Ramusen, 'Creating and Enforcing Norms with Special Reference to Sanctions', *International Review of Law and Economics*, vol.19 (1999), p.369.

⁷² *Ibid*, p.370.

⁷³ Brian Tamanaha, *A General Jurisprudence of Law and Society*, (Oxford: Oxford University Press, 2001) p.224.

⁷⁴ James Scott, *Seeing like a State*, p.34, *op cit*.

occurred had not it been for the lack of popular support for the established order.⁷⁵

But while formal forms of regulation and control are largely informed and influenced by the changing social norms and practices, the reverse process, whereby governors adopt the former for promoting a particular desired behaviour among the members of a community is messy and arduous, exposing the limits of purely top-down governance mechanisms. The history of the human rights regime is a case in point. Brought about by the struggle of individuals everywhere to delegitimise the relations of absolute power, the human rights regime has played a major role in the abolition of colonialism, total war and slavery. At the same time, although most states have officially acceded to and codified at national level the provisions of the international treaties that seek to guarantee a set of universal rights for every human being, practices as gruesome as female genital mutilation (FGM), honour killing and even genocide still persist more than 60 years after the Universal Declaration of Human Rights was signed. The obstacles to effective norm entrepreneurship are further illustrated in the reluctance of democratic governments to impose legal rules which are inconsistent with the prevalent social norms. Hence, the decision of President Lyndon Johnson to sign the Civil Rights Act of 1964 is often cited as an example of political courage, not least because of the public outrage that followed the new law, especially in the southern states. Needless to say, the Act required a substantial degree of enforcement in order to have an effect on lessening racial discrimination and segregation.

The above discussion is indicative of the significant role that social norms play in the regulation of human relatedness, that is, in the governance of social systems. Contrary to the popular belief that regulatory activity could be reduced to rational problem solving, whereby quick and easy fixes could be identified and implemented by those in power, the process of regulation within the social realm is anything but clear and straightforward. Regulation is more often than not a slow and complex task, which, even if performed

⁷⁵ Jim Whitman, *The Fundamentals of Global Governance*, (Basingstoke: Palgrave, 2009) p.80.

effectively, remains unlikely to result in direct and linear effects, control of all possible variation, or eradication of unintended consequences.⁷⁶ It is not an exact science: there are hardly any clear-cut answers, nor are there hard and fast rules that the regulator must follow in order to ensure successful outcomes. This is so, for the task of regulation is one that ‘engages the whole person’.⁷⁷ As such, it encompasses ‘not only the ability to analyse problems and work out rational responses but also, the ability to respond to situations on the basis of feelings and emotions’.⁷⁸ Given the centrality of judgement in the process of regulation, virtually any form of governance that is based primarily or solely on rationality is likely not only to be largely ineffective but also deleterious. From the horrors of the concentration camps run by the Nazi regime⁷⁹ through the destruction of the Aral Sea in the former Soviet Union to the failure of the ‘shock therapy’ designed to facilitate the economic recovery of post-communist Russia in the early 1990s, the pernicious effects of governance mechanisms that are based on sheer rationality in terms of goal-chasing, division of labour and rule-following and that demonstrate neglect of moral and human costs are vividly revealed. Optimisation in the management of machines could potentially increase efficiency and productivity; optimisation in the regulation of social systems inevitably leads to omission of important aspects pertaining to the range of potential complex interactions between man-made and natural systems, and erosion of the established moral principles. Unlike the technical operator who ‘has a single course given outside the system’, the human regulator, individual or collective, ‘controls a system which generates multiple and mutually inconsistent courses. The function of the regulator is to choose and realise one of the many possible mixes, not fully attainable’.⁸⁰ In other words, far from striving to arrive at *optimal* solutions, the regulator has to come up with solutions that are *good enough* in the perceived circumstances.⁸¹ In doing so, he is not acting from the position of an impartial observer placed outside the

⁷⁶ Anders Esmark, ‘The Functional Differentiation of *Governance*’ *op cit*, p. 356.

⁷⁷ Peter Checkland, ‘Systems Theory and Management Thinking’, *American Behavioural Scientist*, vol.38:1 (1994), p.76. See also Charles Lindblom, ‘The Science of “Muddling Through”’, *Public Administration Review*, vol.19:2 (1959), pp.79-88.

⁷⁸ *Ibid*.

⁷⁹ See Zygmunt Bauman, *Modernity and the Holocaust* (Ithaca, NY: Cornell University Press, 2000).

⁸⁰ Geoffrey Vickers quoted in Peter Checkland, ‘Systems Theory and Management Thinking’, p.81, *op cit*.

⁸¹ Peter Checkland, p.79, *op cit*.

system he is supposed to regulate but is an active member of the respective society, and as such, is guided in his deeds and decisions by the prevalent social norms, standards and values. The process of governance and all its forms are thus a manifestation of culture and the need for maintaining desired and eluding undesired relationships within and outside the social system.⁸²

Engineering Governance

The idea that governance is a function of culture has direct and profound implications for the notion of total control. Given the informal logic of social order that emphasises the vitality of social norms and the indispensable role of moral judgement, it is hard to imagine how every aspect of human activity could be subject to formal regulation and constant supervision:

Political systems [...] are not to be modelled on computers, unless they are simplified either by ignoring their more important aspects, which only makes the result misleading, or by controlling their outcome with a completeness, which, if it were possible, would be highly threatening – as it already is in those regimes where it is attempted.⁸³

Despite the influential and quite convincing anti-utopian scenarios presented in George Orwell's *1984* and Aldous Huxley's *A Brave New World*, the utterly totalitarian society in which individuals' behaviour is so closely monitored that instances of disobedience are pre-empted and any alternatives to the dominant power and the lifestyle it imposes are virtually non-existent so far remains a fiction. Even one of the most commonly cited historical examples of totalitarian government, the case of the Soviet Union, tends to reinforce rather than dispel the myth of total control. A careful analysis of the complex processes that took place within the Soviet society throughout the 1930s, a period associated with the 'darkest' days of Stalinist repression, vigorous use of propaganda and censorship, and blatant abuse of government power reveals that 'beneath the "smooth coiffure" of totalitarian culture [...] many

⁸² Geoffrey Vickers quoted in *ibid*, p.81.

⁸³ Geoffrey Vickers, *Human Systems Are Different*, (London: Harper & Row Publishers, 1983), p.xxiii.

cultural worlds remained intact, and there existed a zone in which a mass aesthetic consciousness spontaneously took shape'.⁸⁴ Official culture that sought to shape the 'new man' by praising the ideological superiority of Marx-Leninist postulates and asserting communist values quickly proved incapable of filling the entire cultural space, leaving a niche within which popular culture could comfortably develop and flourish.⁸⁵ Up until the collapse of the communist regime, the borders of the Soviet Union, otherwise largely sealed for human movement, remained permeable to foreign influence which quickly took root in a range of informal practices surreptitiously cherished by the masses. The persistent attempts of power structures to keep literature, theatre and cinemas in check notwithstanding, the 'art of the masses' and 'mass art' obstinately made their way avoiding the dense net of state controls and oppressive sanctions and finding expression through the variety stage, vaudeville, circus, 'under the counter' sale of jazz and foxtrots, and 'de-westernisation' of foreign movies.⁸⁶ Against the background of institutionalised ideologically acceptable art forms, forbidden books, meticulous repertoire planning, and intellectual corruption and silencing, popular culture with its simplicity, light and cheerful spirit, and proximity to everyday life served as a social shield against the horrors conducted by the secret police and the pervasive chill of fear imbuing every level of society. Despite its sophisticated state apparatus, enormous resources, impeccably devised control mechanisms, and efficiently run network of prisons and labour camps, the Soviet Union never fully defeated the forces of mass culture which eventually contributed to its own disintegration, underscoring the limits of government structures and the futility of sheer power in winning the hearts and minds of individuals.

While the tragic fate of the Union of Soviet Socialist Republics (USSR) illustrates the negative outcomes of myopic leadership with regard to popular culture and its creative impulses, it still does not entirely exclude the possibility of comprehensive regulation of human affairs. After all, if the main

⁸⁴ Valentina Lebedeva, 'Totalitarian and Mass Elements in Soviet Culture of the 1930s', *op cit*, p.66.

⁸⁵ *Ibid.*

⁸⁶ *Ibid.*

challenge to governance engineering is culture with its complexity and unpredictability, it seems logical to assume that the simplification of the latter would potentially facilitate the former. But could culture be really simplified to such an extent as to enable intensive coordination and exercise of holistic control? While the immediate answer seems to be 'no', it may be helpful to consider the structure of cultures of work in modern industrialised states. A closer look at the modern professional arena reveals a tightly compartmentalised landscape characterised by a clear division of labour and narrow specialisation. Since most areas of expertise are limited in terms of breadth focusing on the details of a particular subject matter, tailoring professional roles accordingly makes assigning individual responsibilities relatively easy and straightforward. The scope of employees' duties is thus generally restricted to the tasks that have to be performed as part of their respective jobs. The allocation of power follows much the same principle. The lady behind the reception desk at a public institution may advise visitors on the type of forms that are required, the documents that have to be submitted alongside and the typical period for response but she can hardly assist with resolving non-information-related issues: she is neither qualified, nor authorised to do so. Likewise, an operator working within a giant chemical plant is expected to fulfil certain duties with regard to machine maintenance but in case of any major system failure that exceeds his level of competence, he is obliged to report to his superiors and wait for expert assistance before resuming work.

To some extent, cultures of work have been consolidated because of the significant impact of technology. With the rapid advancement and proliferation of high technology over the past century many areas of professional specialisation have been tremendously transformed creating a working environment that emphasises efficiency, safety and effectiveness. From mining and factory processing to transportation and laboratory work the effects of technological optimisation as a substitute for human force are reflected in better quality, increased precision, lessened resource waste, and a reduced range of potential hazards. The air traffic control system is a case in point. Thanks to the improvements made in aircraft design, monitoring and

navigation, the number of plane crashes and collisions has been significantly reduced as a result of which commercial flights are generally perceived as a relatively safe way of travelling.⁸⁷

A direct consequence of the growing reliance upon machines, computers and other technical devices hailed as markers of civilisational progress is the significantly decreased role of the human factor in the performance of tasks and operations. Besides in air traffic control, this trend is also evident in other areas including chemical plant management, laboratory research, and space missions. In all of those fields technical competence is considered of paramount importance and the scope for improvisation is substantially restricted. There are also practical reasons why technology is deemed indispensable in the modern professional arena. The most obvious one is that it works, or at least, it seems to do so to the extent that it allows operations to be performed faster and more effectively. As already mentioned, engineering controls are particularly praised for their contribution to safety. High-containment laboratories equipped with advanced hardware and extra precautions provide life scientists with a favourable environment for conducting experiments on a host of highly dangerous pathogens such as the causative agents of Ebola, HIV/AIDS and smallpox without compromising public welfare. But what really makes technology so attractive is the way in which it appears to facilitate governance. Risk assessment software, manuals containing clear and detailed instructions pertaining to job technicalities, and extensive descriptions of safety procedures and practices are considered valuable tools in the modern management arsenal, not least because they provide employees and managers alike with blueprints of how work within a given institutions is to be organised so that efficiency is maximised and the likelihood for any potential hazards is kept to a minimum. As a result, there is a *prima facie* reason to suppose that the more technical the matter to be governed, say work in a laboratory or at production line, the easier it would be – easy to the degree of approaching the technocratic.

⁸⁷ Charles Perrow, *Normal Accidents: Living with High-Risk Technologies* (New Jersey: Princeton University Press, 1999). See the chapter entitled 'Aircraft and Airways'.

Chapter 2: Governance of Science before 1945

Science as an 'Aristocratic Endeavour'

The Scientific Revolution, a period that culminated in a drastic redefinition of the mediaeval world-view, itself a Christianised elaboration of the scientific and natural philosophical heritage of classical antiquity,⁸⁸ unfolded across most of Europe roughly between 1500 and 1700. In many respects, the Revolution constituted a multi-faceted phenomenon characterised by a radical departure from the prevalent understandings of the features and properties of the natural world. Two key developments jointly marked a turning point in the conceptual evolution of modern science, one being the replacement of the Ptolemaic earth-centred system of astronomy with the Copernican one articulated in the early sixteenth century; and the other – the substitution of the mechanistic philosophy of nature championed by Rene Descartes for Aristotelian natural philosophy.⁸⁹ Among the pinnacles of the Scientific Revolution were the extensive revision of the theories and aims of science; the refinement of methods of scientific enquiry; and the consolidation of a uniform body of knowledge in such areas as mechanics, astronomy and mathematics. But the Revolution also had far-reaching implications for the social organisation of science, transforming both the role of science practice within society and the structures vital for its cultivation, advancement and promotion.

Science in early modern Europe differed tremendously from its nineteenth-century counterpart, the latter being formally recognised as an established professional enterprise that played an indispensable part in the progress of industrialised societies. Back in its infancy, science constituted a broad domain encompassing various fields of inquiry with hardly any clear-cut branches of narrow specialisation. As such, it became differentiated from natural history and natural philosophy only gradually. Its champions were

⁸⁸ See John Schuster, 'The Scientific Revolution' in Robert Olby et al. (ed.) *Companion to the History of Modern Science* (London: Routledge, 1990), pp.217-242.

⁸⁹ *Ibid.*, p.217.

gifted individuals intrigued to explore nature and gain an understanding of its workings. Driven by curiosity and a genuine urge to uncover as many of the secrets of the physical world as possible, they seldom concentrated their energies on one particular intellectual puzzle and eagerly examined concerns of diverse character. Central to their work was the search for the underlying causes of the dynamics and phenomena observed in the world. In their quest for answers, natural philosophers were largely guided by a shared belief that nature could be studied deductively by dint of reason and experience. Hence, their primary goal was the collection of empirical data on the basis of which knowledge could be acquired and accurate theories about the state and order of the natural world could be formulated. Emphasising the theoretical foundations of knowledge, natural philosophers demonstrated a propensity to distinguish themselves from artisans and craftsmen, for the latter were seen as mere practitioners unable to understand the principles that governed their activity.⁹⁰ This attitude is partly grounded in the fact that even though natural philosophy was not utterly alien to contemporary surgeons, engineers, architects and even artists, very few of them actually contributed to its advancement at least until the eighteenth century.⁹¹

Among the challenges that early modern thinkers had to grapple with was the justification of the claims they made about the world. In order to ensure that knowledge was generated, natural philosophers required a fixed frame of reference against which the validity of their propositions could be assessed. In the immediate post-mediaeval period the frame that served this purpose was Christianity. Several reasons account for this trend, including the fact that the authority of religion as the only source of truth at that time was uncontested and the Church continued to play an important role in the social and political affairs of the Western European states. The slow pace of affirming the credibility of Copernican theories and the tragic fate of prominent individuals, such as Galileo Galilei and Giordano Bruno, who openly questioned the Church doctrine, are further indicative of the determination of the Church to maintain its monopoly and final judgement

⁹⁰ See Roger Emerson, 'The Organisation of Science and Its Pursuit in Early Modern Europe' in Robert Olby et al. (ed.) *Companion to the History of Modern Science*, *op cit*, p.965.

⁹¹ *Ibid.*

over what constituted valid knowledge. Yet being devout Christians themselves, most contemporary scientists did not perceive a conflict between their work and religious convictions, not least because their observations and discoveries highlighting the richness and diversity of nature only reinforced the inference that the latter was an intricate clock designed by a skilful clockmaker (God).⁹² This trend is evident from the large number of scientists recruited from the ranks of the clerics and the even larger number of individuals willing to promote science, due to its alleged support for religious beliefs.⁹³ Unsurprisingly, Catholics and Protestants alike saw these developments as a favourable opportunity to expand their influence by providing patronage for the individuals and institutions involved in the study and teaching of science. As a result, many ecclesiastical establishments dedicated space and resources for the pursuit of scientific activity within their institutions, in addition to which a significant number of schools, colleges and universities were brought under the control of the clergy by dint of staffing and funding.⁹⁴

An important feature of the early modern period was the development of a close and multifaceted relationship between science and the court. In fact, the origins of these connections can be traced back to the late Middle Ages and the Italian Renaissance, with city-state rulers and wealthy aristocratic families acting as patrons of individuals demonstrating skill and knowledge in areas such as arts, mathematics, and engineering. Typically resident in noble households and/or holding a court office, early men of science, including Leonardo da Vinci, Michelangelo and Johannes Kepler, diligently strived to promote the value of their expertise, thus enhancing the glory and prestige of their sovereigns. To be sure, aristocracy's support for science was underpinned by considerable vested interests in the practical benefits that could be obtained from such patronage. Fields like gunnery, cartography, navigation and architecture received considerable attention, not least because of the immediate strategic, economic and commercial advantage that could be yielded. With the growing sophistication of technology, there

⁹² Dominick Jenkins, *The Final Frontier: America, Science, and Terror* (London: Verso, 2002), p.234.

⁹³ Roger Emerson, 'The Organisation of Science and Its Pursuit in Early Modern Europe', *op cit*, p.962.

⁹⁴ *Ibid*.

was an increased appreciation for the value of science, particularly among the aristocracy. The advent of the cannon is a case in point. Having exposed the heightened vulnerability of the Italian city-states to foreign invasion, it effectively paved the way for the emergence of the cannon-proof system of fortification – the bastion.⁹⁵ Given the importance of advanced mathematical knowledge for the design and building of reliable fortifications, it was essential that military engineers and warriors of noble birth become mathematically literate.⁹⁶ According to *The Book of the Courtier*, mathematics also featured in the education of young aristocrats.⁹⁷ One critical aspect that further facilitated the embedding of science in the court culture of European monarchies was the rise of prince-practitioners – royal figures who did not merely support the promotion of natural knowledge but were themselves actively engaged in technical and mathematical projects.⁹⁸ By demonstrating their commitment to the procedural values of technical precision, objective observation, systematic collection of information and collaborative effort, such leaders played a crucial role in elevating the status of science, successfully transforming their courts into ‘institutional nodes of technical activity’.⁹⁹

The increasing dependence of modern European societies on science and technology crystallised into a gradual transition from agrarianism to industrialisation. New discoveries about the natural world began to find practical application in various spheres of activity, including transportation, mining, astronomy, medicine, surveying and engineering, leading to considerable improvements in the welfare of modern nations. Seeking to assert their legitimacy and demonstrate an appetite and capacity for power projection, cultural flourish and military conquest, modern states were keen to harness technical expertise and vigorously exploit it to its greatest potential. A direct consequence of this policy orientation was the surge in the number of natural philosophers, engineers and skilful artisans recruited to work at the

⁹⁵ Mario Biagioli, ‘The Social Status of Italian Mathematicians, 1450-1600’, *History of Science*, vol.27:1 (1989), p.45.

⁹⁶ *Ibid.*

⁹⁷ See Baldassarre Castiglione, *The Book of the Courtier: Translated and with an Introduction by George Bull* (London: Penguin, 2003).

⁹⁸ See Bruce Martin, ‘German Prince-Practitioners: Aspects in the Development of Courtly Science, Technology, and Procedures in the Renaissance’, *Technology and Culture*, vol.22:2 (1981), pp.253-274.

⁹⁹ *Ibid.*

service of the state.¹⁰⁰ Because of the specialised knowledge and skills they possessed, those individuals enjoyed the status of experts, and as such, were deemed qualified to offer informed opinion and deploy theoretical and analytical thinking for overcoming practical hurdles and alleviating societal ills. Motivated by the ideal of truth about the natural world and a strong desire to maximise the common good, men of science constantly strived to enhance their understanding of nature and develop novel techniques for its manipulation toward productive ends. In their pursuit for greater effectiveness and efficiency, experts focused on the acquisition of operative knowledge that could be translated into practical outcomes and placed at the service of state, commercial and manufacturing interests.¹⁰¹ By adopting a mechanistic, practice-oriented approach to the study of nature and emphasising the importance of rationality for predicting natural phenomena, they set the scene for an era of 'Technological Enlightenment',¹⁰² which eventuated in the First and Second Industrial Revolutions. The work of experts thus made a valuable contribution to the consolidation of power of modern states, allowing them to expand the scope of their influence by conquering new territories, creating and sustaining global empires and fostering trade networks.¹⁰³

The emergence of science institutions during the Scientific Revolution and especially throughout the Age of Enlightenment had profound implications for the social organisation of scientific enquiry and the popularisation of natural knowledge. Chiefly tasked with the administration and advancement of research, these institutions enhanced the social standing of science and validated the authority of its agents as experts. Most importantly, they facilitated the secularisation of science, taking it outside the churches and universities and placing it within the remit of the state institutional apparatus.¹⁰⁴ Among the early science institutions were observatories and academies. Learned societies were fluid in nature and diverse in terms of

¹⁰⁰ See Anna Maerker, 'Political Order and the Ambivalence of Expertise: Count Rumford and Welfare Reform in Late Eighteenth-Century Munich', *Osiris*, vol.25 (2010), pp.213-230.

¹⁰¹ See Eric Ash, 'Introduction: Expertise and the Early Modern State', *Osiris*, vol.25 (2010), p.23.

¹⁰² *Ibid.*

¹⁰³ *Ibid.*, p. 16.

¹⁰⁴ Roger Emerson, 'The Organisation of Science and Its Pursuit in Early Modern Europe', *op cit*, p.972.

expertise,¹⁰⁵ devised to bring together individuals with an interest in the study of nature and provide them with an arena for deliberation and exchange of key findings. Many of them evolved from the late sixteenth-century clubs in which individuals would gather in an informal manner to discuss concerns of various kinds. Since their members were largely drawn from the high social strata and the ranks of aristocracy, early learned societies were imbued with an air of elitism. Some sixteenth-century Italian academies even existed for the sole purpose of giving expression to, and thus perpetuating, the social differentiations between low-class science *virtuosi* and those belonging to the nobility.¹⁰⁶ A distinct feature and an important source of the legitimacy of learned societies was their proximity to the court. The British Royal Society (1660), the French Royal Academy of Sciences (1666) and the Russian Academy of Sciences (1724) all enjoyed formal recognition by the Crown and strived to combine the advancement of knowledge with loyalty and service to the state's interests. Still, the different path of development these institutions followed indicates that the modes of operation of learned societies were a function of the socio-political and economic context within which they existed.¹⁰⁷ This helps to explain some obvious discrepancies in the functioning, funding and management of learned societies across Europe, manifested in the private patronage of the Royal Society, the state subsidies allocated to the French Academy and the challenges that the Russian Academy faced after the death of Peter the Great. The institutional variations notwithstanding, by and large, learned societies demonstrated an explicit commitment to endorsing and maximising the merits of scientific enquiry. Through the publication of journals, memoirs and proceedings aimed to facilitate the dissemination and exchange of novel ideas and cutting-edge discoveries and through the promotion of joint and collaborative effort at national as well as, international level,¹⁰⁸ academies played an indispensable

¹⁰⁵ See Simon Werrett, 'The Schumacher Affair: Reconfiguring Academic Expertise across Dynasties in Eighteenth-Century Russia', *Osiris*, vol.25 (2010), p.104.

¹⁰⁶ See Mario Biagioli, 'The Social Status of Italian Mathematicians, 1450-1600', *op cit*, p.61-62.

¹⁰⁷ A case in point is the establishment of the Royal Society of Edinburgh in 1783, which arose 'not of necessary organisational demands of science but of the particular position that scientific culture came to occupy in the local context.' See Steven Shapin, 'Property, Patronage, and the Politics of Science: The Founding of the Royal Society of Edinburgh', *The British Journal for the History of Science*, vol.7 (1974), pp.1-41.

¹⁰⁸ See Roger Emerson, 'The Organisation of Science and Its Pursuit in Early Modern Europe', *op cit*, p.973; Derek de Solla Price, *Little Science, Big Science* (New York: Columbia University Press, 1963), p.4.

role in solidifying the position of science as a sphere worthy of professional recognition.

Science as a Vocational Pursuit

Two parallel dynamics had a direct bearing on the transformation of science from a gentlemanly leisure activity into an established professional enterprise with social standing and authority. One was the increasing significance of science practice in society, underpinned by the intensive industrialisation that West European states underwent during eighteenth and nineteenth centuries. The brilliant scientific breakthroughs and technological achievements from the time of the Enlightenment served to sustain the public interest in the work of scientists, highlighting both the practical utility of science and its potential for human betterment. The improvements in transport, infrastructure and communications, the expansion of civil and mechanical engineering, the developments in industrial chemistry, the advances in medicine and the rapid spread of the applications of electricity not only raised the social profile of men of science granting them prominence and respect but also strengthened an awareness of the links between state power, public welfare and technological progress.¹⁰⁹ An illustration of this trend is the surge in career opportunities and paid positions available to individuals in possession of scientific and technical expertise, which made it possible for them to secure full-time contracts in non-academic domains, including industrial engineering, manufacturing and corporate and government consultancy.¹¹⁰ What is worth noting is that the establishment of science as a source of income brought about a shift in the opinion regarding the commercialisation of knowledge. Hence, although up until the second half of the nineteenth century the prospects for making a fortune out of science

¹⁰⁹ Rene Taton, 'Emergence and Development of Some National Scientific Communities in the Nineteenth Century', *International Social Science Journal*, vol.22:1 (1970), p. 95. See also Rainald von Gizycki, 'Centre and Periphery in the International Scientific Community: Germany, France, and Great Britain in the 19th Century', *Minerva*, vol.11:4 (1973), pp.474-494.

¹¹⁰ John Pickstone, *Ways of Knowing: A History of Science, Technology, and Medicine* (Manchester: Manchester University Press, 2000), p.167. See also John Pickstone, 'Sketching Together the Modern Histories of Science, Technology, and Medicine', *Isis*, vol.102 (2011), pp.123-133.

remained rather scant,¹¹¹ few scientists shared the attitude of their Enlightenment counterparts toward profit as a degrading pursuit and even fewer aligned themselves with Faraday's reluctance to patent their inventions and discoveries.¹¹²

The second dynamic in question pertained to the growing sophistication of science and the manner in which knowledge was pursued. The constant refinement of scientific methods helped overcome many experimental deficiencies and minimise errors, thus allowing for greater precision and efficiency in the conduct of research and a higher intensity of knowledge generation. The resultant growth in the volume and complexity of research output gradually turned science into a highly specialised body of knowledge placing it beyond the comprehension of the average individual and making it available only to those possessing specific skills and expertise.¹¹³ Given the ever-increasing demand for science practitioners and the shrinking pool of individuals capable of keeping the engines of technical progress running, by the start of nineteenth century the professionalisation of science could scarcely have been avoided, even if it was not clearly foreseen.

Several developments merit attention in mapping the process of the evolution and consolidation of the practice of science as a distinct professional culture. These include the establishment of a formal system for training and certification; the introduction of institutional and infrastructural reforms in the administration of science; and the emergence of mechanisms for granting credit and acknowledging excellence in science. Since early natural philosophers usually took up science as a pastime activity, seldom did they require any formal preparation. Hence, they were often self-taught. Under the pressures of industrialisation and the need for technological innovation, however, this tendency began to change most notably after 1800 when science *virtuosi* and amateurs were steadily supplanted with formally

¹¹¹ See W.H. Brock, 'The Spectrum of Science Patronage' in G. L'E. Turner ed. *The Patronage of Science in the Nineteenth Century* (Leyden: Noordhoff International Publishing, 1976), p.173. Thomas H. Huxley is famous for saying that, 'science in England does anything but pay. You may earn praise but not pudding!'

¹¹² See John Pickstone, *Ways of Knowing, op cit*, p.168; Sydney Ross, 'Scientist: The Story of a Word', *Annals of Science*, vol.18:2 (1962), p.66.

¹¹³ George Daniels, 'The Process of Professionalisation in American Science: The Emergent Period, 1820-1860', *Isis*, vol.192 (1967), pp.151-167.

educated students of science. In Britain, mechanics colleges founded in most industrial towns made science education available to the working classes; the universities in Oxford and Cambridge began conferring Bachelor of Science degrees; and in Germany, higher technical colleges offered individuals theoretical grounding in engineering.¹¹⁴ In France, too, following the Revolution of 1789 science teaching was given a powerful fresh impetus. Elementary instruction in mathematics and physics was introduced in the new central schools to compensate for the utter neglect of the natural sciences exhibited by colleges of the *ancien regime*.¹¹⁵ Staffed with the most prominent contemporary scientists and equipped with advanced laboratory technologies, the French higher education institutions, including the Ecole Polytechnique, the Ecole des Mines and the Ecole des Ponts et Chaussees provided science students with an extensive theoretical and practical training allowing them to keep pace with the latest developments in research.

Besides the obvious practical benefits of incorporating science teaching in the instruction of prospective engineers, the introduction of formal qualifications served as a mechanism for public certification of competence. This was particularly true of the PhD degree in science awarded by German universities. Not only did the degree provide fresh graduates with an opportunity of pursuing research but it was also indispensable in validating their status as expert practitioners with in-depth theoretical and analytical understanding of science-related disciplines, such as chemistry. Efforts were made in revising and devising teaching procedures and techniques in order to ensure that science students received adequate training. One such initiative was the emergence of instruction materials, including textbooks and manuals, targeting individuals at different levels of education (e.g. school, college and university).¹¹⁶ Yet another was the growing centrality of the university laboratory as a teaching space supplementary to the lecture room. Traditionally used by prospective academics in the process of gaining practical research experience, university laboratories came to be regarded as

¹¹⁴ See John Pickstone, *Ways of Knowing, op cit*, p.166.

¹¹⁵ Rene Taton, 'Emergence and Development of Some National Scientific Communities in the Nineteenth Century', *op cit*, p.98. See also Terry Shinn, 'Science, Tocqueville, and the State: The Organisation of Knowledge in Modern France', *Social Research*, vol.59:3 (1992), pp.533-566.

¹¹⁶ W.H. Brock, 'The Spectrum of Science Patronage', *op cit*, p.192.

an essential training ground where science students could acquire tacit skills and master experimental techniques.¹¹⁷

The institutional and structural reforms in the social organisation of science that took place during the nineteenth century reflected the realities of the time largely shaped under the influence of the ideals of the French Revolution and the drives for maximising the public gains to be reaped from industrialisation and technological progress. Despite the differences in their manifestations stemming from the political, economic and historical specificities of European states, the reforms generally sought to democratise the practice of science while ensuring research quality and integrity; to foster innovation and promote science principles; and to routinise greater commitment and support from the state. As such, they played an instrumental role in creating a sense of community consciousness among those dedicated to the study of nature, thus institutionalising science as a profession of its own and laying the foundations for the development of a national science policy. A case in point is Germany after its consolidation. Generously supported by the Imperial government and offering clear prospects for successful professional realisation, research in the natural sciences quickly became an attractive career path for students at universities and technical schools. With science teaching permanently embedded in the education curricula and the rapid rise in the number of newly-founded research institutes and laboratories, the stage was set for the emergence of an ambitious scientific community with a growing specialisation that mirrored the trends in industrial expansion. Thanks to its proven efficacy of employing the theoretical and practical skills acquired in the educational institutions for the purposes of boosting the economic and political influence of the state, the German model was vigorously praised and aspired to by scientists and policy-makers not only in Western Europe but across the ocean, in the US, as well.

In an attempt to improve the state of a declining British science, individuals of a Liberal stripe and graduates of the Scottish universities led a struggle for

¹¹⁷ J.B. Morrell, 'Professionalisation' in Robert Olby et al. (ed.) *Companion to the History of Modern Science, op cit*, p.983.

reforms against the ruling classes and the Anglican Church, both of which exercised preponderant influence over the academic curricula and the administration of research and jealously clung to their prerogatives.¹¹⁸ To this end, the establishment of the British Association for the Advancement of Science in 1831 was of paramount importance, for it provided the dissenting groups with formal mechanisms for voicing their concerns and, thus, generating public support for their cause. The Association was pivotal to a number of reforms, including the founding of specialised teaching institutions, new laboratories and research institutes, and the increase in state subsidies available for science research.¹¹⁹ In a similar fashion, the American Association for the Advancement of Science (AAAS) played a major part in affirming the professional status of those engaged in the pursuit of science. Set up in 1840, the AAAS embarked on the challenging task of upholding the ideals of truth, objectivity and impartiality that were deemed central to science, while, at the same time, monitoring compliance with professional standards. Given the importance of preserving the integrity of science practice, an explicit distinction between amateurs and professionals had to be drawn, reinforcing the vital role of the latter in fostering and sustaining economic progress and academic excellence. In this regard, the leadership of the Association is evident in its unequivocal commitment to the need for the *advancement* of scientific knowledge instead of its mere *diffusion*; the emergence of highly specialised journals barely accessible to those lacking extensive grounding in science; and the efforts to prescribe more rigid criteria for membership by admitting mainly individuals who had already made a contribution to science.¹²⁰

But institutional reforms sometimes proved insufficient in cultivating a healthy professional culture in which research could flourish. The epitome of this failure is the state of the scientific endeavour in France for most of the nineteenth century. Restructured and renamed as the First Class of the

¹¹⁸ Rene Taton, 'Emergence and Development of Some National Scientific Communities in the Nineteenth Century', *op cit*, p.101.

¹¹⁹ *Ibid*, p.102.

¹²⁰ George Daniels, 'The Process of Professionalisation in American Science', *op cit*, p.159-160. See also Roy Porter, 'Gentlemen and Geology: The Emergence of a Scientific Career', *The Historical Journal*, vol.21:4 (1978), pp.809-836.

Institut National in the aftermath of the Revolution, the French Academy of Sciences strived to promote the pursuit of knowledge by emphasising originality and creativity, as well as to serve in an advisory capacity on issues related to science and technology. The value of research was further heightened by the establishment of the Societe d'Arcueil, a private body set up by Berthollet and Laplace in 1805 for the advanced study of physics, chemistry and mathematics.¹²¹ Yet the government's disregard for the material needs of scientists, the resurgence of saloon activity at the expense of work carried out at laboratories and the inflexibility of the French educational system paved the way for the creation of a professional culture that encouraged private politicking, patronage games and lip service to the ideals of science.¹²² With career prospects heavily determined by political considerations, rather than talent and demonstrated capacities, and the growing divide between the bureaucratic and intellectual concepts of the savant, by 1900 French professional science had yielded a blighted harvest.¹²³

Along with formal training and institutional structures, professions require some form of public recognition in order to achieve full legitimacy. In the case of science, the development of systems and practices for rewarding achievement and celebrating excellence in research, and the organisation of international meetings and symposia exclusively for the purpose of discussing recent developments in science-related disciplines served to solidify its position as an established professional domain. Formal awards were usually granted by the respective national academies and professional associations. While the value attached to them was symbolic rather than material, the honours, prestige and prominence that such prizes brought made them a desired goal for those dedicated to the pursuit of knowledge. Among the exceptions of the time was the fellowship awarded by the British Royal Society, as it did encompass some financial support for the work of the

¹²¹ See Robert Fox, 'Scientific Enterprise and the Patronage of Research in France, 1800-70', *Minerva*, vol.11 (1973), pp.442-473.

¹²² *Ibid*, p. 457; see also Rene Taton, 'Emergence and Development of Some National Scientific Communities in the Nineteenth Century', *op cit*, p.99; J.B. Morrell, 'Professionalisation' in Robert Olby et al. (ed.) *Companion to the History of Modern Science*, *op cit*, p.986.

¹²³ See Robert Fox, 'Science, the Universit, and the State in Nineteenth-Century France' in G.L. Geison (ed.), *Professions and the French State, 1700-1900* (University of Pennsylvania Press, 1984), pp.66-145.

successful fellows.¹²⁴ After 1901, the Nobel Prize became by far the highest and most prestigious award conferred for an outstanding performance in a scientific discipline at an international scale. But even prior to the introduction of the Prize, there were already signs of science overcoming chauvinistic inclinations and creating a sense of professional unity among its practitioners. An example of this trend is the emergence of international congress meetings and conferences that aimed to bring together scientists from different states to provide them with a platform for a discussion and debate on the latest developments, findings and discoveries. Narrowly focused on a specific scientific discipline, such forums not only facilitated the dissemination of research but also allowed scientists to meet in person, share expertise and even foster partnerships and collaborative effort. Examples include the international congresses in statistics held from 1853 onwards; in chemistry from 1860; in botany from 1864; in medicine from 1867.¹²⁵

With science literature becoming more and more sophisticated and barely accessible for individuals without sufficient theoretical grounding; with membership in science institutions (e.g. academies and associations) being restricted to active researchers and scholars; and with the growing sense of solidarity and collegiality among practitioners in different science disciplines, the scientific endeavour steadily drifted away from general culture. Far from being smooth and linear, this process was shaped by vigorous power struggles, radical political and social reforms and a strong desire to democratise the pursuit of knowledge without compromising its integrity. Its pinnacle was the eventual transition of science practice from the hands of the amateur to those of the professional,¹²⁶ explicitly manifested in the establishment of the term 'scientist' as a professional title. Originally coined by William Whewell in 1834, the word served to nurture a sense of unity among individuals specialising in different science sub-fields by denoting

¹²⁴ See W.H. Brock, 'The Spectrum of Science Patronage', *op cit*, p.188-189.

¹²⁵ Rene Taton, 'Emergence and Development of Some National Scientific Communities in the Nineteenth Century', *op cit*, p.97.

¹²⁶ Sydney Ross, 'Scientist: The Story of a Word', *op cit*, p.65.

their shared commitment to the ideals of truth, originality and objectivity.¹²⁷ The established norms of practice (e.g. peer review, publication, mentorship) common across various scientific disciplines and the shared outlook on the role of science in society further served to create a particular group mentality which inevitably left a distinctive stamp on scientists.¹²⁸ Thus, the consolidation of a professional culture featuring specialised language systems, advanced experimental techniques and accepted modes of behaviour, routines, symbols and rituals effectively gave rise to a scientific community with clearly defined frontiers and a relative degree of sovereignty.¹²⁹ The degree to which this community was imagined can be regarded as compelling evidence of scientists' own perceptions of the importance of articulating and reinforcing their nascent professional culture.

Harnessing the Power of Science

The development of science from about the second half of the nineteenth century onwards fully embodied Francis Bacon's famous revelation *scientia est potentia* ('knowledge is power'): knowledge had long been equated with power but it was the political, economic and social arrangements of the late modernity that made its utilisation on a large scale possible and therefore irresistibly attractive. With the professionalisation of science, the scene was set for the mass production of knowledge that could be commercialised, patented, exploited for profit, deployed for military ends and used for boosting the state's economic and political influence internationally. A manifestation of this was the growing recognition of the strategic leverage (industrial, commercial, economic, politico-military) of science that could be accrued through various forms of high-level facilitation, coordination, funding and policy planning. These forms of governance, both public and private, exerted (and continue to exert) a powerful influence on the cultures of science.

¹²⁷ Ibid.

¹²⁸ Robert Maclver, 'The Social Significance of Professional Ethics', *Annals of the American Academy of Political and Social Science*, vol.297 (1955), pp.118-124.

¹²⁹ Benedict Anderson, *Imagined Communities: Reflections on the Origin and Spread of Nationalism* (Cambridge: Verso, 1991), p.6.

Education and Training Opportunities

Up until the nineteenth century the majority of universities across Western Europe were preoccupied with teaching; research was marginal. To the extent that science was taught, courses were generally theoretical providing students with only limited opportunities for gaining practical experience. Inspired by the Humboldtian ideal of linking teaching and research, German universities were among the first to offer science a home where knowledge could be not merely disseminated but also advanced.¹³⁰ As a consequence, they were well-positioned to respond to the technological imperative created by the pressures of industrialisation, managing successfully to combine the cultivation of knowledge with fostering long-lasting and multifaceted links with the consumers of science. The field of chemistry is a case in point. The discovery of synthetic dyes in 1856 gave a fresh impetus to the German economy which culminated in the development of a rapidly expanding coal tar dyestuff industry.¹³¹ Since the companies' growing demand for trained personnel offered clear career prospects for virtually anyone with advanced understanding of chemistry, universities and their respective research institutes attracted a considerable number of students nationwide. The scheme served the interests of professors and students alike, not least because the former earned their income in proportion to the number of enrolments and the latter enjoyed affordable fees thanks to the academic subsidies granted by the Imperial Government.¹³² The close ties with commercial companies, however, often put an extra burden on universities. For instance, when in the 1890s the state transferred the onus of administering the certifying examinations to academia, universities had to devise self-regulation mechanisms to ensure that their graduates were

¹³⁰ Roger Geiger, 'Science and the University: Patterns from the US Experience in the Twentieth Century' in John Krige and Dominique Pestre (ed.), *Science in the Twentieth Century* (Amsterdam: Harwood Academic Publishers, 1997), p.159.

¹³¹ Diarmuid Jeffreys, *Hell's Cartel: IG Farben and the Making of Hitler's War Machine* (New York: Metropolitan Books, 2008), p.18. See also Georg Mayer-Thurow, 'The Industrialisation of Invention: A Case Study from the German Chemical Industry', *Isis*, vol.73:3 (1982), pp.363-381; Robert Baptista and Anthony Travis, 'I.G. Farben in America: The Technologies of General Aniline & Film', *History and Technology*, vol.22:2 (2006), pp.187-224. On the links between German university and industry in other fields, see Wolfgang König, 'Science-Based Industry or Industry-Based Science: Electrical Engineering in Germany before World War I', *Technology and Culture*, vol.37:1 (1996), pp.70-101.

¹³² See Jeffrey Johnson, 'Academic Chemistry in Imperial Germany', *Isis*, vol.76 (1985), p.500-524. On academic physics training during the same period, see Lewis Pyenson and Douglas Skopp, 'Educating Physicists in Germany circa 1900', *Social Studies of Science*, vol.7 (1977), pp.329-366.

properly qualified.¹³³ In doing so, not only had universities to accommodate the requirements of industry by diversifying the curricula and increasing the amount of practical training that students underwent but they also had to heighten the value of the qualifications they offered in order to prevail in the fierce competition with technical colleges which after 1899 began awarding doctoral degrees.¹³⁴

Germany was not an isolated example as far as the symbiosis between academia and industry is concerned. In Britain, too, the advances in electrical engineering, and in particular, the invention of telegraphy helped create bridges between the academic realm and the commercial sector. When the expertise required for the development of a transatlantic cable telegraph outstripped the knowledge of the industrial engineers tasked with the endeavour, the Glasgow university laboratory where Lord Kelvin conducted his studies provided both the research environment and the skills required for the completion of the project.¹³⁵ Apart from being a financial and technological success, the outcome of this collaboration had at least two significant implications. First, it highlighted the value of academic research facilities offering favourable conditions for systematic testing and analysis, as well as, for training and capacity building. And second, it played a crucial role in making the laboratory an integral element of the engineering routine. In a similar fashion, the invention of electric lighting and the resultant demand for qualified technicians in industry vastly facilitated the introduction of formal technical instruction in American universities.¹³⁶

The emergence of the industrial research laboratory constituted a remarkable manifestation of the synergies between commercial firms, government agencies and academic institutions. In 1876 Imperial Germany enacted stringent patent legislation that prohibited the wide-spread copying practices of chemical companies, forcing them to invest in the development of novel

¹³³ See Jeffrey Johnson, 'Academic Self-Regulation and the Chemical Profession in Imperial Germany', *Minerva*, vol.23:2 (1985), pp.241-271.

¹³⁴ *Ibid.*

¹³⁵ John Pickstone, *Ways of Knowing*, *op cit*, p.169.

¹³⁶ *Ibid.*

processes and products.¹³⁷ Making virtue of necessity, the dye and later, pharmaceutical firms began to set up their own research branches providing university chemists with alternative career paths. Fifteen years later, the General Electric Company (GEC) under the directorship of Thomas Edison adopted a similar strategy once the anti-trust laws hindered larger businesses from buying smaller ones in an attempt to acquire their patents.¹³⁸ The GEC laboratory accommodated prominent scientists and engineers, such as Irving Langmuir whose discoveries in surface chemistry brought him the Nobel Prize in 1932. Yet despite its numerous benefits, industry's disposition to 'internalise' research severely disadvantaged academic science by isolating it from the findings obtained in the commercial laboratories on the grounds of patents and corporate secrecy.¹³⁹

Needless to say, industry had a clear vested interest in primarily supporting research that was practically oriented and likely to produce commercially-viable results and products. And to be sure, a few industrialists shared the conviction that since the chief goal of industrial laboratories was money-making, it was impossible to give the staff of investigators a 'perfectly free hand'.¹⁴⁰ The underlying logic behind directed research for economic purposes notwithstanding, many leading companies, including GEC, Du Pont, standard Oil of Indiana and Westinghouse hired physicists and chemists allowing them to pursue lines of unguided science. On other occasions, businesses supported academic research by funding projects (e.g. GEC at Harvard, AT&T at the Massachusetts Institute of Technology (MIT)), donating money for new facilities and equipment, and subsidising fellowships. Just before the outbreak of the First World War, for instance, German academic chemists and industry leaders joined forces to establish three Kaiser Wilhelm Institutes for research in general chemistry, physical chemistry and electrochemistry, and coal chemistry. The Institutes were

¹³⁷ John Beer, 'Coal Tar Dye Manufacture and the Origins of the Modern Industrial Research Laboratory', *Illinois Studies in the Social Sciences*, vol.44 (1959), p.127.

¹³⁸ John Pickstone, *Ways of Knowing, op cit*, p.171; 173.

¹³⁹ Jeffrey Johnson, 'The Academic-Industrial Symbiosis in German Chemical Research, 1905-1939' in John Lesch (ed.), *The German Chemical Industry in the Twentieth Century* (Dordrecht: Kluwer Academic Publishers, 2000), p.19.

¹⁴⁰ Daniel Kevles, *The Physicists: The History of a Scientific Community in Modern America*, (New York: Vintage Books, 1979), p.100. See also Leo Baekeland, 'Science and Industry', *Science*, vol.31:805 (1910), pp.841-852; Willis Whitney, 'Research as a Financial Asset', *Science*, vol.33:853 (1911), pp.673-681.

tasked with the study of pure science, which while expected to produce substantial long-term payoffs, was unlikely to lead to immediate patentable results.¹⁴¹

Science Patronage

During the nineteenth and early twentieth century science patronage took a variety of forms, some of which persisted even after the state largely took up the role of a chief patron following the Second World War. Prior to 1940, lavish state financial support for science, as the one provided in Imperial and later, Nazi Germany and Bolshevik Russia, tended to be an exception rather than a rule. Yet while the policies implemented by the Wilhelminian government were generally praised as an example of best practice both in and outside Germany, those introduced by the Bolsheviks and the Nazis exposed the perils of linking science to ideology, highlighting the deleterious effects that such a linkage could have on the ideals and integrity of science. Adopted first by Prussia after the defeat by Napoleon and subsequently applied nationwide following the unification, the model of promoting science education and research by dint of state sponsorship proved to be a potent force that considerably boosted the political and economic might of the German Empire.¹⁴² Modernised and well-equipped with the cutting-edge technology of the day, the German laboratories and research institutes played an important role in providing the rapidly expanding chemical industry with highly-skilled science cadres, thus illustrating how the synergy between state patronage and academic excellence could lead to economic preponderance. Even though scientists across Western Europe envied the circumstances of their German colleagues and bitterly lamented what they perceived as the neglect of science demonstrated by their respective governments, state subsidies for teaching and research remained marginal,

¹⁴¹ Jeffrey Johnson, 'The Academic-Industrial Symbiosis in German Chemical Research, 1905-1939', *op cit*, p.22.

¹⁴² On the relations between science and the state in Imperial Germany, see David Cahan, 'The "Imperial Chancellor of the Sciences": Helmholtz between Science and Politics', *Social Research*, vol.73:4 (2006), pp.1093-1128; E.S. Althoff and Max Weber, 'The Power of the State and the Dignity of the Academic Calling in Imperial Germany: The Writings of Max Weber on University Problems', *Minerva*, vol.11:4 (1973), pp.571-632; Frank Pfetsch, 'Scientific Organisation and Science Policy in Imperial Germany, 1871-1914: The Foundation of the Imperial Institute of Physics and Technology', *Minerva*, vol.8:1-4 (1970), pp.557-580.

limited to projects from which direct practical military, commercial or national benefits could be immediately accrued.¹⁴³

In spite of, or rather *because of* the pervasive lack of financial commitment to science by the state, alternative forms of patronage evolved. One such example is the multifaceted involvement of industry in supporting the study of science. Many of the emergent British proprietors in civil and mechanical engineering acknowledged the value of combining apprenticeship with theoretical grounding by providing sponsorship for formal scientific education. Likewise, foreign companies dedicated funds to support academic institutions, as evidenced in the case of King's College, London, which ran an engineering laboratory financed by the Siemens Company.¹⁴⁴ At home too, German industry actively sought to promote higher education by subsidising the universities and their respective research institutes. Chemical companies in particular demonstrated a deep and long-standing commitment to this goal. Being scientists by training, prominent industrialists, such as Emanuel Merck, Carl Duisberg and Arthur Weinberg, wanted 'to stay loyal to science' and reinforce the dye industry's 'chemical foundation as a main point'.¹⁴⁵ While the companies' beneficence might indeed have been an expression of a genuine concern for the state of chemistry as an academic discipline, at least in part, it was undoubtedly accompanied by considerable vested interests. When the post-First World War recession hit Germany, for example, the government established an Emergency Community for German Science through which to direct its support for all fields of science. Even though the industry expected to contribute financially, it was to have very little control over how the funds were allocated. In order to counter what they perceived as an over-centralised system, the chemical companies established three funding bodies – the Emil Fischer Society for the Promotion of Chemical Research; the Adolf Bayer Society for the Promotion of Chemical Literature; and the Justus Liebig Society for the Promotion of Chemical Education – to

¹⁴³ W.H.Brock, 'The Spectrum of Science Patronage', *op cit*, p.177. See William Cavendish, 'The Science Commission on the Advancement of Science', *Nature*, vol.12:305 (1875), pp.361-364;

¹⁴⁴ John Pickstone, *Ways of Knowing*, *op cit*, p.170.

¹⁴⁵ Jeffrey Johnson, 'The Academic-Industrial Symbiosis in German Chemical Research, 1905-1939', *op cit*, p.20.

ensure that the industry would be able to channel its support for academic science based on its own judgement.¹⁴⁶

To scientists, academic-industrial partnerships promised considerable benefits, including patent royalties and consultancy contracts. Besides being a valuable source of income, such opportunities were instrumental in compensating for financial scarcities and lack of state support for pure science, as was the case in Britain. On some occasions, funds provided by industry aimed at counterbalancing unemployment at times of economic downturn. The I.G. Farben 'Emergency Fellowships' were to serve precisely this purpose by allowing gifted German students to remain at school as additional assistants until the job market improved; the cartel would be able to employ them at a later stage, and better trained.¹⁴⁷ Its positive features notwithstanding, the symbiosis between universities and industry did not always run so smoothly. For example, many talented individuals were tempted to abandon their modestly salaried academic positions and pursue profitable careers as consultants in the corporate sector. Academia was also negatively affected by outflow of bright graduates drawn by the better facilities and well-paid positions in industry, as illustrated in the complaints of professors that the 'best men [we]re in industry'.¹⁴⁸

Sometimes commercial pressures mounted serious challenges to the integrity of scientific research. The experience of the MIT Research Laboratory of Applied Chemistry in the 1920s in its dealings with industry is a case in point. On numerous occasions the Laboratory was prevented from publishing the results of the studies conducted there on the grounds that the companies that funded the research would be severely disadvantaged *vis-à-vis* their commercial competitors if the information was to be widely shared.¹⁴⁹ Moreover, due to the overemphasis on applied research, the

¹⁴⁶ Ibid, p.26. On the relationship between science and the state during the Weimar Republic, see Paul Forman, 'The Financial Support and Political Alignment of Physicists in Weimar Germany', *Minerva*, vol.12:1 (1974), pp.39-66; Brigitte Schroeder-Gudehus, 'The Argument for the Self-Government and Public Support of Science in Weimar Germany', *Minerva*, vol.10:4 (1972), pp.537-570.

¹⁴⁷ Ibid, p.45.

¹⁴⁸ Ibid, p.26. See also W.H.Brock, 'The Spectrum of Science Patronage', *op cit*, p.186.

¹⁴⁹ See John Servos, 'The Industrial Relations of Science: Chemical Engineering at MIT, 1900-1939', *ISIS*, vol.71:259 (1980), p.541-542; Jeffrey Johnson, 'The Academic-Industrial Symbiosis in German Chemical Research, 1905-1939', *op cit*, p.19.

Laboratory, far from a division of an educational institution, resembled a commercial consulting branch, which in turn not only forced many graduates and faculty members to seek employment elsewhere but also gave rise to an academic outcry over its practices deemed both inconsistent with and detrimental to the ethos of science.¹⁵⁰

Another type of science patronage that merits attention is individual philanthropy. As discussed earlier, up until the nineteenth century the material support for science came largely from royal and private patronage. With the rise of the bourgeoisie over the following decades this trend persisted and intensified. Patrons were typically men of means who expressed interest in the study of nature. Even though many of them had earned their fortune in fields unrelated to science, they were willing to support the advancement of knowledge. Nowhere is this philanthropic phenomenon observed more vividly than in the US. The funds dedicated by wealthy American businessmen, industrialists and proprietors facilitated the establishment of universities (e.g. Johns Hopkins University, Stanford University) and the building of research facilities (e.g. the Mount Wilson Solar Observatory). But the impact of philanthropy was by far the most substantial in the realm of scientific research where large private foundations offered generous support in the form of grants, fellowships and equipment. The Carnegie Endowment, founded in 1902 in Washington with an initial capital equal to that of the entire endowment of Harvard University, distributed both substantial gifts for big projects and some small grants for individual researchers.¹⁵¹ Established a year earlier in New York, the Rockefeller Foundation ran a prestigious postdoctoral research programme for promoting research physics and chemistry.¹⁵²

¹⁵⁰ Unlike other leading universities, including Caltech, Princeton, Harvard and Chicago that enjoyed generous support from private philanthropies, MIT failed to obtain any gift. When the administration tried to seek financial support from the Rockefeller Foundation, the board of trustees justified their reluctance to approve the MIT application on the grounds that the engineering work conducted there was not fundamental science but applied research that was of interest mainly to industry. See *ibid*, p.542. On the ideal of pure science, see H.A. Rowland, 'A Plea for Pure Science', *Science*, vol.2:29 (1883), pp.242-250.

¹⁵¹ Daniel Kevles, 'Foundations, Universities, and Trends in Support for the Physical and Biological Sciences, 1900-1992', *Daedalus*, vol.121:4 (1992), pp.195-222.

¹⁵² *Ibid*, p.202.

During the interwar period, private foundations constituted a major source for support of fundamental science. By the 1920s the amount of money available for research had massively increased, yet so had the number of universities and their demands. The resultant scarcity in resources quickly turned the competition for funds into an elitist game in which the largest and most prestigious universities were typically favoured at the expense of smaller and more obscure ones.¹⁵³ But there was a further cause for concern which heightened in the long term, namely the steadily growing influence of the private foundations. Thanks to the substantial capital at their disposal and the relative absence of chief competitors regarding the funding of pure science, several philanthropic organisations could exert considerable influence on the research agenda and shape the objectives of a sizable fraction of American scholarship.¹⁵⁴

State-Mandated Science Programmes

The interplay of science and political power from 1900 onwards was at least in some respects a continuation of an already existing trend. Nevertheless, given the institutional arrangements inspired by the late modernity that enabled the mass mobilisation of science by the state for the attainment of economic, socio-political and ideological, and military goals, it was a continuation on a very different *scale* and *kind*, unprecedented to that moment in history.

The twentieth century witnessed the consolidation of mechanised warfare: no longer was technology just one of the elements of war-fighting, but it was a crucial factor both for the course of hostilities and for their ultimate outcome. Machine guns, submarines, tanks, radio systems, poison gas, radar detection, atomic bombs and guided missiles, all of which embodied the practical application of scientific principles, alerted the military and politicians alike to the value of research, solidifying their conviction that laboratories

¹⁵³ David Hart, *Forged Consensus: Science, Technology and Economic Policy in the United States, 1921-1953* (New Jersey: Princeton University Press, 1998), p.37.

¹⁵⁴ Daniel Kevles, 'Foundations, Universities, and Trends in Support for the Physical and Biological Sciences, 1900-1992', *op cit*, p.205.

should constitute the state's first line of defence. Having secured the cooperation of the chemist Fritz Haber, the German army was the first to mount a chlorine gas assault in 1915 killing some five thousand Allied troops and causing severe impairment to at least ten thousand more. Caught utterly by surprise and seriously unprepared, the British and French military command quickly moved to foster close ties with academia and launch their own chemical warfare programmes. Besides at the newly established complex at Porton Down, British work on chemical weapons was also carried out in the laboratories at Cambridge, St Andrews, Oxford, London's University College and the Royal Army Medical College. In France, the effort was concentrated in Paris, with College de France and the Sorbonne as the two main centres.¹⁵⁵ Its belated entrance into the hostilities in 1917 notwithstanding, the US army vigorously joined the chemical arms race by setting up the Chemical Warfare Service, the largest research group yet organised by the federal government.¹⁵⁶ As a result of the vigorous employment of scientific expertise, by the end of the war more than twenty chemical agents were developed, including mustard gas, phosgene and arsenicals; Haber's work even allowed Germany to manufacture a form of phosgene that could penetrate gas masks.¹⁵⁷ Despite the international prohibition on the use of asphyxiating and deleterious gases in hostilities that was already in place long before 1914, many chemists willingly put their talents in service to the state and few had doubts about crossing a moral Rubicon.¹⁵⁸

¹⁵⁵ On the British and French effort in chemical warfare, see L.F. Haber, *The Poisonous Cloud: Chemical Warfare in the First World War* (Oxford: Clarendon Press, 1986); Danielle M. E. Fauque, 'French Chemists and the International Reorganisation of Chemistry after World War I', *Ambix*, vol.58:2 (2011), pp.116-135. On the Japanese chemical weapons programme in the First World War see, Yoshiyuki Kikuchi, 'World War I, International Participation, and Reorganisation of the Japanese Chemical Community', *Ambix*, vol.58:2 (2011), pp.136-149.

¹⁵⁶ Hugh Slotten, 'Humane Chemistry or Scientific Barbarism: American Responses to World War I Poison Gas, 1915-1930', *The Journal of American History*, vol.77:2 (1990), p.485. It is worth noting that following the First World War the chemical scientific establishment in the US launched a massive campaign to prevent the ratification of the 1925 Geneva Protocol on the prohibition of chemical warfare. See Daniel Jones, 'American Chemists and the Geneva Protocol', *Isis*, vol.71:3 (1980), pp.426-440.

¹⁵⁷ Diarmuid Jeffreys, *Hell's Cartel*, *op cit*, p.73.

¹⁵⁸ Fritz Haber, the 'father of modern chemical warfare' would counter any accusations of his active involvement in the German use of chlorine during the First World War arguing that to be maimed or killed by gas was no worse than being injured or mutilated by high explosives or shot and killed by a machine gun. In late 1918 he was awarded the Nobel Prize in chemistry for his work on synthetic ammonia. See *ibid*. For further information on the life and political and professional activity of Fritz Haber see Morris Goran, *The Story of Fritz Haber* (Norman: University of Oklahoma Press, 1967); Dietrich Stoltzenberg, *Fritz Haber: Chemist, Nobel Laureate, German, Jew* (Philadelphia: Chemical Heritage Foundation, 2004). On the involvement of chemists in the First World War, see L.F. Haber *The Poisonous Cloud: Chemical Warfare in the First World War* (Oxford: Clarendon Press, 1986).

Within thirty years, the mushroom cloud replaced the poisonous gas as the hallmark of scientific ingenuity in the service of the state. But if scientists' involvement in the First World War was born out of expediency and ended with the armistice, the ties forged between science and the state during the Second World War proved too tight to be broken after 1945. In light of the prospect of being drawn into yet another major war and the resultant urgent need to enhance its military capability, the US embarked on reforming its science policy. Under the chairmanship of the then-president of the Carnegie Institution, Vannevar Bush, a National Defence Research Committee (NDRC) was set up in 1940 to support 'scientific research and development of new instrumentalities or materials of war, or of new methods and materials to be used primarily in the manufacture of instruments of war'.¹⁵⁹ One project the Committee was specifically assigned to by President Roosevelt was the examination of a 'possible relationship to national defence of recent discoveries...of the fission of uranium'.¹⁶⁰ The NDRC undertook a range of steps to overcome the hurdles of getting civilian scientists involved in military research projects. Strict restrictions on access to data and materials, extreme conditions of secrecy and security clearance substituted for the free and open dissemination of information and broad collaboration among scientists, typical for the production and advancement of knowledge. Under Bush's orders, information was subject to compartmentalisation, which precluded anyone associated with the NDRC from accessing classified data non-related to their particular task.¹⁶¹ Later, with the Manhattan Project steadily underway, Bush would craftily make use of patent censorship to ensure that the ownership of both the technology and *ideas* that made the atomic bomb possible remained with the state, at least until the government decided how to handle the governance of nuclear knowledge.¹⁶² Despite its merits, the NDRC was mainly tasked with the coordination of *research* activities and had

¹⁵⁹ Irvin Stewart, *Organising Scientific Research for War: The Administrative History of the Office of Scientific Research and Development*, (Boston: Little, Brown and Co: 1948), p.16. Available at <http://archive.org/details/organizingscient00stew> (accessed 30/11/12). See also National Resources Committee, *Research – A National Resource: Relation of the Federal Government to Research* (Washington DC: Government Printing Office, 1939).

¹⁶⁰ *Ibid.*, p.18.

¹⁶¹ *Ibid.*

¹⁶² Alex Wallerstein, 'Inside the Atomic Patent Office', *The Bulletin of Atomic Scientists*, vol.64:2 (2008), pp.26-31. For a detailed account on the development of the US atomic bomb project, see Henry DeWolf Smyth, *Atomic Energy for Military Purposes: The Official Report on the Development of the Atomic Bomb under the Auspices of the United States Government, 1940-1945* (New Jersey: Princeton University Press, 1945).

no authority over the approval of the *development* of technology. To correct this deficiency, in 1941 President Roosevelt authorised the establishment of an Office of Scientific Research and Development (OSRD) and appointed Bush as its director. The NDRC remained active under the new institution and served as a model for the creation a similar body in the realm of military medicine. Generously financed the government, the OSRD coordinated the construction of the atomic bomb, as well as the development of radar and microwave technology, the proximity fuse and solid fuel rockets. Deeply convinced that the state had to turn defence research into a 'peace-time thing', Bush filed a proposal for the post-war organisation of American science. While many of the ideas outlined in his *Science, The Endless Frontier*, were altered or not fully implemented, its key message, namely the need for extensive state support for science, was permanently embedded in the US policies, as evidenced throughout the Cold War period.¹⁶³

State-mandated science programmes in the early twentieth century were hardly limited to the military domain. Science and technology promised economic might, social prosperity and human health betterment and, as such, constituted potent powers which, if effectively subordinated to the interests of the state, could bring in considerable benefits. In short, for virtually any sphere in which the industrial state might face a challenge, science and technology seemed to offer a solution. However naïve it may sound, this conviction was far from uncommon among scientists and politicians alike, giving rise to the ideal of technocracy: a form of government which assigns the supreme decision making powers to science and engineering experts. Coined by William Smyth in 1919,¹⁶⁴ the term was vigorously promoted by Howard Scott as the panacea to the deleterious effects of the 1929 Wall Street Crash and the resultant depression.¹⁶⁵ But by far the most notorious example of employing technocratic means to state governance is the tragic fate of the Soviet Union. Stressing the nexus

¹⁶³ See Vannevar Bush, *Science, the Endless Frontier: A Report to the President on a Programme for Postwar Science Research* (Washington DC: National Science Foundation, 1945).

¹⁶⁴ See William Smyth, 'Technocracy – Ways and Means to Gain Industrial Democracy', *Industrial Management*, vol.57 (1919), p.385.

¹⁶⁵ See James Olson (ed.) *Historical Dictionary of the Great Depression, 1929-1940*, (Westport CT: Greenwood Press, 2001).

between science and economic recovery, the Bolshevik leaders embarked on an extensive social engineering project featuring mass terror, economic scarcities and environmental degradation. The regime had a detrimental impact on science, depriving the scientific community of its autonomy and politicising scientific authority.¹⁶⁶

The Nazi rule in Germany exerted a similar effect on science, reflected in its support for 'Aryan' versus 'Jewish' physics, mathematics, and medicine.¹⁶⁷ Yet even against the backdrop of assaults that the Third Reich mounted on science, its policies toward racial hygiene vividly stand out. That said, negative eugenics was not a Nazi invention. Long before Hitler's coming to power, the Carnegie Institution and the Rockefeller and the Harriman Foundations supported research in human heredity and by the 1920s several American States had already enacted human sterilisation laws.¹⁶⁸ Drawing upon the US expertise, the Nazi launched Aktion T4 that paved the way for the mass sterilisation and, later 'euthanasia' and murder, of those 'unworthy of life' including social outcasts, physically and/or mentally disabled adults and children, Jews and Gypsies. A Euthanasia Office was established to coordinate the implementation of the project, as well as, academic research in eugenics carried out at German institutes with funds from the Rockefeller Foundation.¹⁶⁹ With the scene thus set, in 1942 the Reich began the implementation of the Final Solution, the plan designed to rid Germany once and for all from the 'Jewish problem'. Some 350 medical doctors, including university professors and lecturers, took part in 'healing the nation' working diligently at Dachau, Auschwitz and Ravensbruck and Buchenwald. But the

¹⁶⁶ David Holloway, 'Scientific Truth and Political Authority in the Soviet Union', *Government and Opposition*, vol.5:3 (1970), pp.345-367. See also James Scott, *Seeing like a State: How Certain Schemes to Improve the Human Condition Have Failed* (Yale University Press, 1998); Charles Maier, 'Between Taylorism and Technocracy: European Ideologies and the Vision of Industrial Productivity in the 1920s', *Journal of Contemporary History*, vol.5:2 (1970), pp.27-61.

¹⁶⁷ On the relations between science and the state during the Nazi regime, see Sandra Harding, 'After the Neutrality Ideal: Science, Politics, and "Strong Objectivity"', *Social Research*, vol.59:3 (1992), pp.567-587; Bernd Gausemeier, 'Genetics as a Modernisation Programme: Biological Research at the Kaiser Wilhelm Institutes and the Political Economy of the Nazi State', *Historical Studies in the Natural Sciences*, vol.40:4 (2010), pp.429-456; Alan Beyerchen, 'What We Now Know about Nazism and Science', *Social Research*, vol.59:3 (1992), pp.615-641; Dieter Hoffmann, 'Between Autonomy and Accommodation: The German Physical Society during the Third Reich', *Physics in Perspective*, vol.7 (2005), pp.293-329. On the German nuclear bomb project, see Ruth Lewin Sime, 'The Politics of Forgetting: Otto Hahn and the German Nuclear-Fission Project in World War II', *Physics in Perspective*, vol.14 (2012), pp.59-94; Mark Walker, 'Heisenberg, Goudsmit and the German Atomic Bomb', *Physics Today*, January 1990, pp.52-60; David Cassidy, 'Heisenberg, German Science, and the Third Reich', *Social Research*, vol.59:3 (1992), pp. 643-661.

¹⁶⁸ Edwin Black, *War against the Weak: Eugenics and America's Campaign to Create a Master Race*, (New York: Four Walls Eight Windows, 2003).

¹⁶⁹ John Cornwell, *Hitler's Scientists: Science, War and the Devil's Pact*, (London: Penguin, 2004), p.350.

implications of the Final Solution were far more profound, not least because it exposed the multifaceted ways in which technical ingenuity, meticulous organisation and careful planning – all legacies of late modernity – could effectively be combined to turn an utterly sinister act into a routine, even ‘normal’ activity.¹⁷⁰

The Rise of the Military-Industrial-Academic Complex (MIAC)

The ‘golden triangle’ of military agencies, high technology industry and research universities¹⁷¹ that developed in the early twentieth century and reached its apogee during the Cold War era, played a key role in determining and shaping the evolution of modern science culture. As we shall see, the close ties forged between academia and commercial companies from the late nineteenth century onwards proved vital both for meeting the wartime demands of governments and for ensuring their peacetime defences, as the latter grew more and more dependent on the acquisition of sophisticated military technology. Born out of the war expediency and nurtured by the states’ vested interest in being able to translate the latest scientific breakthroughs into cutting-edge weaponry, the military-industrial-academic complex gradually acquired a life of its own, accumulating vast amounts of power and resources. The resultant giant, while deemed necessary for the preservation of peace, proved to be a potent force whose ‘unwarranted influence’ brought a ‘revolution in the conduct of research’, effectively substituting government contracts for intellectual curiosity¹⁷² and eroding the science ethos.

The German dye industry was heavily involved in both world wars, presenting the military with a host of powerful techniques and later, exposing the darkest side of the synergies between intellectual corruption, money interests and radical political ideology. During the First World War the dye firms’ contribution was multifaceted, ranging from medicines and paints to

¹⁷⁰ Ibid. See also Zygmunt Bauman, *Modernity and the Holocaust*, *op cit*.

¹⁷¹ Stuart Leslie, *The Cold War and American Science: the Military-Industrial-Academic Complex*, (New York: Columbia University Press, 1993), p.2.

¹⁷² Dwight Eisenhower, *Farewell Address*, (Washington DC: The White House, 1961), available at <http://www.ourdocuments.gov/doc/doc=90&page=transcript> (accessed 3/12/12).

explosives and poison gas. In addition, the industry channelled substantial funds for military-oriented academic research via the Kaiser Wilhelm Foundation for Military and Technical Science directed by the mastermind behind the German chemical weapons programme, Fritz Haber.¹⁷³ A direct consequence of the symbiosis between the scientific community, business and the army was a reciprocal relationship that paved the way for the militarisation of science and industry, as well as, the rise of science-based industry and military.¹⁷⁴ The effects of this relationship became vividly clear during the Nazi regime, when educational and medical institutions joined forces with the military and the industrial conglomerate, IG Farben, on a series of projects demonstrating unquestioned conformity with Hitler's extreme racial discrimination policies, as reflected in the pervasive experimentation on humans, mass murder and vigorous use of slave labour and unquestioned conformity.¹⁷⁵ As evident in the research on chemical weapons, German scientists not only took a full advantage of the funds available for the study of nerve agents but were even eager to use organs from victims of Nazi persecution for testing their military potential.¹⁷⁶

Germany was hardly the only country where academia, industry and the army turned out to be 'mutually supportive resources'.¹⁷⁷ Having witnessed the destructive power of the German U-boats early in First World War, the US National Academy of Sciences (NAS) set up a National Research Council (NRC) to promote both pure and applied research for the ultimate end of 'national security and welfare'.¹⁷⁸ Seeking to establish grounds for broad collaboration among leading scientists, engineers, industrialists, government officials and military experts, the Council played a crucial role in coordinating the development and production of optical glass, nitrates, poison gas, submarine detection technology and flash- and sound-ranging systems. Despite its invaluable contribution to the war effort, the Council still raised

¹⁷³ Jeffrey Johnson, 'The Academic-Industrial Symbiosis in German Chemical Research, 1905-1939', *op cit*, p.24.

¹⁷⁴ Florian Schmaltz, 'Neurosciences and Research on Chemical Weapons of Mass Destruction in Nazi Germany', *Journal of the History of the Neurosciences*, vol.15 (2006), p.186.

¹⁷⁵ See John Cornwell, *Hitler's Scientists*, *op cit*; Diarmuid Jeffreys, *Hell's Cartel*, *op cit*.

¹⁷⁶ Florian Schmaltz, 'Neurosciences and Research on Chemical Weapons of Mass Destruction in Nazi Germany', *op cit*, p.205.

¹⁷⁷ *Ibid*, p.204.

¹⁷⁸ Daniel Kevles, *The Physicists*, *op cit*, p.112.

suspensions among the military, as the latter were convinced that the civilian-controlled laboratories could neither meet the secrecy requirements, nor produce practical battlefield devices without close military oversight.¹⁷⁹ As indicated in the previous section, the comprehensive institutional infrastructure erected to monitor and supervise the process of weaponry development during World War II went to extraordinary lengths to overcome such challenges and secure the long-term cooperation between universities, business and the defence establishment. The wartime work carried out at the MIT's Rad Lab, Caltech and Johns Hopkins highlighted the value of the military-industrial-academic alliance and encouraged other education institutions to join the race for defence contracts. Harvard, Princeton, Michigan, Berkeley and Stanford were just few of the universities that enthusiastically accepted money both from the Pentagon, readily acceding to the establishment of closed campus facilities where classified projects could be conducted. The development of nuclear weapons, air defences, intercontinental ballistic missiles (ICBMs), electronic communications and countermeasures thus became the daily routine of a large fraction of the American scientific establishment, permanently blurring the lines between pure and applied research and making secrecy an indispensable working condition at universities and laboratories. In many respects, academic science turned into a function of military needs and priorities, whereby not only did research agendas focus on questions critical to weapon-oriented technologies but the very idea of what it meant to be a scientist or an engineer underwent a fundamental redefinition, effectively creating a professional elite of arms designers.¹⁸⁰

Toward a Permanent Mobilisation

The Second World War marked a turning point in the evolution of science. Having exposed the tremendous battlefield benefits that the high-level

¹⁷⁹ Ibid, p.132.

¹⁸⁰ Stuart Leslie, *The Cold War and American Science*, p.9. See also Paul Forman, 'Behind Quantum Electronics: National security as Basis for Physical Research in the United States, 1940-1960', *Historical Studies in the Physical and Biological Sciences*, vol.18:1 (1978), pp.149-229. On the issue of social responsibility of scientists, see David Frisch, 'Scientists and the Decision to Bomb Japan', *Bulletin of Atomic Scientists*, vol.26:6 (1970), pp.107-115; Lawrence Badash, 'American Physicists, Nuclear Weapons in World War II, and Social Responsibility', *Physics in Perspective*, vol.7 (2005), pp.138-149.

coordination, organisation and funding of scientific research could yield, the war largely laid the foundations of the post-1945 science policies, featuring skyrocketing R&D (research and development) budgets and mass academic mobilisation. It permanently redefined the relationship between science and the state, cementing the academic-military alliance and bringing scientists under the direct control of government leaders. All those developments had an enormous bearing on the culture of science, effectively substituting top-down management and weapon procurement for the ideals of intellectual curiosity and disinterested pursuit of knowledge and forcing scientists to focus exclusively on the technical aspects of research. Their significant impact notwithstanding, it would be naïve to assert that state-led initiatives were the only factor shaping the governance of science as the Cold War unfolded. True, scientific and technological advancement was central to the extensive planetary competition, in which the Soviet Union and the United States found themselves caught from 1949 onwards, both as a function and a manifestation of the superpowers' insatiable appetite for socio-political and economic expansion, and global domination. While professional science cultures demonstrated a remarkable degree of adaptation to this changed setting, they were hardly static but shaped and influenced the formulation and execution of government policies in turn. The role of business both as a patron and consumer of scientific research was also substantial, especially in the USA, where patents, joint ventures and start-ups mushroomed as a result of the close ties between academic institutions and industry. Even though none of these dynamics was inherently new to science, their pace and intensity were vastly enhanced by the social, political and economic changes that occurred in the aftermath of the Second World War and, as such, required the development of governance relations that were concomitant with the intensification and multiplication of the scientific and technological endeavour.

By and large, post-1945 science policies epitomised the conviction that science and technology were too important to be left free from a wary high-level oversight, planning, funding and facilitation. The underlying rationale behind this type of thinking was that even if science could progress without

material support from the state, any government refusing to invest in the development of science ran the risk of jeopardising its own national security. Against the background of fierce nuclear arms race and diplomacy pervaded by realist fears and zero-sum political calculations, the doctrine of national security provided states with a powerful incentive to assume a posture of military preparedness and remain on permanent alert.¹⁸¹ Highlighting the primacy of state survival, it encouraged governments to adopt a proactive approach to boosting their defences by enhancing their military capabilities and expanding their weapon arsenals. Given the crucial role of science in the acquisition of novel armaments, it was essential that academic and industrial talent and ingenuity were harnessed for the goals of national security.

In the US, first the navy and shortly after that the army, zealously strived to preserve and extend the wartime ties with academia and industry.¹⁸² Following the Korean War, the Department of Defence (DoD) emerged as one of the dominant sources of revenue for science and technology with a R&D budget of 1.8 billion dollars which was three times its pre-war value.¹⁸³ Thanks to its funds MIT, Stanford and Johns Hopkins expanded their pre-1945 military research complexes and other leading universities set up ones of their own; the number of federal weapon-development laboratories multiplied; and the volume of research and development conducted by industrial contractors massively increased, leading some civilian companies, such as GEC, to establish specialised departments to work exclusively on defence-related projects.¹⁸⁴ But the Pentagon money offered scientists and their respective institutions more than financial security; it enhanced their professional status, validating their prominence and prestige. More importantly, it fostered an attitude to which a significant proportion of the American scientific community subscribed, namely that military support for science was to be welcomed and that there was 'no reason for refusing [such] help – granted it is forthcoming – in doing the scientific work that one

¹⁸¹ Daniel Yergin, *Shattered Peace: The Origins of the Cold War and the National Security State* (Boston: Houghton Mifflin Company, 1978), p.196.

¹⁸² See Daniel Greenberg, *The Politics of Pure Science* (Chicago: University of Chicago Press, 1967).

¹⁸³ David Hart, *Forged Consensus, op cit*, p.195.

¹⁸⁴ *Ibid.*

would have tried to accomplish even without such help.¹⁸⁵ Since the majority of scientists were committed to the ideal of basic research, they demonstrated little moral disquiet regarding the sources of funding, as long as it was provided on a regular basis and with limited restrictions attached. To ensure that their projects would eventually be financed, they tended to emphasise the practical utility of their research even when there was hardly any.¹⁸⁶ Besides scientists, businessmen, economists and industrialists were also in favour of the vast DoD expenditure on science and technology, not least because of the 'spinoff effect' of military-oriented research which sparked new civilian industries (e.g. Boeing's passenger jets, IBM's business computers) and facilitated the rise of high-technology start-ups and venture capitalists, leading to productivity growth and economic prosperity.¹⁸⁷ In a similar fashion, the Soviet Union laid an enormous emphasis on the linkage between science and national security. Having successfully tested their first nuclear device in 1949, the Soviets embarked on an immense military build-up featuring an H-bomb project, development of ICBMs and nuclear submarines. In addition, substantial funds were poured into space research which culminated in the launch of Sputnik in 1957. France and Britain, too, set up institutional infrastructure that allowed the smooth integration of scientific milieus into technological and military research.

Given the scale of military expenditure on science, the immediate question that arises is whether and how scientific communities managed to preserve at least some degree of freedom in their practice. After all, science rests upon the ideal of truth and disinterested discovery, which at first sight seem difficult to reconcile with the heavy involvement of governments. To be sure, in totalitarian societies like the Soviet Union, the state did interfere vigorously with the everyday work of scientists not only by dint of funding and coordination but also by directing research and censoring scientific data. Yet even under those severe conditions, scientists still enjoyed some flexibility, if only to avoid the mistakes made by the Nazi regime which seriously hindered

¹⁸⁵ Louis Ridenour, 'Military Support of American Science, a Danger?', *Bulletin of Atomic Scientists*, vol.3:8 (1947), p.223.

¹⁸⁶ *Ibid.*

¹⁸⁷ David Hart, *Forged Consensus*, *op cit*, p.199.

the German weapon-development programmes prior to and during the Second World War. Indeed, the fact that the Soviets succeeded in obtaining the atomic bomb so quickly did not show that the totalitarian governance of science was effective but rather reinforced the belief that even totalitarian states had to allow their scientists some freedom of action in order to reap the benefits of research.¹⁸⁸ Far more explicit were the ways in which scientific communities in democratic societies influenced and shaped the development and implementation of government-led initiatives pertaining to the conduct of research. In the US, for instance, the scientific community jealously clung to its independence striving to keep state interference at an absolute minimum. Thus, although the National Science Foundation (NSF), the government agency established to promote basic research, was eventually put under the direct control of the President, the scientific community largely retained the final word regarding the distribution of funds. This was possible, for the Foundation adopted a referee system, which required that any grant application was screened by a panel of academic experts in the respective field of study, whose decision was almost always undisputed and final.¹⁸⁹ Other governmental agencies, including the National Institutes of Health (NIH), the Atomic Energy Agency (AEA) and the DoD, allocated their financial support on the same principle. While the system played a crucial role in insulating the scientific community from executive scrutiny, it served the interests of distinguished research institutions, creating huge disparities between the nation's leading universities and the smaller and less known ones. Since grants were awarded chiefly on the grounds of merit, the US most prestigious schools and faculties tended to be disproportionately privileged, with those based in California, New York and Massachusetts receiving as much as half of the total support available.¹⁹⁰ The resultant reconfiguration of power effectively gave rise to a 'scientific oligarchy'¹⁹¹ which not only controlled the flow and direction of federal science funding,

¹⁸⁸ Daniel Greenberg, *The Politics of Pure Science*, *op cit*.

¹⁸⁹ Anton Jachim, *Science Policy Making in the United States and the Batavia Accelerator*, (Carbondale and Edwardsville: Southern Illinois University Press, 1975), p.48. See also Daniel Greenberg, *The Politics of Pure Science*, *op cit*.

¹⁹⁰ *Ibid*, p.59. See Editorial, 'Distribution of Research Funds', *Science*, vol.142:3591 (1963), p.453.

¹⁹¹ *Ibid*, p.62. See Stuart Leslie, 'Playing the Education Game to Win: The Military and Interdisciplinary Research at Stanford', *Historical Studies in the Physical and Biological Sciences*, vol.18:1 (1987), pp.55-88; Rebecca Lowen, *Creating the Cold War University: The Transformation of Stanford* (Berkeley: University of California Press, 1997); John Aubrey Douglas, *The Cold War, Technology and the American University*, Research and Occasional Papers Series: CSHE.2.99, July 1999, University of California, Berkeley.

but also maintained close relations with both industry and the military, provided consultancy services and advice to the government and produced a significant part of the American research output, including products and publications.

With the fall of the iron curtain, the close connections forged between science and the state during the Second World War gradually evolved into a marriage of convenience. National security considerations and demands for rapid economic growth translated into lavish financial support and mass academic mobilisation. The display of scientific and technological advancement in the form of sophisticated weapon systems, space programmes and burgeoning industries was just as much an expression of intellectual ingenuity as it was of political and ideological superiority and socio-economic prosperity. For their part, scientific communities took full advantage of the generous support available, as evidenced in the rise of 'big science' and the proliferation of high technology. Large facilities and expensive laboratory equipment made governmental assistance an essential condition for the development of science, fundamentally redefining in the process the ethos and values of science practice. Secrecy, whether for corporate or military purposes, permeated the culture of research, erecting walls within and between universities and eroding collegiality. The governance relations thus fostered paved the way for the mass exploitation of a vigorously expanding scientific and technological endeavour allowing for the attainment of strategic, commercial, industrial and politico-military goals without disturbing the 'cloistered calm of the laboratory'.¹⁹²

¹⁹² Don Price, *The Scientific Estate* (Cambridge MA: Harvard University Press, 1965), p.97.

Chapter 3: Governance and Cultures of Life Science Research during the Cold War

The Life Sciences as a Professional Domain

Life Science Research prior to the Biotechnology Revolution

The origins of modern biology date back to the late eighteenth and early nineteenth centuries, a period characterised by a confluence of developments in thought and practice that facilitated the establishment of a unified study of life, one that was distinct from medicine and natural history. Among those developments were the reformation of the taxonomy system and the subsequent realisation of the extinction of life forms; the emergence of comparative anatomy and palaeontology as distinct disciplines; and the refinement of experimental methods that enhanced the understanding of fundamental physiological processes. Carl Linnaeus introduced the term *biologi* in his *Bibliotheca Botanica* in 1776 and Karl Friedrich Burdach used it in his works when referring to the study of human morphology, physiology and psychology. It also appeared in the writings of the French botanist Jean-Baptiste de Lamarck but it was through the efforts of the social philosopher August Comte that the term gained its widespread currency.¹⁹³ From the 1800s onward the field of biology underwent a rapid expansion vividly expressed in increasing specialisation and the rise of novel sub-disciplines. The significant improvements in optics and microscopy around the 1830s proved crucial to the development of cytology (cell biology) and histology (the study of tissues), allowing scientists to conceptualise the structure of the cell and acquire advanced knowledge of the origins of disease. Microbiology, too, witnessed its first pioneers. Building upon Pasteur's germ theory, Robert Koch conducted ground-breaking work in bacteriology, successfully isolating the bacilli responsible for anthrax, tuberculosis and cholera.¹⁹⁴ The discovery

¹⁹³ On the origins of modern biology, see Robert Olby et al. *Companion to the History of Modern Science, op cit.* In particular, see chapters 23, 31, 32 and 33.

¹⁹⁴ Arguably Robert Koch is best known for his contribution to general bacteriology and pathology. He devised new research methods to isolate pathogenic bacteria and defined a set of guidelines to prove that disease is caused by a specific microorganism. These guidelines became known as Koch's postulates. They include: 1) A specific microorganism is always associated with a given disease; 2) The microorganism can be isolated from the diseased

of the tobacco mosaic virus (TMV) at the end of nineteenth century by the Dutch biologist Martinus Beijerinck effectively laid the foundations of modern virology even though the structure of viruses remained unknown for another forty years.¹⁹⁵

Two more disciplines that emerged at the turn of the twentieth century merit specific attention, as their evolution is closely linked to the advent of the biotechnology revolution that unfolded in the 1950s. One is the study of heredity, which provides the basis for modern genetics. Following the publication of Darwin's theories on natural selection, the issue of the evolution of species attracted considerable interest, spurring vigorous debates between Darwinists and those subscribing to alternative intellectual traditions, including neo-Lamarckism and mutation theory. We will return to one particular aspect of this controversy, namely the rise of Lysenkoism in the 1940s, later on. The founder of modern genetics is commonly accepted to be Gregor Mendel who coined the principles of heredity after observing the inheritance of certain traits in pea plants. While the results of his experiments were published as early as the 1860s, it was not until 1900 that his findings were 'rediscovered' and eventually appreciated. Based on the Mendelian laws of inheritance, Walter Sutton and Theodor Boveri advanced the chromosome theory of heredity, according to which chromosomes were the material carriers of heredity. Hardly substantiated with any hard evidence, the Sutton-Boveri proposition remained deeply controversial for about a decade. Then in 1915, the American geneticist Thomas Hunt Morgan managed to provide experimental data in support of the chromosome theory of heredity using the fruit fly, *Drosophila melanogaster*, as a model.

animal and grown in pure culture in the laboratory; 3) The cultured microbe will cause disease when transferred to a healthy animal; and 4) The cultured microbe will cause disease when transferred to a healthy animal. See <http://www.britannica.com/EBchecked/topic/320834/Robert-Koch> (accessed 30/01/2014). Koch's studies inspired a generation of scientists. In the span of just 30 years – from 1876 to 1906 – the principal bacterial pathogens of human disease were isolated. Hence, the period following Koch's elucidation of the anthrax bacteria is largely regarded as the 'golden age of bacteriology'. See Steve Blevins and Michael Bronze, 'Robert Koch and the "Golden Age" of Bacteriology', *International Journal of Infectious Diseases*, vol.14:9 (2010), p.e750; Thomas Brock, *Robert Koch: A Life in Medicine and Bacteriology* (Berlin: Springer, 1988).

¹⁹⁵ Wendell Stanley, an American biochemist, crystallised tobacco mosaic virus (TMV) in 1935 showing that it is a rod-shaped aggregate of protein and nucleic acid molecules. His work laid the foundations for the application of X-ray diffraction as a method for determining the structure and modes of propagation of viruses. See <http://www.britannica.com/EBchecked/topic/563251/Wendell-Meredith-Stanley> (accessed 30/01/2014).

The second discipline worthy of note is biochemistry, which, according to Robert Kohler, began to acquire conceptual and social organisation around 1890.¹⁹⁶ In some respects, biochemistry can be seen as an extension of physiological chemistry, which emerged around 1840 in Germany and vigorously strived to preserve its autonomy over the following decades *vis-à-vis* the rapidly expanding field of organic chemistry. The majority of research conducted throughout that period was centred on the concept of ‘the living protein’ (protoplasm). Starting in the early twentieth century, novel discoveries on the structure and properties of enzymes, coenzymes, vitamins and hormones helped solidify the position of biochemistry as a separate discipline with an enormous practical utility, thus legitimising the professional status of its practitioners.

For the purposes of the present chapter, there are two chief reasons – one scientific and the other philosophical – why the developments in biochemistry are deemed pertinent to the advent of the biotechnology revolution. As far as the scientific dimension is concerned, the discoveries made in the field of biochemistry, particularly those related to proteins and nucleic acids, served as an important precursor of molecular biology, an area of study actively promoted by the Rockefeller Foundation from the 1930s onwards which largely provided the context for the elucidation of the deoxyribose nucleic acid (DNA) structure and the resultant emergence of genetic engineering. In philosophical terms, by dint of incorporating the study of chemicals as integral to the study of life, biochemistry rests upon the premise that life obeys mechanistic principles and as such, can be understood through the behaviour and properties of particles, elements and compounds. The late nineteenth and especially the early twentieth century witnessed the consolidation and growth of many of the newly-emerged biology-related sub-fields. Yet what needs to be underscored is that, by and large, the establishment of those sub-disciplines was just as much a politically-inspired move aimed at gaining public recognition, professional status and material

¹⁹⁶ Robert Kohler, ‘The History of Biochemistry: A Survey’, *Journal of the History of Biology*, vol.8:2 (1975), p.276.

support as it was an expression of the trajectory of scientific development as it was.¹⁹⁷ This is hardly surprising, for:

disciplines are political institutions that demarcate areas of academic territory, allocate the privileges and responsibilities of expertise, and structure claims on resources. They are the infrastructure of science, embodied in university departments, professional societies, and informal market relationships between the producers and consumers of knowledge. They are creatures of history and reflect human habits and preferences, not a fixed order of nature.¹⁹⁸

The trend toward the professionalisation of the life sciences was also evident in at least three major developments, namely the diversification of academic curricula; the establishment of professional societies and specialised journals; and the multiplication of career opportunities for experts in narrowly-defined areas of biology.

A survey conducted by the American Medical Association (AMA) in 1909 demonstrated that 60 out of the 97 medical schools under scrutiny had established departments in biochemistry and offered courses accordingly.¹⁹⁹ Likewise, by 1913 departments of genetics offering postgraduate training were in place at Cornell, Berkeley, and Wisconsin, and by 1916 the number of American colleges and universities that had taught programmes in genetics was fifty-one.²⁰⁰ In Britain, University College of London introduced an advanced course in physiological chemistry as early as 1884 and it was not long before other leading higher education institutions, including Edinburgh, Oxford, King's College and Cambridge adjusted their curricula

¹⁹⁷ The heated debate between traditional biochemists and the new breed of scientists who called themselves molecular biologists is indicative in this regard. Erwin Chargaff, a renowned biochemist who had demonstrated that the ratios between A:T and G:C in the DNA molecule are constant described molecular biology as the practice of biochemistry without a license. See Robert Kohler, *From Medical Chemistry to Biochemistry: The Making of a Biomedical Discipline*, (Cambridge: Cambridge University Press, 1982), p.332. On the same issue, see also Richard Burian, "The Tools of the Discipline: Biochemists and Molecular Biologists": A Comment', *Journal of the History of Biology*, vol.29 (1996), pp.451-462; Lily Kay, 'Biochemists and Molecular Biologists: Laboratories, Networks, Disciplines: Comments', *Journal of the History of Biology*, vol.29 (1996), pp.447-450; Jean-Paul Gaudilliere, 'Molecular Biologists, Biochemists, and Messenger RNA: the Birth of a Scientific Network', *Journal of the History of Biology*, vol.29 (1996), pp.417-445; Pnina Abir-Am, 'The Politics of Macromolecules: Molecular Biologists, Biochemists, and Rhetoric', *Osiris*, vol.7 (1992), pp.164-191.

¹⁹⁸ Robert Kohler, *From Medical Chemistry to Biochemistry: The Making of a Biomedical Discipline*, *op cit*, p.1.

¹⁹⁹ *Ibid*, p.192.

²⁰⁰ Jonathan Harwood, 'National Styles in Science: Genetics in Germany and the United States between the World Wars', *ISIS*, vol.78 (1987), p.396.

accordingly.²⁰¹ During the first decade of the twentieth century formal instruction in genetics began to feature in German academia, with half of the universities and agricultural colleges offering taught courses in the field.

The proliferation of discipline-specific professional societies was another key development that facilitated the institutionalisation of the life sciences. Founded in 1899, the American Society for Microbiology (ASM) was the first single life science membership organisation in the world set up exclusively for the purposes of promoting research on bacteria, viruses, fungi and other microorganisms. Both the American Society of Biological Chemists organised in 1906-7 and its British counterpart, the Biochemical Society established in 1911, shared the goals of expanding and protecting the interests of their constituencies, particularly with respect to strengthening the occupational position of biochemists in botany, agriculture, the brewing industry, medicine, pathology, and public health.²⁰² In a similar fashion, learned societies in the field of genetics, such as the British Genetics Society of 1919, the German Genetics Society of 1921 and the Genetics Society of America of 1931, sought to elevate the social and professional status of the discipline, advance research and facilitate data-exchange and knowledge-sharing on the basic mechanisms of inheritance.

Besides being an important channel for the communication of findings and an indispensable forum for scientific discussion, discipline-specific journals also constituted an ideal vehicle for enhancing the legitimacy of the newly-emerged fields by delimiting their intellectual boundaries and fostering a shared identity and sense of cohesion among narrow specialists. On some occasions, the establishment of journals preceded the formation of a learned society, as in the case of the American-based *Journal of Biological Chemistry* founded in 1905²⁰³ and *Genetics* founded in 1916. By contrast, the British Genetics Society only began publishing its first journal, *Heredity*, in 1947, or almost twenty years after it had been set up.

²⁰¹ Robert Kohler, *From Medical Chemistry to Biochemistry*, *op cit*, p.44-45.

²⁰² *Ibid*, 198.

²⁰³ Another journal in the field of biochemistry, *Biochemical Journal*, was founded in 1906, almost in parallel with the establishment of the American Society of Biological Chemists. See *ibid*, p.197.

Growing occupational pluralism further enhanced the social standing of the life sciences, as it allowed practitioners to transfer their expertise from academia to the public sphere, confirming in the process the enormous practical utility of their work. While universities remained the chief employer of life scientists attracting them with decent conditions for research, considerable freedom and light, if any, teaching duties, alternative career options were also gradually made available. Private research institutes, such as those established by the Carnegie Endowment and the Rockefeller Foundation in the USA, and the Kaiser Wilhelm Institute for Biology in Germany, vigorously recruited staff for their programmes in genetics, biochemistry and neuroscience. Given the numerous benefits likely to result from the progress of the life sciences, including new and improved diagnostic tests and therapies, food products and animal feeds, research activities began to feature in industrial laboratories, medical research institutes and hospitals. Research in agriculture drew heavily on the discoveries in the life sciences, particularly those in the fields of genetics and biochemistry. Across the USA, agricultural experimental stations employed biologists offering them both a degree of autonomy in the choice of research topics and the opportunity of gaining extensive experience in applied and experimental science.²⁰⁴ Government bureaus, too, hired life science experts in an attempt to improve food and drug regulation, water analysis and testing, hygiene standards, and public health policies. All those developments substantially contributed to the consolidation and establishment of the life sciences as a highly-specialised professional sphere, the steady expansion of which went virtually unchallenged due to the bright prospects for human betterment and social transformation that advanced biological knowledge offered.

While some areas of science, most notably physics and engineering, came under vociferous criticism during the 1930s Depression, due to the overproduction crisis and rising unemployment, public trust in the utility and

²⁰⁴ Jonathan Harwood, 'National Styles in Science: Genetics in Germany and the United States between the World Wars', *op cit*, p.399.

value of biology and its related sub-disciplines remained largely unshaken. By that time, the life sciences had already begun delivering on their extensive promise to maximise societal welfare. Research on hormones and vitamins enabled the development of new medicines and nutrition products; advanced knowledge of botany and genetics facilitated plant hybrid breeding and enhanced crop yields; and improved understanding of disease causes and transmission informed policies on public health and hygiene. For example, the successful commercial cultivation of hybrid corn in the early 1930s was hailed as a major achievement in agriculture, subsequently allowing the US to triple its corn production during the second half of the twentieth century. Laboratory-manufactured hormones, including adrenalin, insulin, thyroxine, and vitamins B and C were made widely available, vividly demonstrating that the progress of life sciences could help alleviate a range of serious chronic conditions. But by far the most remarkable breakthrough in the area of drug development during the first half of twentieth century was the advent of antibiotics, as reflected in the miraculous properties of penicillin. Even though it was discovered in 1928 by Alexander Fleming, it took scientists around fourteen years to successfully utilise penicillin for medical treatment. The large-scale production and distribution of the antibiotic during the Second World War played a crucial role in reducing the number of victims among the Allied troops by preventing deaths and amputations caused by infected wounds.

The wide application of biological knowledge for generating public goods notwithstanding, it would be naïve to assume that the history of the evolution of the life sciences is deprived of 'dark pages' and pernicious legacies. On the contrary, such legacies are indeed vividly present giving rise to wide-ranging debates about the potential for malicious misuse of biotechnology. Two highly controversial areas with which the life sciences have been directly or indirectly involved are eugenics and biowarfare. Despite not being new, the concept of eugenics only won popularity following the publication of Francis Galton's works in the 1860s. Drawing upon Darwin's ideas, Galton advanced the argument that the laws of inheritance applied to humans just as much as they did to other animals, stressing that mental, temperamental

and physical traits were inherited from both parents, which allowed for improving human character and mentality by dint of institutionalised good breeding.²⁰⁵ Based upon this logic, two broad categories of eugenics practices emerged, namely positive and negative. Positive eugenics generally entailed strategies that sought to generate more life (e.g. pronatalist policies and treatment of infertility) and foster healthy lifestyles and living environments (e.g. environmental reforms, public health, policies on youth upbringing and training). By contrast, negative eugenics focused on measures aimed at reducing birth rates (e.g. sterilisation, contraception, segregation, abortion) and even destroying life (e.g. euthanasia, genocide, ethnic cleansing, non-treatment of terminally ill and neonates). Research involving negative eugenics was vigorously pursued in the US²⁰⁶ during the first few decades of the twentieth century thanks to the sterilisation laws enacted in a number of states and the generous grants made available by the Carnegie Endowment, the Rockefeller philanthropies and the Harriman Foundation. The worst excesses of negative eugenics, including gassing, mass murder and racial extermination reached their peak in Nazi Germany during the 1930s and 1940s, allowing life scientists and medical personnel to abandon ethical norms and pursue a whole range of gruesome practices including human experimentation.²⁰⁷ Despite being explicitly condemned in the aftermath of the Second World War and resultant Nuremberg Code, the strategy of using human beings as guinea pigs for the purposes of life science research did not disappear straight away, as evident from the work conducted by American scientists in the late 1940s in Guatemala for the purposes of testing the efficacy of penicillin against sexually-transmitted diseases.²⁰⁸

²⁰⁵ See Diane Paul and James Moore, 'The Darwinian Context: Evolution and Inheritance' and Nils Roll-Hansen, 'Eugenics and the Science of Genetics' in Alison Bashford and Philippa Levine (ed.), *The Oxford Handbook on the History of Eugenics* (Oxford: Oxford University Press, 2010). See also Chloe Burke and Christopher Castaneda, 'The Public and Private History of Eugenics: An Introduction', *The Public Historian*, vol.29:3 (2007), pp.5-17; Mark Adams et al, 'Human Heredity and Politics: A Comparative Institutional Study of the Eugenics Record Office at Cold Spring Harbour (United States), the Keiser Wilhelm Institute for Anthropology, Human Heredity, and Eugenics (Germany), and the Maxim Gorky Medical Genetics Institute (USSR)', *Osiris*, vol.20 (2005), pp.232-262.

²⁰⁶ See Edwin Black, *War against the Weak*, *op cit*. See also Wendy Kline, 'Eugenics in the United States' in Alison Bashford and Philippa Levine ed., *The Oxford Handbook on the History of Eugenics*, *op cit*.

²⁰⁷ See Gerhard Baader et al. 'Pathways to Human Experimentation, 1933-1945: Germany, Japan, and the United States', *Osiris*, vol.20 (2005), pp.205-231.

²⁰⁸ Records have shown that between 1946 and 1948 the US government supported a highly unethical study whereby vulnerable populations in Guatemala were intentionally infected with sexually transmitted diseases (STDs). The purpose of the study was to test whether penicillin could not only cure but prevent early syphilis infection. See Chris McGreal, 'US Says Sorry for "Outrageous and Abhorrent" Guatemalan Syphilis Tests', *Guardian*, 1 October 2010, available at <http://www.theguardian.com/world/2010/oct/01/us-apology-guatemala-syphilis-tests> (accessed

Attempts to use disease as a weapon of war have deep historical roots dating back to antiquity, as illustrated in the resolve of the Carthaginian army to hurl clay pots full of 'serpents of every kind' during a naval battle against King Eumenes of Pergamum in 184 BC.²⁰⁹ During the Middle Ages offensive activities became slightly more 'sophisticated', due to the growing awareness of the pestilential properties of rotten bodies. Two well-documented cases exhibit this tendency. One is the siege of Thun-l'Eveque of 1340, as part of which attackers catapulted dead horses and other animals to force the defenders out of the castle; the other is the 1346 siege of Caffa in which the invading Tatars sent plague-infected human dead bodies over the city walls and subsequently facilitated the second major outbreak of 'Black Death' in Europe.²¹⁰ Cunning tactics to spread disease were also adopted by the British forces during the American War for Independence in the eighteenth century, whereby blankets and handkerchiefs of smallpox victims were distributed among the Native Americans. The Golden Age of Bacteriology largely redefined biological warfare, for, by shedding light both on the mechanisms of disease transmission and the microorganisms responsible for various illnesses, it paved the way for the development of novel and significantly more potent weapons. Biological sabotage against livestock thus featured notably in the First World War, with anthrax and glanders constituting an indispensable element of the German army's arsenal.²¹¹

30/01/2014); *Fact Sheet on the 1946-1948 U.S. Public Health Service Sexually Transmitted Diseases (STD) Inoculation Study*, available at <http://www.hhs.gov/1946inoculationstudy/factsheet.html> (accessed 3/08/2015). Another notorious example is the Tuskegee Study of untreated syphilis conducted by the US Public Health Service and the Tuskegee Institute between 1930s and 1970s. No informed consent was obtained from the participants in the project. Still worse, the experiment involved a considerable number of males infected with syphilis who were not provided with the required treatment even though they were told they were. The study went on for about 40 years before it was exposed by the media in the US causing a massive public outcry. See 'US Public Health Service Syphilis Study at Tuskegee' section on the US Centres for Disease Control (CDC) webpage at <http://www.cdc.gov/tuskegee/timeline.htm#> (accessed 30/01/2014). See analysis of the study and its ethical implications, see Susan Reverby, 'More than Fact and Fiction: Cultural Memory and the Tuskegee Syphilis Study', *The Hastings Centre Report*, vol.31:5 (2001), pp.22-28; Susan Reverby, 'Tuskegee: Could It happen Again?', *Postgraduate Medical Journal*, vol.77 (2001), pp.553-555; Susan Reverby, "'Special Treatment": BiDiI, Tuskegee and the Logic of Race', *Journal of Law, Medicine and Ethics*, vol.36 (2008), pp.478-484; Allan Brandt, 'Racism and Research: The Case of the Tuskegee Syphilis Study', *The Hastings Centre Report*, vol.8:6 (1978), pp.21-29.

²⁰⁹ Edward Eitzen and Ernest Takafuji, 'Historical Overview of Biological Warfare' in Frederick Sidell, Ernest Takafuji and David Franz (ed.), *Medical Aspects of Chemical and Biological Warfare*, (Washington, DC: Office of the Surgeon General, Borden Institute, Walter Reed Army Medical Centre, 1997), p.416.

²¹⁰ Mark Wheelis, 'Biological Warfare at the 1346 Siege of Caffa', *Emerging Infectious Diseases*, vol.8:9 (2002), available at http://wwwnc.cdc.gov/eid/article/8/9/01-0536_article.htm#suggestedcitation (accessed 2/02/2014).

²¹¹ See Erhard Geissler and John Ellis van Courtland Moon (ed.), *Biological and Toxin Weapons: Research, Development and Use from the Middle Ages to 1945*, SIPRI Chemical and Biological Warfare Studies No.18 (Oxford: Oxford University Press, 1999); Gregory Koblenz, *Living Weapons: Biological Warfare and International Security* (Ithaca: Cornell University Press, 2009); James Martin et al. 'History of Biological Weapons: From Poisoned Darts to International Epidemics' in Frederick Sidell, Ernest Takafuji and David Franz (ed.), *Medical*

Following the defeat of the Triple Powers, international efforts to restrict the deployment of biological weaponry in hostilities manifested in the successful negotiation of the Geneva Protocol of 1925. Despite being an important step in the area of arms control, the Protocol proved insufficient to deprive biological weapons of their strategic and symbolic value, something evidenced in the determination of most major powers to pursue offensive programmes in the interwar years and the reluctance of the Allied Forces to impose sanctions against, or otherwise punish the Axis members that launched biological attacks during World War Two.²¹²

Having evolved into a sphere of professional activity during the early decades of the twentieth century, the life sciences were hardly insulated from the complex dynamics triggered by the multiplication of diverse agendas pursued by interested stakeholders, such as funding bodies, industry, state agencies, and the general public. The synergies between those dynamics and their cumulative effects played a crucial role in facilitating the extension and consolidation of the governance of biotechnology, effectively redefining research objectives, reconfiguring power relations and altering established norms. At least four trends are indicative in this regard. First, the policies of funding bodies affected and sometimes even shaped life science research priorities. Prior to the Second World War philanthropic organisations, including private foundations and charities, provided the bulk of material support for science and, as such, were in a position to define, at least to an extent, the lines of scientific enquiry to be pursued. Arguably the relationship between the policies of the Rockefeller philanthropies and the rise of molecular biology²¹³ as a distinct discipline is an illustration of this trend.

Aspects of Chemical and Biological Warfare, op cit, pp.1-20; Simon Whitby, *Biological Warfare against Crops*, (Basingstoke: Palgrave, 2001).

²¹² See John Krige, 'Building the Arsenal of Knowledge', *Centaurus*, vol. 52 (2010), pp.280-296; Nazi War Crimes and Japanese Imperial Government Records Interagency Working Group, *Researching Japanese War Crimes Records* (Washington DC: Library of Congress, 2006), available at <http://www.archives.gov/iwg/japanese-war-crimes/introductory-essays.pdf> (accessed 3/02/2014); Jeanne Guillemin, 'Imperial Japan's Germ Warfare: The Suppression of Evidence at the Tokyo War Crimes Trial, 1946-1948' in Ann Clunan et al. *Terrorism, War, Disease?: Unravelling the Use of Biological Weapons*, (Stanford: Stanford University Press, 2008), pp.165-186; John Gimbel, 'The American Exploitation of German Know-How after World War Two', *Political Science Quarterly*, vol.105:2 (1990), pp.295-309; Asif Siddiqi, 'Germans in Russia: Cold War, Technology Transfer, and National Identity', *Osiris*, vol.24 (2009), pp.120-143.

²¹³ See Lily Kay, *Molecular Vision of Life: Caltech, the Rockefeller Foundation, and the Rise of the New Biology* (Oxford: Oxford University Press, 1993); Warren Weaver, 'Molecular Biology: Origins of the Term', *Science*, vol.170:3958 (1970), pp.581-582. On the impact of the Rockefeller Foundation's policies on Soviet research, see Susan Gross Solomon and Nikolai Kremmentsov, 'Giving and Taking across Borders: The Rockefeller Foundation and Russia', *Minerva*, vol.39 (2001), pp.265-298; Susan Gross Solomon, "Being there": Fact-Finding and

While this relationship has been extensively questioned, the prevalent view in literature still holds that the policies implemented by Warren Weaver, the then director of the natural sciences division of the Foundation, effectively facilitated the 'colonisation' of biology by physical techniques not only in technical but also in philosophical and conceptual terms.²¹⁴ In any event, the explicitly reductionist vision adopted by Weaver manifested in his strong support for the application of new physical and chemical techniques to biology, including the use of isotopes, ultracentrifuges and X-ray crystallography had far-reaching implications for several disciplines, especially biochemistry²¹⁵ and largely provided the context for the major discoveries that triggered the biotechnology revolution.

A second factor impacting on professional life science cultures was the emergence of partnerships between pharmaceutical companies and academia, a process dating back to the early years of the twentieth century. Following the defeat of Germany in the First World War, a significant proportion of the assets and patents held by local pharmaceutical companies were confiscated, as a result of which the centre of drug-manufacturing industry shifted to the most economically-stable country at the time – the US, allowing a greater number of American firms relatively easy and lucrative entry to the drug market.²¹⁶ Heightened competition, coupled with already

Policymaking: The Rockefeller Foundation's Division of Medical Education and the "Russian Matter", 1925-1927', *The Journal of Policy History*, vol.14:4 (2002), pp.384-409; Chris Shepherd, 'Imperial Science: The Rockefeller Foundation and Agricultural Science in Peru, 1940-1960', *Science as Culture*, vol.14:2 (2005), pp.113-137.

²¹⁴ On the impact of the Rockefeller Foundation's policy on the consolidation of molecular biology as a separate discipline, see John Fuerst, 'The Definition of Molecular Biology and the Definition of Policy: The Role of the Rockefeller Foundation's Policy for Molecular Biology', *Social Studies of Science*, vol.14:2 (1984), p.225; Robert Olby, 'The Sheriff and the Cowboys: Or Weaver's Support of Astbury and Pauling', *Social Studies of Science*, vol.14:2 (1984), pp.244-247; Ditta Bartels, 'The Rockefeller Foundation's Funding Policy of Molecular Biology: Success or Failure', *Social Studies of Science*, vol.14:2 (1984), pp.238-243; Edward Yoxen, 'Scepticism about the Centrality of Technology Transfer in the Rockefeller Foundation Programme in Molecular Biology', *Social Studies of Science*, vol.14:2 (1984), pp. 248-252; John Fuerst, 'Role of Reductionism in the Development of Molecular Biology: Peripheral or Central', *Social Studies of Science*, vol.12:2 (1982), pp.241-278. On the arguments that contest this position, see Pnina Abir-Am, 'The Discourse of Physical Power and Biological Knowledge in the 1930s: A Reappraisal of the Rockefeller Foundation's "Policy" in Molecular Biology', *Social Studies of Science*, vol.12:3 (1982), pp.341-382; Pnina Abir-Am, 'Beyond Deterministic Sociology and Apologetic History: Reassessing the Impact of Research Policy upon New Scientific Disciplines', *Social Studies of Science*, vol.14:2 (1984), pp.252-263. An alternative narrative on the origins of molecular biology focusing on the role of comparative and exemplary practices in other fields, see Bruno Strasser and Soraya De Chadarevian, 'The Comparative and the Exemplary: Revisiting the Early History of Molecular Biology', *History of Science*, vol.49:3 (2011), pp.317-336.

²¹⁵ Robert Kohler, 'The Management of Science: The Experience of Warren Weaver and the Rockefeller Foundation Programme in Molecular Biology', *Minerva*, vol.14:3 (1976), p.279. See also Soraya De Chadarevian and Jean-Paul Gaudillière, 'The Tools of the Discipline: Biochemists and Molecular Biologists', *Journal of the History of Biology*, vol.29:3 (1996), pp.327-330.

²¹⁶ Nicolas Rasmussen, 'The Moral Economy of the Drug Company: Medical Scientist Collaboration in Interwar America', *Social Studies of Science*, vol.34:2 (2004), p.164. See also Nicolas Rasmussen, 'Biotechnology Before the "Biotechnology Revolution": Life Scientists, Chemists, and Product Development in 1930s-1940s America', in Carsten Reinhardt and Roald Hoffmann, *Chemical Sciences in the 20th Century*, (Weinheim: Wiley-VCH, 2001), pp.

existing initiatives to ensure drug quality, such as the 1906 federal legislation on ingredient labelling and the establishment of the AMA Council on Chemistry and Pharmacy in 1905, in turn generated strong incentives for pharmaceutical companies to forge close links with universities both for research and clinical trials.²¹⁷ Academic-industrial partnerships took various forms, the most common of which were fellowships for junior scientists and consultancy.²¹⁸ Commercial firms generally benefited from such collaborations in three ways, namely by getting exclusive access to the techniques and tacit knowledge of academic researchers; by obtaining exclusive rights to use the name of a compound made famous by its discoverer as a trademark; and by receiving exclusive license to manufacture a drug or compound that a researcher had patented.²¹⁹ For their part, academic scientists enjoyed material and technical support, royalties and public renown.²²⁰ Even though the linkages between industry and academia fostered during the interwar period did encounter some serious opprobrium among the scientific community, by the late 1930s there were already signs that professional norms were changing, as reflected in the resolve of the American Society for Pharmacology and Experimental Therapeutics (ASPET) to allow its members to consult with industry (1937) and to amend its constitution to admit industry-employed scientists (1941).²²¹ More importantly, university-industry cooperation gave birth to a new breed of life scientists – ‘the life scientist-entrepreneur’ – characterised by a remarkable ability to manage both pure and applied research projects using a ‘two-tiered’ funding strategy with support flowing from industry as well as philanthropic institutions.²²²

Yet another consequential development was the extension of patent law so as to cover discoveries in the field of biotechnology. As early as 1900, the Japanese biochemist Jokichi Takamine managed to isolate the adrenal

201-227; Martin Kenney, *Biotechnology: The University- Industrial Complex*, (New Haven: Yale University Press, 1986).

²¹⁷ Nicolas Rasmussen, ‘The Moral Economy of the Drug Company’, *op cit*, p.165.

²¹⁸ *Ibid.*, p.167.

²¹⁹ *Ibid.*

²²⁰ *Ibid.*

²²¹ *Ibid.*, p.175.

²²² Nicolas Rasmussen, ‘Of “Small Men”, “Big Science” and Bigger Business: The Second World War and Biomedical Research in the United States’, *Minerva*, vol.40 (2002), pp.115-146.

hormone, subsequently patenting his process for adrenaline purification and granting a license for commercial production to Parke-Davis.²²³ Even more revealing is the case of Edward Kendall who in 1916 patented his thyroid hormone preparation method, assigning the intellectual property to the University of Minnesota, which, for its part, granted exclusive license to the Squibb pharmaceutical company in exchange for half of the profits from the marketed product.²²⁴ Kendall's work served as an important precedent, encouraging other life scientists and academic institutions to benefit from intellectual property management, as a result of which by the 1930s there were already concerns that the widespread management of biomedical knowledge for profit was eroding professional science ethos and traditional patterns of data and materials sharing between and even within universities.²²⁵ Yet in stark contrast with the anxieties expressed by those in favour of pure science and disinterested pursuit of knowledge, professional bodies, most notably the American Association for the Advancement of Science (AAAS), demonstrated unequivocal support for medical patents, asserting their vital role both in ensuring public interest and advancing the scientific endeavour, and legitimising the administrative and institutional arrangements through which intellectual property was handled.²²⁶ In a similar fashion, seed companies and the American Seed Trade Association lobbied vigorously for effective intellectual property restrictions on plant breeding innovations, something evident in the passage of the Plant Patent Act of 1930 which provided protection for varieties of plants that could be reproduced asexually by mechanisms other than seeds.²²⁷

Last but not least, along with chemistry and physics, biology also found itself within the compass of the state. The large-scale Nazi programme on racial hygiene which was discussed in some detail in the preceding chapter is but

²²³ Nicolas Rasmussen, 'Biotechnology Before the "Biotechnology Revolution": Life Scientists, Chemists, and Product Development in 1930s-1940s America', *op cit*, p. 204.

²²⁴ *Ibid*, p.205. In 1915 T. Brailsford Robertson patented tethelin, a substance extracted from a gland in the brain which, he believed, promoted growth and as such, could have significant medical applications. Unlike Kendall's work, his discovery proved neither medical, nor financial success and nor revenue was generated. See Charles Weiner, 'Patenting and Academic Research: Historical Case Studies', *Science, Technology and Human Values*, vol. 12 (1987), pp.50-62.

²²⁵ *Ibid*, p.219. Nicolas Rasmussen, 'The Moral Economy of the Drug Company', *op cit*, p.174.

²²⁶ Grischa Metley, 'Reconsidering Renormalisation: Stability and Change in 20th-Century Views on University Patents', *Social Studies of Science*, vol.36:4, (2006), p.576-577.

²²⁷ Frederick Buttel and Jill Belsky, 'Biotechnology, Plant Breeding, and Intellectual Property: Social and Ethical Dimensions', *Science, Technology and Human Values*, vol.12:1 (1987), pp.31-49.

one example of the efforts to organise life science expertise in pursuit of political objectives. The Nazis were hardly the first to do so, either. As early as the time of the First World War, life scientists in Germany and France were tasked with studying biological agents and pathogens in order to facilitate the development of offensive capability. The Soviet Union launched its biowarfare programme in the late 1920s, followed by the Japanese and the British in the mid- and late 1930s, respectively.²²⁸ Run by Army Surgeon Ishii under strict conditions of secrecy, Japan's Unit 731 was arguably hosting the most advanced biological weapons programme at the time: 'a mighty research empire' in which hundreds of talented scientists laboured day and night investigating the warfare potential of a wide variety of diseases, such as plague, anthrax, dysentery, typhoid, paratyphoid, cholera and pneumonia.²²⁹ American life scientists, too, were mobilised during the Second World War. Besides the Committee on Medical Research (CMR) which operated within the remit of OSRD directed by Vannevar Bush, the War Production Board (WPB), the War Department, and the Army's Manhattan District funded and coordinated large-scale programmes in plant biology, bacteriological warfare, and radiation biology.²³⁰ The CMR alone was in charge of managing around 600 research contracts²³¹ covering a broad spectre of fields and encompassing a significant number of academic scientists. In doing so, the Committee heavily relied upon the already established framework of project-oriented university-industry collaborations, which enabled the rapid development of a range of pharmaceuticals and products, including penicillin, steroids and manufactured collagen.²³²

Thus, by a variety of means, a scientific, technological, institutional and regulatory foundation for what would later be recognised as the 'revolution in biology' was already in place in the early decades of the twentieth century.

²²⁸ Milton Leitenberg and Raymond Zilinskas, *The Soviet Biological Weapons Program: A History*, (Cambridge, MA: Harvard University Press, 2012); Peter Hammond and Grandon Carter, *From Biological Warfare to Healthcare: Porton Down, 1940-2000*, (Basingstoke: Palgrave, 2002); Brian Balmer, *Britain and Biological Warfare: Expert Advice and Science Policy, 1930-65*, (Basingstoke: Palgrave, 2001).

²²⁹ Peter Williams and David Wallace, *Unit 731: The Japanese Army's Secret of Secrets*, (London: Hodder and Stoughton, 1989), p.19; 30. See also, Sheldon Harris, *Factories of Death: Japanese Biological Warfare 1932-45 and the American Cover Up*, (London: Routledge, 1994).

²³⁰ Nicolas Rasmussen, 'Of "Small Men", "Big Science" and Bigger Business', *op cit*, p.117. See also Kenneth Thimann, 'The Role of Biologists in Warfare', *Bulletin of Atomic Scientists*, vol.3:8 (1947), pp.211-212.

²³¹ *Ibid*.

²³² Nicolas Rasmussen, 'Biotechnology Before the "Biotechnology Revolution"', *op cit*.

And this is why the discovery of the structure of DNA in 1953 and subsequent work on recombinant DNA were not only scientific sensations but also the triggers for the advances, possibilities and challenges of 21st century biotechnology.

'The Eighth Day of Creation': From a Double Helix to Gene Splicing

By the early 1950s efforts to decipher the secrets of life had already yielded some results. The field of molecular biology was steadily expanding with cutting-edge research giving insights into the structure and function of the macromolecules found in living cells, most notably, proteins. There are two main reasons why proteins attracted such considerable attention during that period. First, unlike the rest of the large biological molecules – carbohydrates, lipids and nucleic acids – which were dismissed as chemically and conceptually boring substances composed of monotonous repetitions of one or a few subunits in entirely predictable order, proteins were deemed interesting not only because of the amino acid chains which made them up but also because of the crucial part they played in the biochemistry of living organisms.²³³ Among the chief characteristics of proteins is their property to serve as enzymes or biological catalysts and thus facilitate the cell metabolic activity. Given the supposed (and later confirmed) link between cell metabolism and gene expression, the process that determines what kind of traits an organism would exhibit, proteins were considered essential to unravelling the mechanisms of how life manifested itself. Second, throughout the first several decades of the twentieth century there was a general consensus that genes had a protein-based structure and it was not until the late 1940s that this assumption was seriously questioned. Then, in 1949, Frederick Sanger managed to demonstrate by dint of chromatography that, far from being governed by a natural law, protein sequencing required

²³³ Up until the late 1940s the majority of scientists worked on the assumption that nucleic acids, in particular DNA, were similar in structure and composition to carbohydrates and lipids: long but simple and hardly performing any important role in cell processes. It suffices to mention that according to Max Delbruck, one of the pioneers of molecular biology, nucleic acids were 'stupid molecules' that could not specify anything. See Horace Freeland Judson, 'A History of the Science and Technology behind Gene Mapping and Sequencing' in Daniel Kevles and Leroy Hood (ed.), *The Code of Codes: Scientific and Social Issues in the Human Genome Project*, (Cambridge, MA: Harvard University Press, 1992), pp.37-80. For further discussion on the precursors to the biotechnology revolution, see Horace Freeland Judson, *The Eighth Day of Creation: Makers of the Revolution in Biology*, (London: Penguin Books, 1979); Eric Vettel, 'The Protean Nature of Stanford University's Biological Sciences, 1946-1972', *Historical Studies in the Physical and Biological sciences*, vol.35:1, (2004), pp.95-113.

specific instructions from the gene. Even more importantly, the following year Erwin Chargaff using the same method disproved that DNA was also a 'boring' molecule, showing that it was indeed at least as specific in its composition as proteins.²³⁴ Taken together, the studies constituted an important indicator of the looming paradigm shift in molecular biology, which asserted the primacy of nucleic acids in the study of life. But the culmination of this rapid turn of events took the form of a letter, which *Nature* published in 1953. There, the authors James Watson and Francis Crick sought 'to suggest a structure for the salt of deoxyribose nucleic acid (D.N.A.)' which, they believed, possessed 'novel features...of considerable biological interest.'²³⁵ According to proposed model, the DNA molecule consisted of 'two helical chains each coiled round the same axis' and their 'specific pairing' suggested 'a possible copying mechanism of genetic material.'²³⁶

The conceptual metamorphosis of DNA occurred overnight. Far from being a 'stupid molecule' that fulfilled no interesting function, it seemed to be a holder of the code of life. The sensational discovery galvanised the scientific community worldwide. Its profound implications quickly became evident, as life scientists struggled to comprehend the novel paradigm and adjust their research programmes accordingly. Failure to adapt to the altered conceptual landscape jeopardised individual careers and threatened to erode the prestige of renowned research facilities, something vividly illustrated in the case of Wendell Stanley and the Biochemistry and Virus Laboratory (BVL) which he directed at Berkeley.²³⁷ In scientific terms, the elucidation of the DNA structure proved to be a truly catalytic event, not least because it led to a substantive redefinition of the gene, which made it possible to map its sequence:

the moment molecular biologists understood the
gene as a specific sequence of bases of DNA, then
they could begin to think of analysing the growth

²³⁴ See Horace Freeland Judson, 'A History of the Science and Technology behind Gene Mapping and Sequencing', *op cit*, p. 53.

²³⁵ James Watson and Francis Crick, 'Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid', *Nature*, vol.171: 4356, (25 April 1953), p.737.

²³⁶ *Ibid.*

²³⁷ Eric Vettel, *Biotech: The Countercultural Origins of an Industry*, (Philadelphia: University of Pennsylvania Press, 2006).

and functioning of organisms from the inside out – as it were in parallel with the natural processes of the organism – by identifying functional base sequences and finding out what they determine in the living creature.²³⁸

Throughout the 1950s and 1960s the double helix model enabled molecular biologists to substantially expand the amount of theoretical knowledge available about genetic activity and the processes taking place within the cell. Within a relatively short time-frame the genetic code was cracked; the cellular machinery responsible for DNA replication and protein synthesis was explained in detail; the metabolic pathways involved in replication, expression and natural recombination were defined and the enzymes that facilitated those processes were identified; and the regulation of protein synthesis in bacteria was successfully modelled.²³⁹ On the practical side, the manipulation of DNA was vigorously pursued, as reflected in the test-tube replication of viral DNA and the completion of the first chemical synthesis of a gene in 1972.²⁴⁰ Even though by 1970 the knowledge generated in molecular biology had little practical application, there was a shared conviction among researchers in the field that increased understanding of the role of genes in development and differentiation might potentially create a possibility for the efficient regulation and control of these processes, thus allowing the production of better organisms.²⁴¹ Indeed, efforts to deliberately modify the genetic makeup of organisms were well underway in the late 1960s. In many respects, the announcement of the first successful gene-splicing experiment conducted by Paul Berg at the University of Stanford in 1971 had a snowball effect on genetic engineering and by 1973 researchers had already demonstrated that genes from completely unrelated bacterial species

²³⁸ Horace Freeland Judson, 'A History of the Science and Technology behind Gene Mapping and Sequencing' in Daniel Kevles and Leroy Hood (ed.), *The Code of Codes: Scientific and Social Issues in the Human Genome Project*, (Cambridge, MA: Harvard University Press, 1992), p.40.

²³⁹ Susan Wright, 'Recombinant DNA Technology and Its Social Transformation, 1972-1982', *Osiris*, vol.2 (1986), p.305. For a detailed summary of the developments in molecular biology in the 1950s and 1960s, see David Freifelder (ed.), *Recombinant DNA: Readings from Scientific American*, (San Francisco: W.H Freeman, 1986).

²⁴⁰ Ibid. On the synthesis of the first artificial gene, see also H.G. Khorana et al. 'Total Synthesis of the Structural Gene for an Alanine Transfer Ribonucleic Acid from Yeast', *Journal of Molecular Biology*, vol.72:2 (1972), pp.209-217.

²⁴¹ Susan Wright, 'Recombinant DNA Technology and Its Social Transformation, 1972-1982', *op cit*, p.306.

functioned in their new bacterial host.²⁴² This was a fascinating breakthrough of unprecedented gravity:

For the first time, there is now available a method which allows us to cross very large evolutionary barriers and to move genes between organisms which have never had genetic contact...These species barriers have so long been accepted as logical and almost absolute that it is only within the past months that scientists have seriously contemplated the ramifications of breaking these species barriers.²⁴³

In crude terms, recombinant DNA techniques, generally referred to as 'genetic engineering', presented scientists with the opportunity to alter and control life at will on a scale unimaginable before. Due to its far-reaching implications, from the outset the technique was deemed highly controversial. The wide-ranging debate that it spurred will be discussed later on in this chapter. At this stage, it suffices to note that from the outset an explicit emphasis was laid on the benefits that could be derived from this development. In particular, the prospects for potential commercial exploitation of the technique occupied a central place in the debate. By contrast, while various concerns of social, environmental, ethical and political character were raised, those remained largely marginal in the overall discussion on whether and under what conditions work involving recombinant DNA should proceed.²⁴⁴

Given the highly wide-ranging adaptable applications of genetic engineering that were readily apparent as early as the late 1970s, it is hardly surprising that the technique was largely hailed as beneficial and hence, worthy of support. In medicine, for example, gene technology was vigorously applied to studying the mechanisms of disease and exploring possibilities for early diagnostics and treatment. As a result of these efforts, by the turn of the

²⁴² Ibid, p.314.

²⁴³ Sydney Brenner quoted in *ibid*, p.315.

²⁴⁴ See Susan Wright. *Molecular Politics: Developing American and British Regulatory Policy for Genetic Engineering, 1972-1982*, (Chicago IL: The University of Chicago Press, 1994); Susan Wright, 'The Social Warp of Science: Writing the History of Genetic Engineering', *Science, Technology, and Human Values*, vol.18:1 (1993), pp.79-101; Judith Swazey et al. 'Risks and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Research Controversy', *Southern California Law Review*, vol.51 (1977-78), pp.1019-1078.

century the transformation of biology from a descriptive to predictive science was steadily becoming a reality. The successful mapping of the human genome in 2003 arguably constituted the pinnacle of this transformation. In addition, genetic engineering facilitated the development of an array of new drugs, including hormones (e.g. somatostatin, human insulin and human growth hormone), vaccines, antibiotics and anti-viral agents (e.g. interferon). Agriculture and food production were also expected to benefit substantially from the application of recombinant DNA techniques in the form of novel plant breeds, increased yields, nutritious products, and synthesis of vital substances, such as amino acids and vitamins. Finally, genetic engineering was likely to contribute to pollution control, manufacturing, mineral refining and food processing.

Throughout the final decades of the twentieth century gene technology, that is, the tools required for large-scale recombinant DNA experimentation, developed exponentially. Whereas the early methods for manipulating genetic material were limited to gene-splicing and gene-cloning, by the early 1990s scientists were already employing techniques as sophisticated as DNA synthesis, automated DNA fluorescence sequencing, and polymerase chain reaction.²⁴⁵ Taken together, those innovative technologies considerably shortened the time necessary for conducting experimental work, while at the same time, enhancing accuracy and quality. But the impact of genetic engineering was hardly limited to the development of novel devices and research methods. In broader terms, it reinforced the notion of the cell as an information-processing machine that could be effectively reprogrammed to perform functions outside its inherent capacity.²⁴⁶ Based on this computer analogy, DNA came to be regarded as little more than a piece of software, the scope for modification and tuning of which was limited only to the boundaries of scientists' imagination. And those scientists did not even need to be specialists in biology *per se*. Along with individuals who had their academic grounding in chemistry and physics, from the mid-1960s onwards,

²⁴⁵ See Horace Freeland Judson, 'A History of the Science and Technology behind Gene Mapping and Sequencing' *op cit*, p. 74.

²⁴⁶ See Martin Kenney, *Biotechnology: The University-Industrial Complex* (New Haven: Yale University Press, 1986), p.21.

molecular biology attracted scientists with backgrounds in inherently practical disciplines, such as engineering and medicine.²⁴⁷ The growing interdisciplinarity of the field was further reflected in the consolidation of novel sub-disciplines, including bioinformatics, ‘the study of informatic processes in biotic systems’ which relied heavily upon computational methods for analysis of genomic data.²⁴⁸ DNA manipulation was steadily turning into a domain of practice open to a wide range of constituencies with varying levels of expertise in biology. We will return to this point when looking into the governance challenges arising from the advances in the 21st century biotechnology in Chapter 4.

Even as rapid advances were altering the professional and institutional cultures of an emerging life sciences arena, none of these was free standing of the encompassing national cultures, particularly the prevailing political ethos and government, which in any event retained a close direct interest in these developments, not least through funding and regulatory arrangements.

Life Science Research in the East and West

Cold War Inertia

The Cold War deepened and extended the organisational and governance tools for the procurement of cutting-edge, highly sophisticated weapon systems developed during the Second World War and solidified the wartime marriage of convenience between science and the state, whereby the former was finally lifted out of the scarcity of funds that pervaded its earlier history; and the latter rapidly and efficiently availed itself of the enormous scientific expertise found in academia and industry. More importantly, it considerably enhanced the value attached to scientific and technological prowess turning it into a critical asset of state power and national security. Hence, it can be argued that the Cold War was a technological race for military, strategic and

²⁴⁷ Eric Vettel, *Biotech: The Countercultural Origins of an Industry*, *op cit*, p.173.

²⁴⁸ Paulien Hogeweg, ‘The Roots of Bioinformatics in Theoretical Biology’, *PLOS Computational Biology*, vol.7:3 (2011), pp. 1-5.

economic advantage, just as much as it was a political and ideological confrontation for global domination.

In the immediate aftermath of the Hiroshima and Nagasaki bombings, physics enjoyed explicit preferential treatment in terms of government and military investment. The Soviet acquisition of the bomb and the launch of *Sputnik* in 1957 both illustrated this trend and served as catalysts for its steady perpetuation. Among its tangible expressions were nuclear weapons, intercontinental ballistic missiles, and space exploration to name a few – emblematic artefacts of the vigorous arms race between the superpowers and vivid symbols of scientific supremacy and technological might. High-technology in the form of electronics, data-processing tools and computer devices flourished, too, as epitomised by the rapid growth and economic success of the Silicon Valley – a Cold War creation whose infrastructure and paths of opportunity were fundamentally shaped by the era’s political institutions and imperatives.²⁴⁹ Yet the physical sciences were not the only area that was explicitly brought under the compass of the state. On the contrary, the life sciences attracted no lesser degree of interest from government agencies and the military, something evidenced in the massive resources and efforts dedicated to their expansion on both sides of the iron curtain. This trend was largely a result of the rapid growth of the biological disciplines and the fascinating discoveries made during the first half of the twentieth century, including the advent of antibiotics. Unlike the investments in physics whose payback had implications chiefly for the armament sector and industry, funding biology-related research promised enormous benefits in terms of social welfare, food security and economic prosperity. The ‘tremendous optimism’ that enveloped the study of disease during the 1950s and 1960s is indicative in this regard:

Nearly every week the medical establishment declared another ‘miracle breakthrough’ in humanity’s war with infectious diseases. Antibiotics, first discovered in the early 1940s, were now growing in number and potency...Medicine was

²⁴⁹ Margaret Pugh O’Mara, ‘Cold War Politics and Scientific Communities: The Case of the Silicon Valley’, *Interdisciplinary Science Reviews*, vol.31:2 (2006), p.122.

viewed as a huge chart depicting disease incidence over time: by the twentieth-first century every infectious disease on the chart would have hit zero. Few scientists or physicians of the day doubted that humanity would continue on its linear course of triumphs over microbes.²⁵⁰

Even prior to the biotechnology revolution and the emergence of genetic engineering there were clear indications that well-organised and generously supported life science research could make a significant contribution to combating threats to public health. At the same time, advances in plant breeding and hybridisation offered novel ways of boosting crop yields and producing food of better quality and higher nutritional value. Besides its vast array of civilian applications, biomedical knowledge also possessed proven military potential which, if utilised efficiently, could facilitate the development of a sophisticated biowarfare arsenal. Given the multifaceted leverage likely to be accrued through the high-level coordination and governance of the life sciences, neither of the superpowers spared energy or resources to ensure that ground-breaking discoveries in the field were fully utilised for the purposes of the Cold War.

Despite the obvious differences between the US and the USSR at systemic and social levels, the similarities in terms of the dynamics that shaped and impacted on the professional life science cultures in both countries were profound. This is hardly surprising, since both superpowers were scientific states²⁵¹ preoccupied with national security, economic preponderance and political power; both employed radical rhetoric and constructed ideological narratives to justify their grand strategies and bolster their international standing; and both underscored the benefits of social transformation achieved by dint of scientific and technological advancement. Three sets of dynamics are indicative in this regard. One was the post-war linkage between scientific research and national security that largely dictated the 'Big Science' expenditure and helped fuel and sustain the growth of the military-industrial

²⁵⁰ Laurie Garrett, *The Coming Plague: Newly Emerging Diseases in a World out of Balance*. (New York: Farrar, Straus and Giroux, 1994), p.30.

²⁵¹ On the concept of 'scientific state', see Jurgen Schmandt and James Everett Katz, 'The Scientific State: A Theory with Hypotheses', *Science, Technology, and Human Values*, vol.11:1 (1986), pp.40-52.

complex. But zero-sum calculations and realist fears did much more than bring scientists, policy-makers and the military together. They motivated states on either side of the conflict to exercise an unprecedented degree of control over the practice of science, sanctioning deeply controversial methods for ensuring conformity and obedience which erected barriers to science internationalism and academic freedom, and eroded scientific openness. With scientific knowledge treated as an asset of strategic significance that had to be protected at all costs, secrecy and mutual distrust came to permeate the professional science ethos.²⁵²

Second, the growing bureaucratisation of science, coupled with the significant increase in the influence of science administrators constituted another set of consequential dynamics that had bearing on its governance and cultures during the Cold War. Given the unique nature of science as a professional endeavour dedicated to the pursuit of truth and knowledge, there was a shared conviction among scientists that their work was entitled to a special status when it came to regulation and policy-making. In particular, most scientists were deeply sceptical of the ability of lay people, be they politicians or the general public to make informed decisions regarding the course of development of scientific research. In their view, those who were directly engaged in science were ideally suited to determine and assess the needs of the sphere so that it could flourish, for they solely possessed sufficient expertise and knowledge of its internal workings. Being the intermediate between researchers and the government, science administrators strived tirelessly to reconcile various political pressures with

²⁵² Writing in the 1960s, Norbert Wiener described the growing secrecy in government laboratories in the US during the Cold War as follows:

There is no doubt that the present age, particularly in America, is one in which more men and women are devoting themselves to a formally scientific career than ever before in history. This does not mean that the intellectual environment of science received a proportionate increment. Many of today's American scientists are working in government laboratories, where secrecy is the order of the day, and they are protected by the deliberate subdivision of problems to the extent that no man can be fully aware of the bearing of his own work. These laboratories, as well as the great industrial laboratories are so aware of the importance of the scientist that he is forced to punch the time clock and to give an accounting of the last minute of his research. Vacations are cut down to a dead minimum, but consultations and reports and visits to other plants are encouraged without limit, so that the scientist, and the young scientist in particular, has not the leisure to ripen his own ideas.

See Norbert Wiener, *I am a Mathematician*, (Cambridge, MA: MIT Press, 1964), p. 361.

the demands of their constituencies for preserving research autonomy. Coping with this task was far from straightforward and attempts to strike a balance often generated friction and/or encompassed serious trade-offs between maintaining science professional ethos and complying with political imperatives.

The third set of dynamics pertained to the shift in attitude toward the role of science and technology in society. Novel discoveries in fundamental research offered a variety of applications with potential for enhancing public health, alleviating environmental damage, and maximising social welfare. Science and technology thus came to be regarded as important sources of solutions not only to problems of purely technical character but also to issues that were inherently social and political. Having embraced technological optimism as a dominant paradigm in the realm of public policy, politicians on both sides of the iron curtain demonstrated unequivocal trust in the expert judgement of scientists, further bolstering their social image. As a consequence, scientific objectivity and preference for quick technological fixes largely supplanted public deliberation not only in tackling pressing socio-economic concerns but also in assessing the desirability and utility of scientific breakthroughs.

The complex synergies between the three sets of dynamics described above and their cumulative effects facilitated the development of forms and modes of science governance that were, by and large, consistent with the prevalent Cold War mentality of the day. In other words, virtually any aspect of science practice from everyday routines through professional norms to top-down government regulation reflected and was influenced by the socio-political and economic contingencies of the period.²⁵³ But if state-led initiatives and

²⁵³ On the impact of the Cold War on science, see Naomi Oreskes and John Krige, (ed.), *Science and Technology in the Global Cold War*, (Cambridge, MA: MIT Press, 2014); Walter McDougall, 'The Cold War Excursion of Science', *Diplomatic History*, vol.24:1 (2000), pp.117-127; Hunter Heyck and David Kaiser, 'Focus: New Perspectives on Science and the Cold War: Introduction', *Isis*, vol.101 (2010), pp.362-366; Gregg Herken, 'In the Service of the State: Science and the Cold War', *Diplomatic History*, vol.24:1 (2000), pp.107-115; Walter McDougall, 'Technocracy and Statecraft in the Space Age: Toward a History of Saltation', *The American Historical Review*, vol.87:4 (1982), pp.1010-1040; David van Kruen, 'US Intelligence Gathering and Its Scientific Cover at the Naval Research Laboratory, 1948-1962', *Social Studies of Science*, vol.vol.31:2 (2001), pp.207-229; David Hart, *Forged Consensus: Science, Technology, and Economic Policy in the United States, 1921-1953* (New Jersey: Princeton University Press, 1998), see Chapter 8 'The Past in the Present: The "Hybrid" in the Cold War and Beyond', pp.206-233; Joseph Manzione, "Amusing and Amazing and Practical and Military": The Legacy of Scientific Internationalism in

measures sought to codify and institutionalise the Cold War scientific and technological objectives, it was the informal, tacit elements of science conduct, such as shared values, beliefs, standards and collective memory that reinforced official rules and ensured their endurance and validity. Given the constant interplay between professional science cultures and the larger encompassing cultures within which they operated, the relations of governance fostered during the period achieved stability and acquired inertia. Within the organisational theory literature, the concept of inertia refers to the property of structural, normative and institutional arrangements to guarantee order and predictability by providing a stable and reliable context that supports performance. Since it is key to the maintenance of the status quo, inertia is deemed a hindrance to change and/or to '*strategic renewal outside the current frame of strategy*'.²⁵⁴ Sources of inertia include organisational attributes, such as capabilities, controls, culture and conduct.²⁵⁵ While inertia plays a salient part in increasing the momentum that drives organisations forward, over time, organisational inertia and momentum become mutually reinforcing.²⁵⁶ There are sufficient grounds to argue therefore that the inertia of the governance arrangements in the area of the life sciences put in place during the Cold War would accrue resistance to change and make their adaptation to a different political or organisational ecology difficult. To substantiate this point, the remaining sections of this chapter will look into the Cold War modes of the governance of biotechnology, focusing on three dimensions, namely procedural, structural and normative. The next chapter will then elucidate the nature and range of governance challenges posed by the rapid advances in the life sciences in the twenty-first century.

American Foreign Policy, 1945-1963', *Diplomatic History*, vol.24:1 (2000), see pp.53-55; John Sutton, 'Organisational Autonomy and Professional Norms in Science: A Case Study of the Lawrence Livermore Laboratory', *Social Studies of Science*, vol.14 (1984), pp.197-224; Slava Gerovitch, 'Stalin's Rocket Designers' Leap into Space: The Technical Intelligentsia Faces the Thaw', *Osiris*, vol.23 (2008), pp.189-209; Sonja Schmid, 'Organisational Culture and Professional Identities in the Soviet Nuclear Power Industry', *Osiris*, vol.23 (2008), pp.82-111.

²⁵⁴ C Kinnear and G Roodt, 'The Development of an Instrument for Measuring Organisational Inertia', *Journal of Industrial Psychology*, vol. 24:2 (1998), p.44 [emphasis as original].

²⁵⁵ C Fombrun, *Leading Corporate Change* (New York: McGraw-Hill, 1992).

²⁵⁶ C Kinnear and G Roodt, 'The Development of an Instrument for Measuring Organisational Inertia', *op cit*.

Procedural Dimension

The purpose of this section is to look into the regulatory and policy mechanisms adopted for the governance of biotechnology during the Cold War. As such, it provides an overview of some of the key international and national legally-binding measures and standard-setting documents, recommendations, and guidelines. The section also sketches the main trends in national life science policies in terms of funding, strategic planning and definition of priorities during the Cold War.

a. International Regulatory Framework

Given its wide scope of applications, biotechnology was gradually brought within the compass of multiple international regimes, with the breadth and depth of the regulations in place varying depending on their nature and goals.²⁵⁷ To be sure, not all regulations were directly pertinent to the conduct of life science research as such. Standards on food safety,²⁵⁸ animal,²⁵⁹ plant²⁶⁰ and environmental protection,²⁶¹ for example, while long-standing and extensive, had limited direct bearing on everyday practices within laboratories. It is indicative to note that even though the *International Sanitary Regulations* adopted by the World Health Organisation (WHO) in 1951²⁶² explicitly required State Parties to provide ‘facilities for bacteriological investigation [and] for the collection and examination of rodents for plague

²⁵⁷ For an overview of the international regulation of biotechnology, see Catherine Rhodes, *International Governance of Biotechnology: Needs, Problems, and Potential*, (London: Bloomsbury, 2010).

²⁵⁸ The Codex Alimentarius Commission established in 1963 by the UN FAO and WHO is the principal international authority that develops and oversees the implementation of harmonised international food standards, guidelines and codes of practices in food trade. See <http://www.codexalimentarius.org/> (accessed 5/02/2014).

²⁵⁹ The World Organisation for Animal Health (OIE) founded in 1924 is the international authority that develops and oversees the implementation of the international regulations related to animal health and welfare. Among the principal international legal documents in the area is the Terrestrial Animal Health Code (1968) which includes a chapter on the use of animals in research and education. For further information see <http://www.oie.int/international-standard-setting/terrestrial-code/> (accessed 5/02/2014).

²⁶⁰ The International Plant Protection Convention (IPPC) is an international plant health agreement. Signed in 1951, the Convention seeks to protect cultivated and wild plant species by preventing the introduction and spread of pests. See <http://www.ippc.int/about> (accessed 5/02/2014).

²⁶¹ The UN Conference on Human Environment held in 1972 in Stockholm was the first ever international summit that focused explicitly on the interactions between human activities and the environment. It concluded with the acceptance of the Declaration of the UN Conference on the Human Environment. See <http://legal.un.org/avl/ha/dunche/dunche.html> (accessed 5/02/2014).

²⁶² The 1951 ISR are listed as Second edition, taking into account that the treaty drafted in 1851 at the international sanitary conference addressed cholera, plague and yellow fever. Full text of the ISR is available at [http://treaties.fco.gov.uk/docs/fullnames/pdf/1962/TS0022%20\(1962\)%20CMND-1704%20INTERNATIONAL%20SANITARY%20REGULATIONS%20ADOPTED%20BY%20THE%20WORLD%20HEALTH%20ASSEMBLY%20ON%20MAY%2025.PDF](http://treaties.fco.gov.uk/docs/fullnames/pdf/1962/TS0022%20(1962)%20CMND-1704%20INTERNATIONAL%20SANITARY%20REGULATIONS%20ADOPTED%20BY%20THE%20WORLD%20HEALTH%20ASSEMBLY%20ON%20MAY%2025.PDF) (accessed 21/09/2015).

infection', as well as to ensure that every sanitary airport had at its disposal 'a bacteriological laboratory, or facilities for dispatching suspected material to such a laboratory', the Regulations made no specific provisions regarding biological safety in research facilities and/or the conduct of work on pathogenic microorganisms. Indeed, it was not until 1983 that the WHO issued its *Laboratory Biosafety Manual* – a guidance document seeking to promote the development of codes and standards for the safe handling of pathogens in laboratories. Prior to the publication of the *Manual*, countries were assigned two broad sets of obligations as part of the international efforts to control the spread of infectious diseases, namely to notify the WHO about outbreaks of specified infectious diseases in their territories; and to limit disease-prevention measures that interfered with trade and travel to those based on scientific evidence and public health principles.²⁶³

Yet this is not to say that international rules did not impact on the cultures of life science research before the 1980s. On the contrary, in addition to the evolution of biosafety guidelines (discussed below), there are at least four areas of international law that merit attention as far as work in biology-related disciplines is concerned. Those include the transfer of dangerous goods and substances; the protection of intellectual property; biological non-proliferation and arms control; and research ethics.

In 1956 the Committee of Experts on the Transport of Dangerous Goods of the UN Economic and Social Council (ECOSOC) published its *Recommendations on the Transport of Dangerous Goods*, which largely informed subsequent legal developments in the field.²⁶⁴ The regime is coherent insofar as it comprises legally-binding provisions for any mode of transport - that is, air, road, rail, sea, and post, based on a common system of classification divided into nine categories. Class six is subdivided into two parts, covering poisonous (toxic) substances and infectious substances, respectively. The regime thus covers the transport of pathogens and toxins

²⁶³ David Fidler, 'From International Sanitary Conventions to Global Health Security: The International Health Regulations', *Chinese Journal of International Law*, vol.4:2 (2005), p.328.

²⁶⁴ Full text of the subsequently revised *Recommendations* is available at http://www.unece.org/fileadmin/DAM/trans/danger/publi/unrec/rev13/English/00E_Intro.pdf (accessed 21/09/2015).

alike. Biological specimens and cultures would also fall into this category. Collectively, the regulations define the standards and requirements for packaging, labelling, handling and transportation of dangerous goods. Given the importance of data sharing and exchange of samples and materials among life scientists, sufficient awareness of and familiarity with the provisions of and changes in the regulations was an important aspect of research practice in order to ensure the safe handling of pathogenic microorganisms.

The regulations pertaining to the carriage of dangerous substances by air were introduced in the mid-1950s. Two international agencies were tasked with their administration, the International Air Transport Association (IATA)²⁶⁵ and the International Civil Aviation Organisation (ICAO).²⁶⁶ Prior to the entry into force of the regulations, there was a complete ban on the carriage of toxic, flammable or corrosive materials on board planes. In the mid-1960s, an additional set of legal rules was introduced, the Live Animal Regulations, which laid down the standards for the in-flight welfare of animals.²⁶⁷ The transport of dangerous substances by road is regulated by the *European Agreement concerning the International Carriage of Dangerous Goods by Road* (ADR) which was signed in 1957 in Geneva under the UN Economic Commission for Europe. Similar agreements were later adopted by countries in other regions, including South America and South-East Asia.²⁶⁸ The *Convention concerning International Carriage by Rail* (COTIF) was signed in 1980 and entered into force five years later.²⁶⁹ The event was marked by the establishment of the Intergovernmental Organisation for International Carriage by Rail (OTIF) which was tasked with the administration of the treaty. *The Regulation concerning the International Carriage of Dangerous*

²⁶⁵ Founded in 1945, the International Air Transport Association seeks 'to promote safe, regular and economical air transport for the benefit of the peoples of the world, to foster air commerce, and to study the problems connected therewith' and 'to provide means for collaboration among the air transport enterprises engaged directly or indirectly in international air transport service'. See

http://www.iata.org/about/Pages/history_2.aspx (accessed 5/02/2014).

²⁶⁶ Founded 1944, the International Civil Aviation Organisation (ICAO) is a UN specialised agency that seeks to promote the safe development of international civil aviation around the world. Annex 18 of the Chicago Convention (1944) that set out the standards for international civil aviation addressed the safe transport of dangerous goods on board of passenger aircraft. See

<http://www.icao.int/safety/DangerousGoods/Pages/annex-18.aspx> (accessed 5/02/2014).

²⁶⁷ See http://www.iata.org/about/Pages/history_3.aspx (accessed 5/02/2014).

²⁶⁸ For full text of the ADR Agreement, see

http://www.unece.org/fileadmin/DAM/trans/danger/publi/adr/ADRagree_e.pdf (accessed 21/09/2015).

²⁶⁹ For full text of COTIF, see http://www.otif.org/pdf_external/e/cotif-1980-e.PDF (accessed 21/09/2015).

Goods (RID) is contained in Annex C of the Convention. The criteria for transporting dangerous goods by sea were established by the 1974 *International Convention for the Safety of Life at Sea (SOLAS)*.²⁷⁰ Its provisions are mandatory for each State Party. Based on the text of the Convention, the International Maritime Organisation (IMO) developed and adopted in 1965 the *International Maritime Dangerous Goods Code*, which covered matters such as packing, container traffic and stowage, specifically emphasising the need for segregation of incompatible substances.²⁷¹ Lastly, Article 16 of the *Universal Postal Convention* adopted by the Universal Postal Union (UPU) in 1964 sets out the regulations regarding the shipment of dangerous goods via mail services.²⁷²

The origins of the international legal framework for the protection of intellectual property date back to the late nineteenth century. A landmark treaty of that period was the *Paris Convention for the Protection of Industrial Property* adopted in 1883 and last revised in 1979. The Convention is broad in scope applying to industrial property 'in the widest sense, including patents, marks, industrial designs, utility models, trade names, geographical indications, and the repression of unfair competition.'²⁷³ Initially the Convention was administered by the United International Bureaux for the Protection of Intellectual Property (BIRPI), an international body set up in 1893 which later, in 1970, evolved into the World Intellectual Property Organisation. The provisions of the Paris Convention regarding patents were subsequently incorporated into the World Trade Organisation (WTO) *Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)*, a treaty that has proved to be very consequential for biotechnology,

²⁷⁰ The 1974 SOLAS replaced its earlier counterpart negotiated in 1960. Full text of the Convention is available at <https://treaties.un.org/doc/Publication/UNTS/Volume%201184/volume-1184-I-18961-English.pdf> (accessed 21/09/2015).

²⁷¹ On the International Maritime Dangerous Goods Code, see http://www.imo.org/blast/mainframe.asp?topic_id=158 (accessed 5/02/2014).

²⁷² For information on the Universal Postal Union, see <http://www.upu.int/en/the-upu/the-upu.html> (accessed 17/09/2016). The full text of the Universal Postal Convention is available at <https://lettersblogatory.com/wp-content/uploads/2011/08/universal-postal-convention.pdf> (accessed 17/09/2015).

²⁷³ For a summary of the 1883 Paris Convention, see http://www.wipo.int/treaties/en/ip/paris/summary_paris.html (accessed 5/02/2014); for the evolution of the international regime on intellectual property protection, see <http://www.wipo.int/treaties/en/general/> (accessed 5/02/2014).

especially in the area of drug innovation and distribution.²⁷⁴ Two more international legal instruments developed as part of the efforts to synchronise the standards on the protection of intellectual property across various countries were the *International Convention for the Protection of New Varieties of Plants* (UPOV) of 1961 and the *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure* of 1977. Under the UPOV Convention, a variety is defined as ‘any cultivar, clone, line, stock or hybrid which is capable of cultivation’ and this criterion is applicable to ‘all botanical genera and species’. According to Article 5 of the Convention concerning breeders’ rights, prior authorisation from individual breeders is required ‘for the production, for purposes of commercial marketing, of the reproductive or vegetative propagating material, as such, of the new variety, and for the offering for sale or marketing of such material.’ The Budapest Treaty aims to facilitate the patent application procedures involving microorganisms. One of the chief requirements for granting a patent on an invention is disclosure, which usually takes the form of a written description. Where an invention involves a microorganism or the use thereof, a deposit of a sample is used as a substitute for a description in writing. The value of the Treaty thus lies in the fact that it allows applicants to deposit biological material with an ‘international depository authority’, rather than asking them to submit samples in every country in which they are pursuing patent protection.²⁷⁵ By establishing a uniform system of deposit, the Budapest Treaty makes the patent system of contracting States more attractive and provides patent applicants with a cost-effective mode of securing intellectual property rights.

The third set of regulations under scrutiny includes those prohibiting the development and spread of biological weapons. The proscription of ‘poison or poisoned arms’ in war has a long-standing tradition in customary

²⁷⁴ See, for example, Sherry Marcellin, *The Political Economy of Pharmaceutical Patents: US Sectional Interests and the African Group at the WTO*, (Farnham: Ashgate, 2010); Ellen t’Hoen, ‘TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha’, *Chicago Journal of International Law*, vol.3:1 (2002), pp.27-46; Michael Westerhaus and Arachu Castro, ‘How Do Intellectual Property Law and International Trade Agreements Affect Access to Antiretroviral Therapy’, *PLOS Medicine*, vol.3:8 (2006), pp.1230-1236; Robert Ostergard (ed.), *HIV/AIDS and the Threat to National and International Security*, (Basingstoke: Palgrave, 2006).

²⁷⁵ For a summary of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977), see http://www.wipo.int/treaties/en/registration/budapest/summary_budapest.html (accessed 5/02/2014).

international law. From at least the late nineteenth century the ban has also been explicitly codified in several agreements, including *The International Declaration concerning the Laws and Customs of War* (1874) and *The Hague Conventions with Respect to the to the Laws and Customs of War on Land* (1899; 1907).²⁷⁶ Following the First World War, in which belligerents on both sides procured and deployed chemical and biological weapons, in 1925 the League of Nations adopted a *Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous, or Other Gases, and of Bacteriological Methods of Warfare* (Geneva Protocol).²⁷⁷ Whilst legally binding, those agreements applied only in times of war and, as such, hardly contained any provisions regarding peacetime research and development of biological (and chemical) weapons. This trend began to change in the late 1960s, partially as a result of the public outcry triggered by the Vietnam War and the vivid reports demonstrating the deleterious effects of the widespread use of Agent Orange, a dioxin-rich defoliant.²⁷⁸ In 1969, the US unilaterally renounced 'the use of any form of deadly biological weapons that either kill or incapacitate.'²⁷⁹ Three years later, in 1972, the *Biological and Toxin Weapons Convention* (BTWC) was opened for signature. The Convention outlaws the development, stockpiling, acquisition and retention of 'microbial or other biological agents, or toxins whatever their origin or method of production, of types and quantities that have no justification for prophylactic, protective or other peaceful purposes'.²⁸⁰ Thus defined, the general purpose criterion contained in Article 1 extends the international legal prohibition on biological weapons to encompass all future scientific and technological developments relevant to the Convention. In other words, the use of virtually any biological agent and/toxin is legal, as long as such use is directed toward peaceful and preventive purposes. No official organisation was specifically

²⁷⁶ For full text of the 1874 Brussels Declaration, see <https://www.icrc.org/ihl/INTRO/135> (accessed 21/09/2015). Full text of the Hague Conventions (II and IV) is available at <https://www.icrc.org/ihl/INTRO/150?OpenDocument> (accessed 21/09/2015) and <https://www.icrc.org/applic/ihl/ihl.nsf/0/1d1726425f6955aec125641e0038bfd6> (accessed 21/09/2015), respectively.

²⁷⁷ For the full text of the Geneva Protocol, see <https://www.icrc.org/ihl/INTRO/280?OpenDocument> (accessed 21/09/2015).

²⁷⁸ See Tom Fawthrop, 'Vietnam's War against Agent Orange', *BBC News*, 14 June 2004, available at <http://news.bbc.co.uk/1/hi/health/3798581.stm> (accessed 5/02/2014).

²⁷⁹ Richard Nixon, *Remarks Announcing Decisions on Chemical and Biological Defence Policies and Programmes*, 25 November 1969, available at <http://www.presidency.ucsb.edu/ws/?pid=2344> (accessed 5/02/2014).

²⁸⁰ Full text of the BTWC is available at [http://www.unog.ch/80256EE600585943/\(httpPages\)/77CF2516DDC5DCF5C1257E520032EF67?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/77CF2516DDC5DCF5C1257E520032EF67?OpenDocument) (accessed 21/09/2015).

established or otherwise nominated to administer the implementation of the Convention. This was in part due to the fact that the treaty itself lacked provisions for verifying State Parties' compliance. Since the formal entry into force of the Convention in 1975, State Parties have been holding a Review Conference every five years to evaluate the state of the treaty, clarify common understandings and adopt any measures deemed relevant to ensure the regime integrity. At the Second Review Conference of the BTWC in 1986, State Parties agreed to the voluntary exchange of Confidence-Building Measures (CBMs) 'in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions and in order to improve international cooperation in the field of peaceful biological activities.'²⁸¹ Over the years the CBMs have undergone several revisions and at present remain the only mechanism for ensuring State Parties' compliance with the Convention.

The Convention on the Prohibition of Military or any Hostile Use of Environmental Modification Techniques adopted in 1976 introduced further restrictions on the application of biotechnology for the purposes of warfare. While the Convention defines the term 'environmental modification technique' broadly as 'any technique for changing [...] the dynamics, composition or structure of the Earth, including its biota, lithosphere, hydrosphere and atmosphere, or of outer space', its scope is nevertheless severely constrained by the narrowly worded common understandings enshrined in Article 1.²⁸² This may also explain why the Convention has remained unpopular, with only 76 states acceding to it.

A final point relates to the role of ethics in scientific research. The issue came to the fore in the aftermath of the Second World War when the full scale of the horrors conducted by medical workers in the Nazi concentration camps was revealed. In an attempt to overcome the shortcomings of Hippocratic

²⁸¹ For information on Confidence Building Measures, see <http://www.unog.ch/bwc/cbms> (accessed 5/02/2014).

²⁸² The common understandings related to Article 1 define the terms 'widespread', 'long-lasting', and 'severe' as follows:

- a) "widespread": encompassing an area on the scale of several hundred square kilometres;
- b) "long-lasting": lasting for a period of months, or approximately a season;
- c) "severe": involving serious or significant disruption or harm to human life, natural and economic resources or other assets.

For further information see

<http://www.icrc.org/applic/ihl/ihl.nsf/Article.xsp?action=openDocument&documentId=A951B510E9491F56C12563CD0051FC40> (accessed 5/02/2014).

ethics to guarantee that the rights of those taking part in medical and scientific experiments were fully observed, the *Nuremberg Code* was adopted in 1947.²⁸³ The Code outlined ten basic principles by which life science and medical practitioners had to abide in their work. In particular, it made informed consent an essential condition for any study involving human subjects. While the *Nuremberg Code* was not legally binding, some its provisions have been enshrined in national and international legislation. For instance, Article 7 of the *International Covenant on Civil and Political Rights* (ICCPR) agreed in 1966 explicitly reads that ‘no one shall be subjected without his free consent to medical or scientific experimentation.’²⁸⁴ Likewise, the *Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects* that was issued by the World Medical Association (WMA) in 1964 echoed the basic tenets of the Code.²⁸⁵ In order to facilitate the implementation of the principles contained in the declaration worldwide, the Council for International Organisations of Medical Sciences (CIOMS) in conjunction with the WHO published in 1982 *Proposed International Ethical Guidelines for Biomedical Research Involving Human Subjects*.²⁸⁶

Another international actor that actively sought to promote the centrality of ethics in the practice of scientific research was The United Nations Educational, Scientific and Cultural Organisation (UNESCO). In 1974, UNESCO adopted a *Recommendation on the Status of Scientific Researchers*. Despite being non-binding in character, the document articulated a set of norms intended to inform individual Member States’ science policies. The Recommendation emphasised the indispensable role of science and technology in ‘the preservation of international peace and the elimination of want’, as well as in tackling problems on a global scale,

²⁸³ On the limitations of the Hippocratic Oath and the role of physicians in the development of the Nuremberg Code, see Evelyn Shuster, ‘Fifty Years Later: The Significance of the Nuremberg Code’, *The New England Journal of Medicine*, vol.337:20 (1997), pp.1436-1440. Full text of the Nuremberg Code is available at <http://www.hhs.gov/ohrp/archive/nurcode.html> (accessed 21/09/2015).

²⁸⁴ For full text of the International Covenant on Civil and Political Rights see <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CCPR.aspx> (accessed 5/02/2014).

²⁸⁵ For full text of the WMA Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, see <http://www.wma.net/en/30publications/10policies/b3/> (accessed 5/02/2014).

²⁸⁶ For more information on the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* and its revised version published in 2002, see http://www.cioms.ch/publications/layout_guide2002.pdf (accessed 5/02/2014). In 2009, the Council for International Organisations of Medical Sciences (CIOMS) and WHO published *International Guidelines for Ethical Review of Epidemiological Studies*. The provisional text of the *Guidelines* is available at <http://www.ufrgs.br/bioetica/cioms2008.pdf> (accessed 5/02/2014).

including 'pollution monitoring and control, weather forecasting and earthquake prediction.' It also drew attention to the 'civic and ethical aspects of scientific research' urging the adoption of methods that were 'humanely, socially and ecologically responsible' and highlighting the need for 'vigilance as to the probable and possible social and ecological consequences of scientific research and experimental development activities'. Perhaps the most notable manifestation of this point was the emergence and consolidation of a separate academic discipline that sought to examine the ethical implications of the life sciences – bioethics. That said, the friction between the increasing reliance upon science and technology in addressing socio-economic and political ills and the need for accommodating the various social, ethical and legal implications of advancing biotechnology, far from going away, would acutely come to the fore from the late 1990s onwards. Some of its manifold expressions will be discussed in detail in the next chapter. Lastly, the Recommendation called upon Member States to ensure that adequate health and safety conditions were in place within research establishments and that those in employ were properly trained in safety procedures.²⁸⁷

b. Laboratory Biosafety Guidelines

The evolution of internationally agreed guidelines on laboratory biosafety merits being addressed in a separate section for two reasons. First, the story tracing the codification of laboratory biosafety procedures in international and national legislation²⁸⁸ is a deeply fascinating one, not least because it depicts the transformation of a professional norm developed explicitly for the purposes of exploiting the military potential of the life sciences into an essential requirement for professional competence in scientific research. And second, unlike the regulations discussed above, the international legal framework pertaining to laboratory biosafety did not have its roots in the Cold

²⁸⁷ For full text of the UNESCO's *Recommendation on the Status of Scientific Researchers*, see http://portal.unesco.org/en/ev.php-URL_ID=13131&URL_DO=DO_TOPIC&URL_SECTION=201.html (accessed 5/02/2014).

²⁸⁸ It is worth highlighting that national regulations on laboratory biosafety only emerged in the early 1990s. International regulations were not developed until 2005.

War period and largely remained in its infancy up until the early twenty-first century.

The history of biological containment, whereby microorganisms can be safely manipulated within a laboratory setting with a minimal risk of infection and contamination, dates back at least to the 1940s when the US vigorously embarked on developing its offensive biowarfare capability.²⁸⁹ A note of caution is required here. While to the US the field of biological warfare was 'an undiscovered country' prior to the Second World War, this was hardly the case with other states, including Germany, Japan and the USSR.²⁹⁰ It is plausible therefore to assume that some techniques and tools for the safe handling of highly pathogenic agents might have already existed in those countries before the 1940s. Such an assumption is hardly unfounded, since both American scientists and the military heavily drew upon the Japanese expertise with research, development and testing of biological weapons. Indeed, Fort Detrick, the backbone of the US offensive biological endeavour which became the first training ground in laboratory biosafety for American researchers, conducted several investigations in Japan after the war which allowed its personnel to gain an in-depth understanding of the work carried out in the top secret Unit 731. From the outset, a variety of protection measures were examined, so as to minimise the risks of scientists' exposure to virulent microorganisms. Those included studying vaccines, toxoids, disinfectants, antibiotics, and antiseptics; devising strategies and techniques for detecting, sampling, and identifying pathogens and their toxic products; and implementing procedures for sterilisation and decontamination. Among the pioneers of laboratory biosafety were Arnold Wedum, the Industrial Health and Safety Director at Fort Detrick; Newell Johnson, an Army officer responsible for the modifications and design of safety equipment at Fort Detrick; and Hubert Kaempf, then a soldier who produced the first prototype

²⁸⁹ See Norman Covert, *Cutting Edge: The History of Fort Detrick*, 3rd ed. 1997 [online], see http://www.detrick.army.mil/cutting_edge/chapter04.cfm (accessed 5/02/2014). For an evaluation of the US bioweapons programme, see Alastair Hay, 'A Magic Sword or a Big Itch: A Historical Look at the United States Biological Weapons Programme', *Medicine, Conflict, and Survival*, vol.15:3 (1999), pp.215-234.

²⁹⁰ See Erhard Geissler and John Ellis van Courtland Moon (ed.), *Biological and Toxin Weapons: Research, Development and Use from the Middle Ages to 1945*, *op cit*.

of a Class III biosafety cabinet.²⁹¹ The Laminar Flow Hood was yet another item fashioned by the staff for the purposes of ensuring the health and safety of investigators during work with pathogenic microorganisms. The device is still in use in our time and its present-day design differs little from its original conception.

Even though the American Biological Safety Association (ABSA) only came into existence in 1984, formal deliberations within the scientific community on the value of improving health and safety procedures within research facilities began as early as the mid-1950s. The idea of organising a conference arose from the need for better coordination of safety policy adopted by the three principal biological warfare laboratories of the US Army, namely Camp Detrick (Maryland), Pine Bluff Arsenal (Arkansas) and Dugway Proving Grounds (Utah). As a result, the first cycle of Biological Safety Conferences, which spanned the period between 1955 and 1965, featured closed sessions solely accessible to life scientists involved in the procurement of biological weapons.²⁹² Given the sensitive nature of the work in question, the papers presented at the meetings had to be cleared by security officers and virtually none of the proceedings were shared with researchers outside the military establishment. The scope of topics discussed was broad ranging from incident analyses through ways for reducing the number of laboratory-acquired infections to export and import controls applicable to the shipment of infectious and toxic materials. From 1964 the number of participants at the conferences increased substantially, as no classified material was discussed any longer and civilian federal agencies, including the NIH and the Communicable Disease Centre (Centre for Disease Control and Prevention – CDC), employed extensive effort to make information regarding laboratory biosafety available to the general scientific community. This trend further intensified during the second cycle of biosafety conferences between 1966 and 1977. Civilian participation grew, as more government agencies, universities, colleges, laboratories and industries were involved. From 1977

²⁹¹ On the classes and types of biosafety cabinets, see <http://www.biologicalsafety cabinet.co.uk/> (accessed 5/02/2014).

²⁹² For an overview of the development of the American Biosafety Association, see <http://www.absa.org/abohistory.html> (accessed 5 February 2014).

onwards the conference attendance acquired an international dimension as well.

In the mid-1970s issues related to laboratory biosafety entered the international policy arena. In 1976 the WHO launched four special programmes focusing on laboratory safety elements; emergency services; shipment of infectious substances; and maximum containment laboratories. As part of its campaign in support of laboratory biosafety, the Organisation published a brochure entitled *Public Health Aspects and Safety Regulations in General Experimentation* and actively encouraged member-states to implement respective programmes at local level and report cases of occupationally-acquired infections. In 1983 the WHO Special Programme on Safety Measures in Microbiology produced a *Laboratory Biosafety Manual*, a non-binding document providing internationally applicable guidance on biological safety.²⁹³ The Manual laid a considerable emphasis on the importance of safe practice and training in preventing laboratory accidents and minimising the risk of infection and contamination. It further classified biological agents according to their degree of pathogenicity and outlined the corresponding basic criteria of laboratory design that had to be met to ensure safe conduct of research. Additional WHO-led activities designed to promote biosafety expertise globally included the organisation of ‘train-the-trainer’ workshops and the establishment of biosafety collaborating centres.

c. Trends in National Science Policy-Making

The formulation of national and international life science policies and regulatory initiatives on both sides of the Berlin Wall generally reflected five main trends: governmental expenditure; linkage between biotechnology progress and economic growth; military exploitation of the life sciences; technocratic approaches to the governance of research; and limited options for public participation in devising governance mechanisms.

²⁹³ See US CDC, ‘Biologic Safety’, *MMWR*, vol.32:47 (2 December 1983), pp.622-3, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000183.htm> (accessed 5/02/2014).

Whereas prior to the Second World War the idea of state support for science invoked negative connotations, for it was largely considered an attribute of dictatorial regimes (USSR, Imperial Japan, Nazi Germany), after 1945 it came to be regarded as an essential prerequisite for national security and economic prosperity, something evident in the resolve of long-established democracies such as the USA and UK to fully embrace the 'Big Science' mentality.²⁹⁴ The biomedical sciences were hardly an exception in this regard. On the contrary, the US government investment in the life sciences grew at enormous pace, as illustrated in the substantial increase in the number of grants for biology-related research allocated by the Office of Naval Research (ONR) and the AEA.²⁹⁵ Similarly, the NIH, the principal agency tasked with channelling federal funding into the life sciences, experienced a remarkable budget expansion, especially after the Soviet launch of Sputnik in 1957, with funding levels rising from 25 just before the event to 135 million dollars just after.²⁹⁶ Thus, by the early 1960s the US 'Manhattan Project for biology' was 'almost as much of an obsession to Congress as it was for scientists at the NIH.'²⁹⁷

The UK, too, demonstrated a deep commitment to the goal of financing biomedical research, with overall state expenditure on science and technology increasing dramatically by 44 per cent between the fiscal years 1956 and 1965.²⁹⁸ In contrast to the American system, in which funds were distributed in accordance with state priorities, in Britain grants were awarded by government-supported research councils which vigorously strived to preserve their autonomy.²⁹⁹ By the 1960s, all of the four existing research councils – the Department of Scientific and Industrial Research, the Medical Research Council (MRC), the Agricultural Research Council (ARC) and the Natural Conservancy (NC) – to a greater or lesser extent provided funds for research in biology-related disciplines.

²⁹⁴ See George Brown, 'The Role of the Federal Government in Supporting Research and Development', *Science, Technology, and Human Values*, vol.7:39 (1982), pp.35-36.

²⁹⁵ Eric Vettel, 'The Protean Nature of Stanford University's Biological Sciences, 1946-1972', *Historical Studies in the Physical and Biological sciences*, vol.35:1, (2004), p.100.

²⁹⁶ *Ibid.*, p.102. The funding policy of the National Science Foundation followed a similar trend.

²⁹⁷ Eric Vettel, 'The Protean Nature of Stanford University's Biological Sciences, 1946-1972', *Historical Studies in the Physical and Biological sciences*, vol.35:1, (2004), p.100.

²⁹⁸ Susan Wright, *Molecular Policy, op cit*, p.31.

²⁹⁹ *Ibid.*

From the mid-1960s and throughout the 1970s state funding for science in the West largely fluctuated due to a combination of factors. Economic stagnation coupled with growing social awareness of environmental degradation and health hazards, and public outrage at the Vietnam War forced Western governments to re-evaluate their priorities and direct financial support to initiatives with immediate socio-economic impact. Following the advent of genetic engineering, public investment in biotechnology surged once more, with France, Britain and Japan spending (respectively) 0.0215, 0.015 and 0.05 per cent of their gross domestic product (GDP), respectively. In the USA, the annual GDP share allocated for life science research was by far the highest, 0.058 per cent, which amounted roughly to 3 billion dollars.³⁰⁰

The idea that there was a direct cause-and-effect link between scientific prowess and economic prosperity constituted another cornerstone of the Cold War science policies. For the Soviet Union and the members of the Warsaw Pact, such a linkage, at least in principle, was beyond question, for it was deeply embedded in the socialist ideology of dialectical materialism. Yet as later chapters will reveal, the cult of science was a prominent phenomenon in Imperial Russia long before the Bolshevik Revolution and Russian liberals, no less than their communist counterparts, were deeply convinced that science was synonymous with social and economic progress.³⁰¹ That said, during Soviet times this conviction was taken to extremes, with research practice in virtually all fields strictly guided by economic and political imperatives dictated by the Communist Party. In Western capitalist countries, by contrast, the linkage between scientific and technological innovation and economic growth took the form of regulatory initiatives and policies designed to foster favourable conditions for business development and capital investment. In the area of the life sciences, this trend is particularly vivid from the 1970s onwards. Following the entry into force of the UPOV Convention in 1968, the American Seed Trade Association (ASTA) vigorously lobbied for changes in the US intellectual

³⁰⁰ Ibid, p.439.

³⁰¹ Alexei Kojevnikov, 'The Phenomenon of Soviet Science', *Osiris*, vol.23 (2008), p. 116.

property legislation to ensure that its constituencies were well placed *vis-à-vis* their European competitors.³⁰² As a result, in 1970 the US passed the Plant Variety Protection Act (PVPA), which granted breeders the right to exclusive control over novel plant varieties, whether sexually reproduced or tuber propagated, for seventeen years, provided that they met the criteria of being distinct, uniform and stable.

Given the enormous commercial viability of recombinant DNA (rDNA) techniques, further measures were adopted to promote the surge of the biotechnology industry. In the USA, aggressive policies toward economic liberalisation and cuts in corporate tax rates, coupled with developments in patent law provided strong incentives for business investments and capital flow. The passage of the 1980 Bayh-Dole Act was hugely important in this regard, not least because it enabled federal grantees, including individual scientists, universities, not-for-profit organisations and commercial companies, to patent and license discoveries arising from publicly funded research.³⁰³ Nevertheless, the implications of the law in the area of the life sciences would not have been so far-reaching had it not been for a decision of the US Supreme Court issued several months earlier. On 16 June 1980, Ananda Chakrabarty, a biochemist working for General Electric, won an eight-year long legal battle for obtaining a patent for his 'invention', a genetically altered bacterium capable of digesting both crude oil and commercially valuable petroleum.³⁰⁴ Prior to the Supreme Court momentous ruling, patents were granted only for the *process* devised to extract natural products but not for the *products* themselves, as the latter were not considered results of human ingenuity. By proclaiming that genetically altered microorganisms constituted inventions, the Court took a strictly technical view on the matter, effectively paving the way for the extension of patent law to

³⁰² Frederick Buttel and Jill Belsky, 'Biotechnology, Plant Breeding, and Intellectual Property', *op cit*, p.35. For a detailed account on the evolution of plant patents and intellectual property law, see Glenn Bugos and Daniel Kevles, 'Plants as intellectual Property: American Practice, Law, and Policy in World Context', *Osiris*, vol.7 (1992), pp.74-104.

³⁰³ See Steven Vallas et al. 'Political Structures and the Making of US Biotechnology' in Fred Block and Matthew Keller, *State of Innovation: The US Government's Role in Technology Development* (Boulder, CO: Paradigm Publishers, 2011), p.63. The Act is available at: <https://history.nih.gov/research/downloads/PL96-517.pdf> (accessed 16/09/2015).

³⁰⁴ See Daniel Kevles, 'Ananda Chakrabarty Wins a Patent: Biotechnology, Law and Society', *Historical Studies in the Physical and Biological Sciences*, Vol.25:1 (1994), pp.111-135. See also Donna Smith and Jonathan King, 'The Legal and Legislative Background', *Environment: Science and Policy for Sustainable Development*, vol.24:6 (1982), pp.24-37.

cover multicellular living organisms.³⁰⁵ Besides the Bayh-Dole Act, three more laws played a role in establishing the infrastructure that facilitated the expansion of biotechnology industry, namely the Stevenson-Wydler Technology Innovation Act (1980), the Small Business Innovation Development Act (1982) and the Orphan Drug Act (1983).³⁰⁶

Yet another set of measures vigorously pursued by governments in East and the West alike was designed to enable the large-scale utilisation of the military potential of the life sciences. To some countries, the respective policies implemented after 1945 were hardly new but rather constituted a continuation of an already established trend. Such is the case with Great Britain, for instance. The British military establishment began exploring the utility of biological weapons in the 1930s chiefly as a result of a perceived threat of biological attacks from Germany. In 1940 the Biology Department of Porton, a unit specifically designated to carry out activities related to the British biological warfare programme, was established at Porton Down.³⁰⁷ While the initial intention was to conduct research primarily for purposes of biodefence, options for offensive capability were also examined, including attempts to design a biological bomb (Project Red Admiral).³⁰⁸ By the late 1960s when the British government was zealously advocating for an international ban on research and development of biological weapons, offensive activities at Porton Down had largely come to a halt. The French biological warfare programme followed a similar course of development,

³⁰⁵ In 1985 the patent Office Appeals Board awarded a patent on a type of corn genetically engineered to contain certain quantity of free tryptophan. In 1987, the Board held in *ex Parte Allen* that patents could be granted, at least in principle, on non-human animals. As a result, in 1988, Harvard University managed to obtain a patent for any non-human mammal genetically engineered to incorporate in its genome an oncogene tied to a specific promoter. *Ibid.*, p.133.

³⁰⁶ For full text of the Stevenson-Wydler Technology Innovation Act of 1980, Public Law 96-480, see <http://www.csrees.usda.gov/about/offices/legis/techtran.html> (accessed 5/02/2014). For full text of the Small Business Innovation Development Act of 1984, Public Law 97-219, see <http://history.nih.gov/research/downloads/PL97-219.pdf> (accessed 5/02/2014). For full text of the Orphan Drug Act of 1983, Public Law 97-414, see <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=51cf70689d51f0ea4147c0a8ac649321&rgn=div5&view=text&node=21:5.0.1.1.6&idno=21> (accessed 5/02/2014).

³⁰⁷ For a detailed overview of the work carried out at Porton Down, see Peter Hammond and Gradon Carter, *From Biological Warfare to Healthcare: Porton Down, 1940-2000* (Basingstoke: Palgrave, 2002).

³⁰⁸ Brian Balmer, 'The UK Biological Weapons Programme' in Mark Wheelis et al. (ed.), *Deadly Cultures: Biological Weapons since 1945* (Cambridge, MA: Harvard University Press, 2006), p.54; Brian Balmer, 'Killing "Without the Distressing Preliminaries": Scientists' Defence of the British Biological Warfare Programme', *Minerva*, vol.40 (2002), pp.57-75; see also Erhard Geissler and John Ellis van Courtland Moon (ed.), *Biological and Toxin Weapons: Research, Development and Use from the Middle Ages to 1945*, *op cit.* For a detailed overview of the British biowarfare programme from its inception, see Brian Balmer, *Britain and Biological Warfare: Expert Advice and Science Policy, 1930-1965* (Basingstoke: Palgrave, 2001).

running from the early 1920s until 1972 when the government signed the BTWC and all offensive activities were terminated.

As already mentioned, the US joined the biowarfare race later than its European counterparts and it was not until the end of the Second World War that significant progress in developing offensive biological capability was made. From the outset, the US military attached a considerable strategic value to the advances taking place in the life sciences, comparing them to the developments in the field of nuclear physics that enabled the construction of the atomic bomb.³⁰⁹ Over the next two decades, the American leadership translated this conviction into a well-organised system for the procurement of biological weaponry. Concerns over public health and environmental safety, coupled with vigorous public opposition toward the use of defoliants in Vietnam forced the government to re-evaluate its biowarfare policies and effectively paved the way for President Nixon's resolve of 1969 to convert the American biological weapons programme into a biological research programme solely directed toward civilian and defensive purposes.³¹⁰ Two points merit scrutiny regarding the conversion process. The first pertains to National Security Decision Memorandum 35 of 25 November 1969, a document which delimited the scope of legitimate activities in the area of biological research. According to its text, the US 'bacteriological/biological programmes will be confined to research and development for defensive purposes...[which] does not preclude research into those offensive aspects of bacteriological/biological agents necessary to determine what defensive measures are required.'³¹¹ Since the permissibility of studies was to be assessed not on the basis of the expected *results* but on the *rationale* that motivated them in the first place, some commentators have argued that the criterion outlined in Memorandum 35 effectively 'allowed for research in a grey area where defensive and offensive activities could not be easily

³⁰⁹ Susan Wright (ed.) *Preventing a Biological Arms Race* (Cambridge, MA: MIT Press, 1990), p.30.

³¹⁰ For a detailed account of the US renunciation of biological weapons, see Jonathan Tucker and Erin Mahan, *President Nixon's Decision to Renounce the US Offensive Biological Weapons Programme*, Centre for the Study of Weapons of Mass Destruction, Case Study Series (Washington, DC: National Defence University Press, 2009). Available at http://www.ndu.edu/press/lib/pdf/CSWMD-CaseStudy/CSWMD_CaseStudy-1.pdf (accessed 19/06/2013).

³¹¹ National Security Council, National Security Decision Memorandum 35, (25 November 1969, Washington DC). Available at <http://2001-2009.state.gov/r/pa/ho/frus/nixon/e2/83596.htm> (accessed 19/06/2013).

distinguished.³¹² The second point is related to the policies adopted by the Nixon administration that enabled the military to retain considerable influence in spurring research and development in the area of biotechnology without attracting the animosity of academic scientists.³¹³ In particular, it has been suggested that the primary objective of the New Technology Opportunities (NTO) Programme launched in 1971 was to replace the military-academic partnership with industry-academic partnership while providing the White House with substantial leverage over federal science policy.³¹⁴

Some countries went to great lengths to ensure that their respective military establishments enjoyed carte blanche to take full advantage of cutting-edge life science advances, even after the entry into force of the BTWC. Following the First Gulf War in the early 1990s, it was revealed that the Iraqi government possessed an extensive offensive biological capability developed and kept in conditions of utmost secrecy. Despite the lack of sufficient reliable information regarding the strategy and/or the objectives of the programme, its scope and key facilities were well documented by the United Nations Special Commission (UNSCOM) on Iraq and its successor, the United Nations Monitoring, Verification and Inspection Commission (UNMOVIC) that sought to ensure the complete disarmament of Baghdad.³¹⁵ The fact that Iraq had formally signed the BTWC in 1972 hardly precluded the country's leadership from expanding and intensifying the efforts to procure biological weaponry two years later. In a similar fashion, the apartheid government of South Africa, having ratified the BTWC in 1975, authorised the launch of Project Coast, which sought to 'establish a research, production and development capacity with regard to biological warfare.'³¹⁶ In order to conceal the involvement of the military, the programme was run through front commercial companies, Roderplaat Research Laboratories (RRL) and Delta G Scientific, which enabled the import of dual-use

³¹² Susan Wright (ed.) *Preventing a Biological Arms Race*, *op cit*, p.41; see also Susan Wright and Robert Sinsheimer, 'Recombinant DNA and Biological Warfare', *Bulletin of the Atomic Scientists*, vol.39:9 (1983), pp.20-26.

³¹³ See Shelley Hurt, 'The Military's Hidden Hand: Examining the Dual-Use Origins of Biotechnology in the American Context, 1969-1972' in Fred Block and Matthew Keller, *State of Innovation*, *op cit*, pp.31-56.

³¹⁴ *Ibid.*

³¹⁵ Graham Pearson, 'The Iraqi Biological Weapons Programme' in Mark Wheelis et al. (ed.) *Deadly Cultures*, *op cit*, pp.167-190.

³¹⁶ See Chandre Gould and Alastair Hay, 'The South African Biological Weapons Programme' in Mark Wheelis et al. (ed.) *Deadly Cultures*, *op cit*, p.191-212.

equipment and materials without raising international suspicion. Political backing coming from the West, especially the US under the Reagan administration, further provided favourable conditions in which the South African biowarfare programme could flourish virtually unconstrained.

By far the most long-standing and sophisticated offensive biological weapon programme was allegedly initiated and developed by the Soviet Union. It reportedly originated back in the late 1920s under the Bolsheviks and ran largely uninterrupted throughout the Cold War years. Perhaps the most egregious aspect of the Soviet effort to acquire biowarfare capability was the blatant disregard for the international legal prohibition on biological weapons demonstrated in the Politburo's unequivocal resolve to provide the legal and institutional infrastructure required for the perpetuation of the programme.³¹⁷ As a result, one of the depositary states of the BTWC was among the first to violate it, craftily ensuring that its clandestine network of research facilities under the auspices of the military could function undisturbed in civilian guise up until the early 1990s.

A fourth trend underpinning national life science policies during the Cold War was the propensity of governments to favour narrowly-focused technocratic approaches to the governance of research whereby biotechnology was stripped of its broader socio-political and ethical implications and any issue likely to hinder its advancement was side-lined and/or framed in purely hypothetical terms. The regulation of genetic engineering is a case in point. Given the revolutionary nature of the technology, its vast array of possible applications and far-reaching implications, policy-makers found themselves compelled to take action and ensure that any potential hazards likely to arise therefrom were reduced to a minimum. This turned out to be a challenging endeavour due to at least three reasons. One was the limited data available regarding the type and extent of perils posed by recombinant DNA experiments. Very little was yet known about the behaviour of genetically modified organisms, as a result of which many of the possible scenarios entertained appeared far-fetched and imaginary. Second, in order to ensure

³¹⁷ See Milton Leitenberg and Raymond Zilinskas, *The Soviet Biological Weapons Programme*, *op cit*.

that the safety measures were enforceable, the demands of the scientific community had to be taken into account.³¹⁸ Lastly, the pressures of international competition dictated that any government-driven initiatives had to be devised in ways that did not stifle innovation.³¹⁹

A pivotal event in the evolution of recombinant DNA policy was the Asilomar Conference, an international meeting convened in California to bring together multiple stakeholders allowing them to discuss and determine what an adequate mechanism for the governance of the new technology should comprise. To achieve this goal, the conference chose to approach the issue of genetic engineering in terms of costs and benefits, whereby experimentation could continue unfettered provided that adequate precautions against potential hazards were adopted. Since ‘complicated questions of what is right and what is wrong’ and the possible utilisation of recombinant DNA for biowarfare were considered only ‘peripheral to the meeting’, they were barely addressed to avoid confusion.³²⁰ The subsequent policies implemented in the US and UK, the *NIH Guidelines* (1976) and the recommendations of the Williams Committee (1976), reflected the Asilomar legacy at three levels.³²¹ First, both documents gave explicit priority on laboratory biosafety, stressing that the hazards that certain experiments entailed could be matched with a series of containment controls of two types, biological and physical. Still, this was hardly surprising given that the two advisory bodies tasked with policy development, the Recombinant DNA

³¹⁸ See Sheldon Krimsky, *Genetic Alchemy: The Social History of the Recombinant DNA Controversy*, (Cambridge, MA: The MIT Press, 1982), p.332.

³¹⁹ See Susan Wright, *Molecular Politics*, *op cit*, in particular Chapter 7, section 7.1.

³²⁰ *Ibid*, p.149. On the same point, see Roger Dworkin, ‘Science, Society and the Expert Town Meeting: Some Comments on Asilomar’, *Southern California Law Review*, vol.51 (1977-78), pp.1471-1482; Valerie Fogleman, ‘Regulating Science: An Evaluation of the Regulation of Biotechnology Research’, *Environmental Law*, vol.17 (1986-1987), pp.183-273. For detailed analysis of the multifaceted issues that rDNA raised, see Harlyn Halvorsen, ‘DNA and the Law’, *Southern California Law Review*, vol.51 (1977-78), pp.1167-1180; John Robertson, ‘The Scientists’ Right To Research: Constitutional Analysis’, *Southern California Law Review*, vol.51 (1977-78), pp.1203-1279; Joseph Fletcher, ‘Ethics and Recombinant DNA Research’, *Southern California Law Review*, vol.51 (1977-78), pp.1131-1140; Peter Barton Hutt, ‘Research on Recombinant DNA Molecules: The Regulatory Issues’, *Southern California Law Review*, vol.51 (1977-78), pp.1435-1450; Jane Friedman, ‘Health Hazards Associated with Recombinant DNA Technology: Should Congress Impose Liability without Fault?’, *Southern California Law Review*, vol.51 (1977-78), pp.1355-1379; Raymond Zilinskas, ‘Recombinant DNA Research and the International System’, *Southern California Law Review*, vol.51 (1977-78), pp.1483-1501; Robert Neville, ‘Philosophic perspectives on Freedom of Enquiry’, *Southern California Law Review*, vol.51 (1977-78), pp.1115-1129; Carl Cohen, ‘Restriction of Research with recombinant DNA: The Dangers of Enquiry and the Burden of Proof’, *Southern California Law Review*, vol.51 (1977-78), pp.1081-1113; Liebe Cavalieri, ‘Science as Technology’, *Southern California Law Review*, vol.51 (1977-78), pp.1153-1165.

³²¹ See Susan Wright, *Molecular Politics*, *op cit*, p.168, p.213.

Advisory Committee (RAC)³²² in the US and the Health and Safety Executive appointed to the Williams Committee, had very limited representation in areas such as law, ethics, environmental protection and industrial safety. Second, neither of the advisory bodies grappled with the possible deployment of genetic engineering techniques by private companies and/or the military but focused exclusively with experiments conducted as part of government-funded projects. Third, both countries took steps to expand research involving recombinant DNA before proper risk assessment mechanisms were developed. The underlying assumption upon which this resolve rested held that more experimental data needed to be collected in order to evaluate the scope of potential risks. Apart from their narrow focus, the policies have been criticised for their overemphasis on physical controls as a means of preventing the release of genetically altered pathogens, not least because while higher laboratory containment level proved to reduce the instances of laboratory-acquired infections, it did not eliminate the risks altogether.³²³ Moreover, the policies did not address the possibility of sabotage or long-range hazards such as those posed by the unwise use of recombinant DNA.³²⁴ Lastly, as the guidelines applied only to research supported with public funds, concerns were raised that life scientists were likely to be disadvantaged *vis-à-vis* their colleagues in industry.

The final trend to be examined pertains to the limited options for public participation in the decision-making process on biotechnology.³²⁵ Two main reasons, one intrinsic and one extrinsic to the life sciences account for this development. The extrinsic reason was the linkage between science and national security which granted policy-makers a crucial say in setting priorities and defining research objectives. As to the intrinsic one, there was a

³²² On the creation of the rDNA Advisory Committee, see Michael Yesley, 'The Use of an Advisory Commission', *Southern California Law Review*, vol.51 (1977-78), pp.1451-1469.

³²³ Smallpox is a case in point. In 1973, a laboratory technician at the London School of Hygiene and Tropical Medicine unknowingly acquired the infection and managed to pass it to two more people before being properly diagnosed and isolated. In 1978, a woman at the University of Birmingham got infected with smallpox. Her office was located a floor above a laboratory where research on live smallpox was carried out. See S.L. Kotar and J.E. Gessler, *Smallpox: A History* (Jefferson: McFarland & Co, 2013), p.375.

³²⁴ Francine Robinson Simring, 'The Double Helix of Self-Interest', *The Sciences* (New York), 17:3 (1977), p.11.

³²⁵ On the importance of public participation in science policy making, see Halsted Holman and Diana Dutton, 'A Case for Public Participation in Science Policy Formation and Practice', *Southern California Law Review*, vol.51 (1977-78), pp.1505-1534; Marc Lappe and Patricia Martin, 'The Place of the Public in the Conduct of Science', *Southern California Law Review*, vol.51 (1977-78), pp.1535-1554; Clifford Grobstein, 'Regulation and Basic Research: Implications of Recombinant DNA', *Southern California Law Review*, vol.51 (1977-78), pp.1181-1200;

considerable resistance from within the scientific community to allowing lay people to determine the course of science evolution. Among the source of this opposition was a widely-held conviction among scientists that their profession occupied a unique niche in society and as such, hardly lends itself to regulation by people without sufficient understanding of its intricacies. In short, scientists viewed self-regulation as the sole viable and most adequate mechanism for the governance of research. The combination of these two dynamics reinforced the marriage of convenience sealed between science and the state after the Second World War effectively insulating the conduct of research from public scrutiny.

To be sure, this trend manifested with far greater severity in the countries of the Soviet bloc where the supremacy of the Communist Party and the rigidity of political structures and hierarchies virtually precluded any direct public involvement in policy development. By contrast, in democratic states like the US, public protests not only were considered a legitimate form of opinion expression but did have some impact on government-led initiatives. For instance, following the public outcry at the devastating effects of scientific progress on society and the environment, Congress passed extensive legislation to address issues of health, safety and environmental protection. While some commentators have shown scepticism about the effectiveness of the new laws in facilitating public participation in the decision-making process,³²⁶ civil society was still an important factor in the US political life. Similarly, despite the fact that the development of regulations involving recombinant DNA largely took place away from the public domain, the publication of the *NIH Guidelines* spurred controversies in several states extending the debate on genetic engineering outside the university campuses to encompass local communities. At one of the forums held in Massachusetts to discuss the potential perils of the novel technology, the public was in control of the event to the extent that it openly and symbolically challenged the self-governance of science ideal.³²⁷ Besides Massachusetts, public-driven initiatives regarding the safety of recombinant DNA technology swept

³²⁶ Susan Wright, *Molecular Politics*, *op cit*, p.43.

³²⁷ Sheldon Krimsky, *Genetic Alchemy*, *op cit*, p.301.

across various parts of the country, including, New Jersey, New York, Maryland, California and Illinois.³²⁸

Structural Dimension

This section aims to uncover and analyse the interactions between life scientists and the consumers of research, including the state, the military, industry, and the general public during the Cold War. To this end, it will enquire into the prevalent power dynamics, elucidating the multiple ways in which the larger socio-political and economic structures moulded and impacted on professional cultures and were in turn influenced by the scientific establishment.

a. State Control over Science

Following the Second World War, science was accorded a special status, whereby it was deemed a state asset of paramount importance that merited special support and protection. Some level of governmental control was therefore deemed not only essential but also morally justified to ensure that scientists were brought in line with national priorities and aspirations. While the type and extent of such control varied substantially across different countries, it is worth noting that the politicisation of science and the use of strong-arm tactics including state-led surveillance and infringement of civil liberties were foreign to neither side of the Cold War.³²⁹

Having assumed the responsibility for providing science with financial security, governments were able to determine at least in part the terms and conditions under which research was to be carried out. This development stood in stark contrast with the original proposal for the post-war organisation of science outlined in Vannevar Bush's emblematic work, *Science: The*

³²⁸ Ibid, p.307.

³²⁹ State-imposed restrictions on science were already in place in non-democratic countries, including the Soviet Union and Nazi Germany prior to 1945. For a comparative analysis of those policies and the measures introduced by the US after the Second World War, see Ronald Doel et al, 'National States and International Science: A Comparative History of International Science Congresses in Hitler's Germany, Stalin's Russia, and Cold War United States', *Osiris*, vol.20 (2005), pp.49-76.

Endless Frontier, where the author made a compelling case in favour of science autonomy *vis-a-vis* increased political scrutiny. The fact that the debate over the governance of the US NSF – the principal body tasked with funding basic research – was ultimately won by Bush’s opponents was a clear sign that even in democratic societies the state was eager to keep the scientific community in check – and/or developing in directions which most concerned it. This trend persisted during the 1950s fuelled by the intensive efforts to contain the spread of communism that culminated in McCarthy’s witch-hunt. As early as 1949 Congress passed legislation (the O’Mahoney Amendment) under which all recipients of the Atomic Energy Commission fellowship were subject to mandatory background checks by the Federal Bureau of Investigation (FBI).³³⁰ The following year, another controversial bill – the McCarran Act – was signed into law despite President Truman’s veto. The Act sanctioned the establishment of the Subversive Activities Control Board which, along with the House Committee on Un-American Activities (HUAC) and the Senate Internal Security Subcommittee (SISS), launched a series of policies with far-reaching implications for scientists. Loyalty investigations, state-orchestrated surveillance of individuals and institutions, constriction of political discourse, visa and passport denials, and infringement of civil liberties vigorously employed to curb any seditious activities encroached the established norms of science practice, fostering an atmosphere of suspicion and mutual distrust on campuses and hindering knowledge sharing and international exchange.³³¹

But if democratic mechanisms still guaranteed science some degree of freedom from state intervention even in an ‘age of anxiety’, the absence of clearly articulated checks and balances in totalitarian societies largely left it at

³³⁰ See Jessica Wang, *American Science in an Age of Anxiety: Scientists, Anticommunism and the Cold War*, (Chapel Hill, NC: The University of North Carolina Press, 1999).

³³¹ See Jessica Wang, *American Science in an Age of Anxiety*, *op cit*; Sigmund Diamond, *Compromised Campus: The Collaboration of Universities with the Intelligence Community, 1945-1955*, (New York: Oxford University Press USA, 1992); Lawrence Badash, ‘Science and McCarthyism’, *Minerva*, vol.38 (2000), pp.53-80; Jessica Wang, ‘Science and the Problem of the Public in Cold War America, 145-1960’, *Osiris*, vol.17 (2002), pp.323-347; John Shattuck, ‘Harvard University Basic Science, Secrecy, and National Security: Federal Restrictions on the Free Flow of Academic Information and Ideas’, *Minerva*, vol.22:3-4 (1984), pp.424-436. Lawrence Badash, ‘From Security Blanket to Security Risk: Scientists in the Decade after Hiroshima’, *History and Technology*, vol.19:3 (2003), pp.241-256.

the disposal of government officials.³³² For a decade before the Cold War, the repressive security apparatus in the Soviet Union utilised a wide range of coercive measures as part of Stalin's Great Purges, which while not specifically directed against the scientific community, did deprive it of a significant proportion of leading researchers. And even when the repressions eased toward the late 1940s, the Communist Party barely loosened its grip on science, as travel restrictions, control over knowledge sharing and animosity toward 'bourgeois' scientists persisted throughout the subsequent decades up until the fall of the Berlin Wall. Unpatriotic activities including perceived servility toward the West were condemned as incompatible with Soviet morale and punishable in honour courts through which the Politburo sought to re-educate the Soviet intelligentsia in the spirit of Soviet patriotism and devotion to the Soviet state's interests.³³³ The rapid rise of Trofim Lysenko was yet another manifestation of the egregious assault launched by Soviet propaganda on the life sciences. Born out of the confluence of Marxist ideology, Stalinist agricultural practices, and institutional centralisation, the pseudoscience of Lysenkoism grounded its principal claims about the inheritability of acquired characteristics in Darwinian notions of the origins of species, thus rejecting the principles of Mendelian genetics. Flawed as they might have been, Lysenko's theories quickly became dogma for the entire Soviet community of biologists, allowing the Communist Party to promote its devoted members within the scientific community regardless of their academic credentials and to discredit and even punish those who dared to question their credibility.³³⁴ Besides in academia, the deleterious influence of Lysenkoism was acutely felt in agriculture where the new, purportedly scientific system for plant breeding that the state introduced in the countryside proved instrumental for extending and consolidating party control and organising peasants into attentive labour but miserably failed to bring the promised increase in yields.³³⁵

³³² This is not to say that the scientific enterprise in totalitarian countries was a passive entity; rather, the point here is to emphasise the virtually unconstrained power that the state possessed there. The point is elucidated later in this section (subsection c).

³³³ Nikolai Krementsov, *Stalinist Science*, (New Jersey: Princeton University Press, 1997), p.137.

³³⁴ Paul Josephson, *Totalitarian Science and Technology*, 2nd ed. (Amherst, NY: Humanity Books, 2005), see p.37-42.

³³⁵ *Ibid*, p.42.

b. The Social Context of Life Science Research

Political power structures were not alone in shaping the professional life science cultures. On the contrary, other actors, including the military, industry and the general public played an important role as well. Given the centrality of the arms race in the East-West confrontation, the military managed to retain considerable influence on the direction of life science research and mobilised significant capacity for the purposes of weapons procurement. Perhaps the most vivid manifestation of this trend was the growth and consolidation of the massive MIACs that developed in the USA and the USSR. Their similarities in terms of organisation and role notwithstanding, the structures differed tremendously in their interactions with the state. In contrast to the American MIAC which had a significant say in governmental policies, its Soviet counterpart was strictly restrained in its activities by the political system in which the concentration of power in the central party organs and the ubiquitous role of the party-state apparatus left military and defense-industry interests little or no freedom of independent action.³³⁶ Moreover, the Politburo's preoccupation with military-oriented projects and its monopoly on research funding meant that a significant proportion of the Soviet scientific community was likely to be in one way or another involved in the expansion of the MIAC. The leading position of scientists in the direction of MIAC need not be taken for granted though, as even the role of scientific and technical elite in the Soviet system was restricted to the level of technical expertise, with its impact on policy decisions being only marginal.³³⁷

Unlike their Soviet colleagues, American scientists enjoyed both a wider career choice and greater influence on policy matters. While substantial, federal funding constituted just one of several sources of financial support for

³³⁶ On this point, see Mark Harrison ed. *Guns and Rubles: The Defense Industry in the Stalinist State*, (New Haven, CT: Yale University Press, 2008). On the MIC in the US, see Binoy Kampmark, 'Science and War: Remembering the Military Industrial Complex', *New Zealand International Review*, vol.36:4 (2011), pp.11-14; Christoph Bluth, 'The Soviet Union and the Cold War: Assessing the Technological Dimension', *Journal of Slavic Military Studies*, vol.23 (2010), pp.282-305.

³³⁷ Irina Bystrova, 'Russian Military-Industrial Complex', *Aleksanteri Papers*, vol.2 (2011), p.12. Available at http://www.helsinki.fi/aleksanteri/julkaisut/tiedostot/ap_2-2011.pdf (accessed 9/07/13). For a detailed overview of the Soviet military-industrial complex, see [in Russian] Irina Bystrova, *Voенно-промышленный комплекс СССР в годы холодной войны: вторая половина 40-х – начало 60-х годов*, (Moscow: Institut Rossiiskoi Istorii RAN, 2000). On the Soviet military budget, see Timothy Sasnovy, 'The Soviet Military Budget', *Foreign Affairs*, vol.42:3 (1964), available at <https://www.foreignaffairs.com/articles/russian-federation/1964-04-01/soviet-military-budget> (accessed 16/09/2015).

the life sciences, with private philanthropies and the industry allowing the pursuit of research outside the compass of the state. This was particularly true in the case of genetic engineering, since the 1976 *NIH Guidelines* applied only to work conducted with governmental funds, which in turn automatically exempted scientists working in the industry from formal regulation.³³⁸ The state-led initiatives to promote the commercial exploitation of biotechnology further empowered the private sector, allowing it to play a significant part in the articulation and implementation of national policies. A direct consequence of this development was the move toward the relaxation of various regulatory measures, most notably those pertaining to health and safety, so as to enable the uninhibited advancement of the life sciences.³³⁹

Yet another external factor that affected biotechnology not only in the USA but in the West generally was public opinion. For instance, it was the increasing social discontent over the limited practical utility of the life sciences in the 1960s that mainly drove Congress to revise the government expenditure on pure research and demand for the redirection of funds to practically-oriented projects. Exacerbated by the thalidomide scandal,³⁴⁰ the calls for a fight against extreme poverty and the worrying reports of the US involvement in Vietnam, the vociferous public criticism levelled at life scientists put a lot of pressure on them to accept social responsibility and concentrate their efforts on generating public goods. According to Vettel, the dynamic events of the period characterised by growing public awareness of the implications, both positive and negative, of the life sciences largely provided the context that inspired the architects of the biotechnology revolution.³⁴¹ Public attitudes also featured vividly in the debates on how genetically modified organisms (GMOs) should be regulated. Heightened

³³⁸ See Susan Wright, 'Recombinant DNA Policy: From Prevention to Crisis Intervention', *Environment: Science and Policy for Sustainable Development*, vol.21:9 (1979), pp.34-42. On the growth of academic-industrial partnerships in the US, see Dorothy Nelkin et al. 'Commentary: University-Industry Alliances', *Science, Technology, and Human Values*, vol.12 (1987), pp.65-74; Martin Kenney, *Biotechnology*, *op cit*.

³³⁹ See Susan Wright, 'Down on the Animal Pharm: Splicing Away Regulations', *The Nation*, vol.262:10 (1996), pp.16-20; Susan Wright, 'The Status of Hazards and Controls', *Environment: Science and Policy for Sustainable Development*, vol.24:6 (1982), pp.12-17.

³⁴⁰ Thalidomide was marketed as an over-the-counter drug during the late 1950s and 1960s deemed to alleviate the symptoms of morning sickness during pregnancy. It attracted wide-spread criticism when it was revealed that its use caused severe birth defects. For an overview of the thalidomide scandal, see Michael Magazanik, *Silent Schock: The Men behind the Thalidomide Scandal and an Australian Family's Long Road to Justice*, (Melbourne: Text Publishing, 2015).

³⁴¹ Eric Vettel, *Biotech: The Countercultural Origins of an Industry*, *op cit*.

concerns about the potential health and safety of GMOs among European citizens crucially accounted for the development and implementation of far more stringent regulations than those adopted in the US.³⁴²

c. Role of Life Science Communities

Far from being static, professional life science cultures constantly strived to adapt and respond to the extrinsic pressures exerted by the prevalent political and socio-economic dynamics in different countries, vigorously reconfiguring the established relations of governance in the process. As such, they were not merely passive victims of external power but sought to maintain, even under turbulent political circumstances, as well as they could, traditional patterns of professional authority and to collaborate with external authority.³⁴³ This tendency is evident in the activity of learned societies and professional bodies, significantly empowered as a result of the institutionalisation and bureaucratisation of the life sciences. As the principal bodies responsible for the administration and promotion of science in their respective states, the Soviet Academy of Sciences and the US NAS skilfully utilised any room for manoeuvre available to secure a mutually-beneficial relationship with the government and thus further enhance their social standing. Needless to say, such an ambitious objective entailed making certain concessions. For instance, according to some commentators, the reluctance of NAS leadership to overtly oppose the anti-communist measures adopted by the political and security structures in the early days of the Cold War constituted an integral part of its strategy to forge a post-war partnership with the national security state.³⁴⁴ The Soviet Academy went to even greater lengths to solidify its positions by demonstrating political conformity, extending its membership to politically-reliable cadres and individuals from a lower-class background with dubious scientific credentials and endorsing the

³⁴² Diahanna Lynch and David Vogel, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics* (Washington DC: Council on Foreign Relations, 2001). Available at <http://www.cfr.org/agricultural-policy/regulation-gmos-europe-united-states-case-study-contemporary-european-regulatory-politics/p8688> (last accessed 10/07/13).

³⁴³ Richard Bayler, Alexei Kojevnikov, and Jessica Wang, 'Purges in Comparative Perspective: Rules for Exclusion and Inclusion in the Scientific Community under Political Pressure', *Osiris*, vol.20 (2005), p.24.

³⁴⁴ Three cases are indicative in this regard, namely the 1948 Condon Affair, the battle over the AEC fellowship programme, and the formation of the Committee on Loyalty in Relation to Government Support of Unclassified Research. For details see Ibid, p.39 and Jessica Wang, *American Science in an Age of Anxiety*, *op cit*.

prevalent ideological vocabulary and political culture rules and rituals of the day.³⁴⁵

National academies were not the only actors that favoured the tactic of avoiding a direct confrontation with political power structures in their dealings with the state. Wary of the rising animosity toward the spread of communism in the US, the Rockefeller Foundation resolved to withhold grants to scientists of a communist stripe, both at home and in Europe. To achieve this goal, the Foundation leadership mapped a clear science/nonscience demarcation onto the democracy/totalitarianism distinction, which allowed it to counter any accusations of discrimination on political grounds by justifying its decision based on the assumption that communist scientists were *a priori* unfit for academic merit.³⁴⁶ Much more subtle but just as much effective was the approach preferred by the Genetics Society of America (GSA) to handling the Lysenko affair. Rather than openly condemning the Communist Party's encroachment on science, the Society staged a grand four-day celebration to mark the golden jubilee of the re-discovery of Gregor Mendel's work, which sought, above all, to offer the Mendelian project as an alternative to Lysenkoism.³⁴⁷ Framed in a manner that unflinchingly underscored the practical value of modern genetics, particularly in the area of agriculture and medicine, the event was intended as an indirect rebuttal of the Communist criticisms of Western genetics and, as such, constituted yet another vivid manifestation of the unavoidable presence of the Cold War in the culture of post-war science.³⁴⁸

Having negotiated a relationship of mutual benefit with the state, life science administrators on both sides of the iron curtain hardly hesitated to utilise their increased influence for advancing the interests of their constituencies and thus preserve a degree of autonomy in matters of governance. The

³⁴⁵ Richard Bayler et al, 'Purges in Comparative Perspective', *op cit*, p.34, 36.

³⁴⁶ John Krige, *American Hegemony and the Postwar Reconstruction of Science in Europe*, (Cambridge, MA: The MIT Press, 2006), p.118.

³⁴⁷ Audra Wolfe, 'The Cold War Context of the Golden Jubilee, or, Why We Think of Mendel as the Father of Genetics', *Journal of the History of Biology*, vol.45 (2012), pp.389-414; see also Rena Selya, 'Defending Scientific Freedom and Democracy: The Genetics Society of America's Response to Lysenko', *Journal of the History of Biology*, vol. 45 (2012), pp.415-442; Audra Wolfe, 'What Does It Mean to Go Public? The American Response to Lysenkoism, Reconsidered', *Historical Studies in the Natural Sciences*, vol.40:1 (2010), pp. 48-78.

³⁴⁸ *Ibid*, p. 403-404.

distribution of funds for research was a case in point. In the US, peer-review of grant applications guaranteed that scientists and not state officials were in charge of allocating financial support which was largely hailed as a mechanism that both respected the values of science and acknowledged academic excellence.³⁴⁹ While considerably more stringent and centralised, the funding system put in place in the Soviet Union still assigned the Academy of Science a leading role in administering a substantial proportion of research monies. It is worth noting that the move toward protecting life science autonomy was an expression of the widely shared perception among researchers that the governance of life sciences had to be dealt with by scientists themselves, as they were by far the best suited to evaluate and determine the conditions required for science progress. Hence, allowing non-scientists to impose their value system on what should be chiefly scientific decisions was deemed undesirable and even dangerous.³⁵⁰ To be sure, this conviction manifested itself much more explicitly in the USA where the democratic practices and modes of decision-making stood in stark contrast with the rise of what appeared to be a totalitarian scientific clique.³⁵¹ The 1975 Asilomar Conference convened to discuss the prospects and perils of genetic engineering largely constituted the pinnacle of the efforts of life scientists to ensure the self-regulation of biotechnology. From the outset, the meeting was intended as a closed event limited to by-invitation-only participants, the majority of whom were life scientists with a vested interest in taking full advantage of the novel gene-splicing techniques. Press coverage was carefully monitored to keep the deliberations as far from the public domain as possible. Most importantly, the organising committee gave special attention to the choice of speakers and topics to be addressed, fencing off issues related to the ethical implications of genetic engineering and its potential military applications that were likely to cause controversy. As a result, the conference agenda was so set as to produce its final outcome: a

³⁴⁹ For a critical appraisal of the peer-review mechanism, see Daryl Chubin and Sheila Jasanoff (ed.), Special Issue on 'Peer Review and Public Policy', *Science, Technology, and Human Values*, vol.10:3 (1985), pp.3-100.

³⁵⁰ David Dickson, *The New Politics of Science* (Chicago: University of Chicago Press, 1984), p.233.

³⁵¹ For the idea of science and technology as totalitarianism in Cold War America, see Jessica Wang, 'Scientists and the Problem of the Public in Cold War America, 1945-1960', *Osiris*, vol.17 (2002), pp.323-347.

list of guidelines which once implemented would allow rDNA experiments to carry on uninhibited.³⁵²

Normative Dimension

The final section focuses on the tacit aspects of governance, such as norms and other cultural intangibles (e.g. beliefs, attitudes, and routines) that underpinned professional life science practice during the Cold War.

a. Secrecy

An oft made observation about the changes that occurred in professional life science cultures during the Cold War is the substitution of the norm of openness with a norm of secrecy.³⁵³ At least two factors played a key role in fostering favourable context for this trend. One is the politics of mutual distrust that pervaded the superpowers' relations and fuelled the antagonism toward the 'rival other' at various levels of interaction by no means limited to the top echelon of the government and military. Geltzer, for instance, argues that the Cold War heavily influenced the analytical framework which scientists on both sides of the iron curtain used for understanding not only each other but also their own place in the world.³⁵⁴ Her analysis shows that the notions produced within this framework too often were distorted, even irrational, and imbued with suspicion rather than based on sound judgement, as a result of which US and Soviet researchers not only failed to see eye to eye politically but also misunderstood each other's scientific enterprise and exhibited reluctance to participate in collaborative projects unless there were powerful political grounds for such a collaboration.³⁵⁵ The other factor that merits attention is the significant emphasis laid on the value of science and technology for achieving military preponderance and economic superiority. Since surprise was deemed an indispensable weapon in the multifaceted

³⁵² See Susan Wright, *Molecular Politics*, *op cit*.

³⁵³ Here 'openness' is used to refer to the norm of communism in science, as defined by Robert Merton. For further discussion, see Robert Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (Chicago, IL: University of Chicago Press, 1973).

³⁵⁴ Anna Geltzer, 'In a Distorted Mirror: The Cold War and US-Soviet Biomedical Cooperation and (Mis)understanding, 1956-1977', *Journal of Cold War Studies*, vol.14:3 (2012), pp.39-63.

³⁵⁵ *Ibid*, p.63-63.

planetary competition between the two superpowers, substantial effort was dedicated to ensuring that any activities related to research and innovation were meticulously coated in layers of secrecy. In the Soviet Union this trend was taken to extremes as early as 1947 when the Supreme Soviet issued a decree entitled 'On Responsibility for Disclosure of State Secrets'.³⁵⁶ Besides information related to projects of military and economic significance, the document contained a separate section on scientific research, which listed as state secrets any 'discoveries, inventions, technical improvements, research and experimental work in all spheres of science, technology and national economy until they are finally completed and permission has been obtained for publication'. Disclosing state secrets of any kind constituted a serious legal offence liable to confinement to a labour camp for up to twenty years.

Yet the notion of secrecy requires some conceptual unpacking if we are to develop an appreciation of the far-reaching implications of its various manifestations. At a very basic level, the act of keeping secrets entails the concealment of information and/or activity so as to limit the number of individuals with knowledge of it. Following this logic, secret science could be viewed as open science conducted behind closed doors, with secrecy serving as an opaque envelope that leaves the activity it is meant to hide intact. Accounts about classified research communities which, despite being limited in terms of membership, had their own professional organisations, published journals and held conventions and seminars are indicative in this regard. Attractive as it may appear, this definition conceptualises secrecy as a static phenomenon characterised by a clearly drawn distinction between those granted access to knowledge and the rest, thus obscuring the complex interactions and multifaceted power relations through which secrets are born, perpetuated and sustained. An alternative way of construing secrecy is to treat it as a dynamic process that facilitates, and in turn proliferates through, various forms of knowledge production.³⁵⁷ Within this context, secrecy is a

³⁵⁶ Nikolai Kremontsov, *Stalinist Science, op cit*, p.141.

³⁵⁷ Brian Balmer, 'How Does an Accident Become an Experiment? Secret Science and the Exposure of the Public to Biological Warfare Agents', *Science as Culture*, vol.13:2 (2004), p.223.

social order that entails commitment to many auxiliary complexes and modes of behaviour:³⁵⁸

Secrets do not develop in a social vacuum. Rather, the construction of a web of secrecy is a social process that defines relationships between those inside and outside the web, the conditions under which secrets are wholly or partially revealed, and the conditions of access and denial.³⁵⁹

Military-related research is a case in point. According to Dennis, the phrases 'Secret', 'Top Secret' and 'Restricted' intended to keep unwarranted readers away from documents and institutions are crucial to understanding how visible, public aspects of intellectual life were inseparable from a web of institutions and ideas to which access was barred.³⁶⁰ His argument effectively defies the binary logic of civil-military relations replacing it with the concept of an archipelago comprising discrete islands of civilian life connected by a larger, generally invisible, military framework.³⁶¹ Sustaining such a complex system required both commitment and discipline. Task fragmentation, compartmentalisation of knowledge, and strict control over the exchange of data even in informal settings aimed to limit the amount of information available to individual scientists and thus minimise the damage caused in case of defection. For their part, civilian researchers took the act of keeping secrets seriously, not least because they regarded it as an essential condition for gaining credibility. Accepting the military's rules about information distribution seemed attractive, for it allowed one the possibility of actually having at least some effect upon their actions.³⁶² At a more fundamental level, some commentators make the claim that the knowledge produced under the conditions of secrecy is inherently different than what might be produced in a more open space, which in turn makes it virtually inaccessible to outsiders.³⁶³

³⁵⁸ Ibid, p.199.

³⁵⁹ Susan Wright and David Wallace, 'Varieties of Secrets and Secret Varieties: The Case of Biotechnology', *Politics and the Life Sciences*, vol.19:1 (2000), p.45.

³⁶⁰ Michael A. Dennis, "Our First Line of Defense": Two University Laboratories in the Postwar American State', *Isis*, vol.85:3 (1994), p.454.

³⁶¹ Ibid.

³⁶² Michael A. Dennis, 'Secrecy and Science Revisited: From Politics to Historical Practice and Back' in Judith Reppy, (ed.), *Secrecy and Knowledge Production*, Occasional Paper No.23 (1999), Ithaca, New York, Cornell University Press.

³⁶³ Ibid, p.13-14.

Far from limited to the domain of weapon procurement, research secrecy was a fairly common phenomenon among academic scientists, too, especially those with close ties with industry. This trend became particularly acute in the late 1970s when the commercial prospects of genetic engineering lured the private sector to invest heavily in the emerging technology. The changes in the US patent law outlined in the earlier sections further accelerated the growth of academic-industrial cooperation. While the partnership between universities and commercial firms *per se* hardly constituted a novel development its pace and pervasiveness were unprecedented, triggering profound changes in the professional culture of life science research and redefining established patterns of behaviour.³⁶⁴ With research for profit no longer deemed inconsistent with science values, the scientist-entrepreneur became a popular character on university campuses. The race for patents quickly gained momentum rendering secrecy an integral part of science ethos. Results were often published with a significant delay only after a patent was obtained and some findings never got widely disseminated; papers and conference remarks had to be cleared by the legal representatives of partner companies before they could be presented in public; and more and more scientists demonstrated reluctance to discuss their work even in informal settings out of fear of having their ideas stolen.³⁶⁵ Growing secrecy not only eroded the relations of collegiality among research workers but also affected the ways in which prospective scientists were trained, allowing industrial espionage to flourish under the guise of pedagogy.³⁶⁶

b. 'Scientifying' Risk and Regulation

The increased reliance of states upon science and technology fundamentally redefined the role of experts in society, elevating their status and granting them considerable influence over the resolution of a vast array of issues by

³⁶⁴ See Mark Peter Jones, 'Entrepreneurial Science: The Rules of the Game', *Social Studies of Science*, vol.39:6 (2009), pp.821-851; Martin Kenney, *Biotechnology: The University-Industrial Complex*, *op cit*.

³⁶⁵ See David Dickson, *The New Politics of Science*, *op cit*, p.77-78.

³⁶⁶ Michael A. Dennis, 'Secrecy and Science Revisited: From Politics to Historical Practice and Back', *op cit*, p.15.

no means limited to technical subtleties. Scientific rationality, rigorous data and hard evidence came to be regarded as essential prerequisites for making informed decisions not only about the feasibility and design of novel technology but also about its desirability, social utility and safety. The underlying logic of this trend was that if the risks of new technologies, their nature and causes could be identified and assessed with precision, then regulation could easily be reduced to a technocratic exercise, something evident in the emergence of cost-benefit analysis as a reliable tool for evaluating cutting-edge devices and products.³⁶⁷ There were, of course, practical considerations that favoured such simplified and efficient approaches to technology governance. In a highly competitive global environment where national security was almost deemed a function of scientific prowess, it was essential that the regulatory mechanisms put in place were compatible with, and not a restriction on, continued technological change and economic growth.³⁶⁸ Within the policy and science circles alike, public deliberation on the social, ethical and environmental implications of scientific work that could effectively pave the way for extensive regulation and even re-consideration of the safety and value of certain research programmes was largely perceived as a threat that had to be kept in check. The Communist Party in the USSR took this conviction to extremes in its attempt to engineer virtually every aspect of social life based on scientific ideology while, at the same time, effectively discouraging any form of social discussion that was inconsistent with the official Party line.

³⁶⁷ David Dickson, *The New Politics of Science*, *op cit*, p.263.

³⁶⁸ *Ibid*, p.268.

Chapter 4: 21st Century Governance Challenges in the Life Sciences

Biotechnology Advancement in the 21st Century

Depending on its application, biotechnology falls into three broad categories: 'red' biotechnology encompassing R&D in medical and healthcare sectors (e.g. drug development, disease diagnostics, prevention and treatment); 'green' biotechnology related to agriculture (e.g. increasing plant resilience to drought, herbicides and pesticides); and 'white' biotechnology covering innovation for industrial purposes (e.g. environment-friendly products).³⁶⁹ The expansion of all three types of biotechnology over the past several decades has been truly breathtaking, both in qualitative and quantitative terms. Forty years ago scientists were fascinated to manipulate the manifestations of life by dint of gene-splicing, while the tools and technologies available in the beginning of twenty-first century have enabled them to *create* life forms from scratch.³⁷⁰ Similarly, when initially conceived the Human Genome Project (HGP) seemed a daunting undertaking, but within less than ten years of its completion the areas of genome-based diagnostics and therapeutics are now growing at a remarkable pace; and if once cutting-edge life science research used to be confined to prestigious universities and state-of-the-art laboratories found in the highly industrialised countries in the global North, nowadays studies involving highly dangerous microbes are conducted in research facilities scattered around the globe from Indonesia and Vietnam through Kenya and Morocco to Moldova and Pakistan. One authoritative high-level review has even gone so far as to suggest that the 'life sciences knowledge, materials and technologies are advancing worldwide with

³⁶⁹ Henrik Noes Piester et al. *Trends and Drivers of Change in the Biomedical Healthcare Sector in Europe: Mapping Report* (Dublin: European Foundation for the Improvement of Living and Working Conditions, 2007), p.2. See also Eric Grace, *Biotechnology Unzipped: Promises and Realities*, (Washington DC: Joseph Henry Press, 1997).

³⁷⁰ See, for example, J Cello et al. 'Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template', *Science*, vol.297:5583 (2002), pp.1016-1018; Eckard Wimmer, 'The Test-Tube Synthesis of a Chemical Called Poliovirus: The Simple Synthesis of a Virus Has Far-Reaching Societal Implications', *EMBO Reports*, vol.7 (2006), S3-S9; Ian Sample, 'Craig Venter Creates Synthetic Life Form', *The Guardian*, 20 May 2010, available at <http://www.theguardian.com/science/2010/may/20/craig-venter-synthetic-life-form> (last accessed 9/10/2013).

Moore's Law-like speed.³⁷¹ And whilst some commentators have questioned the extent to which the on-going progress of biotechnology has translated into practical applications and novel products,³⁷² there is some consensus that the biotechnology landscape has been fundamentally transformed over the recent decades with the possibilities now unlocked holding revolutionary potential. Indeed, rapid advances in the field have produced a knowledge base and set of tools and techniques that enable biological processes to be understood, manipulated and controlled to an extent never possible before,³⁷³ they have found various applications in numerous spheres of life, generating enormous benefits and offering bright prospects for human betterment; and they have come to be regarded as a key driver of economic development with potential to close the gap between resource-rich and resource-poor countries.³⁷⁴

The progress of biotechnology has been largely driven by three sets of forces, namely social, political and economic.³⁷⁵ The social dynamics at work in this context are understood as the efforts to improve public health and overall wellbeing of individuals both in the global North and global South, boost agricultural yields and encourage environment-friendly practices to mitigate the adverse effects of climate change. Several factors account for the significant value attached to the life sciences in the context of intense globalisation and continuous change. Surging population numbers and extended life expectancy are augmenting the demand for developing effective and affordable medications, novel approaches for the treatment of chronic diseases and additional cost-effective sources of energy and food production. At the same time, rising global trade and travel, coupled with

³⁷¹ Moore's Law pertains to the rapid rate of technological development and advances in the semiconductor industry, specifically the doubling of the number of transistors on integrated circuits that occurs approximately every 18 months. Although advances in the life sciences occur at more random intervals and are driven by new conceptual breakthroughs in understanding of biological processes, it is a useful metaphor for the exponential growth of knowledge related to biology. See Committee on the Advances in Technology and the Prevention of Their Application to Next Generation Bioterrorism and Biological Warfare Threats, *An International Perspective on Advancing Technologies and Strategies for Managing Dual-Use Risks: Report of a Workshop*, (Washington DC: National Academies Press, 2005).

³⁷² See, for example, Michael Hopkins et al. 'The Myth of the Biotech Revolution: An Assessment of Technological, Clinical and Organisational Change', *Research Policy*, vol.36 (2007), pp.566-589; Paul Nightingale and Paul Martin, 'The Myth of the Biotech Revolution', *Trends in Biotechnology*, vol.22:11 (2004), pp.564-569.

³⁷³ Ibid.

³⁷⁴ National Research Council, *Globalization, Biosecurity and the Future of the Life Sciences* (Washington DC: National Academies Press, 2006), p.2.

³⁷⁵ Ibid, p.79.

increased urbanisation, and an uneven distribution of wealth are creating optimal conditions for disease outbreaks, pandemics and environmental degradation.³⁷⁶ Against this backdrop, biotechnology appears full of promise and critical to tackling social and natural concerns; enhancing disease prevention, preparedness and surveillance; promoting development; and alleviating human suffering.³⁷⁷

Economic dynamics include national expenditure on research and development, purchasing power, trends in consumerism and market pressures and fluctuations. Besides public funding for R&D which remains a key factor in the growth and flourishing of bioindustry in developed and emerging economies alike, private investment from venture capital firms, start-up companies and transnational corporations (TNCs) have also played an indispensable role in capturing new markets and further facilitating the extension of bioeconomy on a global scale. DuPont's significant footprint in India is indicative in this regard, not least because of the depth and diversity of the activity that the company has undertaken via its offshore R&D centres ranging from crop science to biofuels.³⁷⁸ Likewise, Merck has outlined a 1.5 billion dollar commitment to expand R&D in China, as part of which it intends to establish an Asia headquarters for innovative drug discovery in Beijing.³⁷⁹

Political dynamics are triggered by states' increasing commitment to support the progress of biotechnology as a way of maximising their power and boosting their status in the international arena.³⁸⁰ In the aftermath of 9/11 and the 'Anthrax letters' attack of October 2001, substantial effort has been given to harnessing life science research for the purposes of national security. Biodefence and bioterrorism preparedness are thus considered high-priority areas for national investment by government agencies and the military alike.

³⁷⁶ Jeffrey Macher and David Mowery, (ed.), *Innovation in Global Industries: U.S. Firms Competing in a New World* (Washington DC: National Academies Press, 2008), p.239.

³⁷⁷ See, for example, Tara Acharya et al. 'Biotechnology and the UN's Millennium Development Goals', *Nature Biotechnology*, vol.21:12 (2003), pp.1434-1436; Abdallah S. Daar, 'Top Ten Biotechnologies for Improving Health in Developing Countries', *Nature Genetics*, vol.32 (2002), pp.229-232.

³⁷⁸ Charles Wessner and Alan Wolff (ed.), *Rising to the Challenge: U.S. Innovation Policy for Global Economy*, (Washington, DC: National Academies Press, 2012), p.38.

³⁷⁹ Burrill & Co, *Biotech 2012: Innovating in the New Austerity*, Burrill & Co's 26th Annual Report on the Life Sciences Industry, (San Francisco CA: Burrill and Co, 2012), p.15. See also Burrill & Co, *Biotech 2013: Capturing Value*, (San Francisco CA: Burrill and Co, 2013).

³⁸⁰ National Research Council, *Biosecurity, Globalization and the Future of the Life Sciences*, *op cit*, p.79.

An illustrative example of this two-tiered approach is the funding policy in the USA, where biodefence research is financed by the NIH, Department of Homeland Security (DHS) and Defense Advanced Research Projects Agency (DARPA), to name a few.

Under the synergistic influence of these three sets of forces – social, economic and political – biotechnology has been transformed into a truly global fast-evolving enterprise encompassing a multitude of stakeholders, delivering considerable benefits and holding out still greater promise, with profound and far-reaching implications for virtually every aspect of human well-being and social life.

The pharmaceutical industry is a case in point, for its steady expansion would hardly be possible were it not for the vast array of techniques and methods enabled by the progress of the life sciences. Worth roughly 400 billion dollars, the global pharmaceutical market dominates the life sciences industry and arguably determines the trajectory of life sciences-related technological development and global spread.³⁸¹ Gene cloning, DNA sequencing and recombinant construction of cell lines, to name a few, are all deemed indispensable for the development of novel medicines and therapeutics. It suffices to mention that more than half of the top selling commercially available drugs in the USA would not exist without those methods.³⁸² Agriculture, too, has been heavily influenced by the on-going biotechnology revolution, as evidenced in the rapid growth and dispersion of commercialised transgenic crops (biotech crops) and the efforts to use GMOs (both animals and plants) for the production of vaccine antigens and other biologically active proteins ('biopharming').³⁸³ Indeed, the increase in the area of farmland planted with transgenic crops rose dramatically from 1.7 hectares in 1996 to about 60 million hectares in 2002³⁸⁴ and is still growing.

³⁸¹ National Research Council, *An International Perspective on Advancing Strategies for Managing Dual-Use Risks*, (Washington, DC: National Academies Press, 2005), p.36.

³⁸² Roger Brent, 'In the Valley of the Shadow of Death', *DSPACE@MIT*, 22 November 2006, p.3, available at <http://dspace.mit.edu/handle/1721.1/34914> (accessed 10/03/2013).

³⁸³ National Research Council, *Biosecurity, Globalization and the Future of the Life Sciences*, p.94, *op cit*.

³⁸⁴ United Nations Conference on Trade and Development, *The Biotechnology Promise: Capacity-Building for Participation of Developing Countries in the Bioeconomy*, UNCTAD/ITE/IPC/MISC/2004/2, (New York/Geneva: United Nations, 2004), p.1. Available at <http://www.unctad.info/upload/STDEV/docs/biotech.pdf> (accessed 21/10/13).

In addition, technological convergence³⁸⁵ between biotechnology, nanotechnology, information technologies and cognitive science has unlocked a broad scope of opportunities for maximising public (and private) welfare, offering substantial benefits in wide-ranging areas such as medicine, pharmacy, crime investigation and national security by ensuring precision and reliability, while at the same time, reducing the amount of time previously required for the performance of certain tasks.

Four key features of biotechnology make it so appealing to the majority of stakeholders involved. First, biotechnology innovation is characterised by *duality*, whereby research yields results that simultaneously lead to advances in basic knowledge and stimulate product development.³⁸⁶ Second, the output that the life sciences generate in the form of new medicines, improved nutrition products, enhanced yields and novel materials, is 'strongly positive'.³⁸⁷ The increasing utility of tools and strategies for human enhancement, whether in professional sport, for cosmetic and aesthetic purposes, or on the battlefield, vividly reflects the firm conviction that the transformative capacity of biotechnology, even at the most fundamental level, is something to be welcomed and vigorously embraced. What is more, biotechnology possesses proven economic viability, as illustrated in the burgeoning industries and new markets it has spurred. Against this backdrop, the high rate of biotechnology expansion is anything but surprising, since

every increment in biological capability pays back the researcher and the researcher's sponsors in short order. Payback comes in the esteem of peers, in promotions, and in increases in the academic or corporate salaries of the researchers whose work generates knowledge and new therapies. Payback comes in the form of profits for the manufacturers of kits to perform the manipulations, royalties for the writers of the methods manuals profits for the

³⁸⁵ See, for example, James Spohrer and Douglas Engelbart, 'Converging Technologies for Enhancing Human Performance: Science and Business Perspectives', *Annals of the New York Academy of Sciences*, vol. 1013 (2004), pp.50-82; Alfred Nordmann, *Converging Technologies – Shaping the Future of European Societies* (Brussels: European Communities, 2004); Tsjalling Swierstra et al. 'Taking Care of the Symbolic Order: How Converging Technologies Challenge Our Concepts', *Nanoethics*, vol.3 (2009), pp.269-280; Carl Elliot, 'Enhancement Technologies and the Modern Self', *Journal of Medicine and Philosophy*, vol.36 (2011), pp.364-374; George Khushf, 'The Ethics of NBIC Convergence', *Journal of Medicine and Philosophy*, vol.32 (2007), pp.185-196; William Bainbridge, 'Converging Technologies and Human Destiny', *Journal of Medicine and Philosophy*, vol. 32 (2007), pp.197-216; Franc Mali, 'Bringing Converging Technologies Closer to Civil Society: The Role of Precautionary Principle', *Innovation: The European Journal of Social Science Research*, vol. 22:1 (2009), pp.53-75.

³⁸⁶ Jeffrey Macher and David Mowery, ed. *Innovation in Global Industries*, *op cit*, p.237.

³⁸⁷ Roger Brent, 'In the Valley of the Shadow of Death', p.4, *op cit*.

drug industry. Payback comes for the public in the form of new drugs and therapies.³⁸⁸

Fourth, besides being cost-effective, many of the benefits that biotechnology offers are easy to obtain and disseminate. In other words, many of the various prospects for public (and private) betterment are not situated at some distant moment in the future but can be realised immediately, as a result of which pressing problems can be alleviated, if not fully resolved, and substantial revenue can be generated in the short term. Last but not least, while there are some risks and concerns associated with the advancement of biotechnology, few of those are deemed urgent or significant enough to impact on the pace of innovation. As the actual manifestation of such risks is often contingent upon the interplay of a variety of factors, this renders the likelihood of a major crisis unfolding as a result of the progress of biotechnology low. Moreover, there is a genuine belief that any challenges that may arise from the proliferation of novel technologies can either be foreseen or dealt with on a case-by-case basis. Given the enormous potential of biotechnology for addressing societal, economic and environmental challenges, it is unsurprising that most states have readily endorsed scientific and technological innovation and embarked on large-scale generously-funded R&D programmes in the life sciences.

Trends in Biotechnology Governance

Given the powerful multifaceted impetus for biotechnology advancement, it is possible to identify at least five key trends in the governance of biotechnology that are common for highly industrialised and developing countries alike. Those include: high-level coordination, facilitation and funding; synergies within and between both the public and private sector; emphasis on strategic and competitive interests at the expense of precaution; regulations that seek to promote rather than restrict scientific and technological progress; and overreliance on technical solutions.

³⁸⁸ Ibid.

High-Level Coordination, Facilitation and Funding

At international level, the on-going expansion of biotechnology has been hailed not only as an inherently positive development but also as an essential prerequisite for enhancing human welfare and addressing various socio-economic, environmental and health concerns. In its 2013 World Health Report, the WHO called for:

Increased international and national investment and support in [life science] research aimed specifically at improving coverage of health services within and between countries.³⁸⁹

The WHO has also strived to promote research on specific diseases, such as HIV/AIDS, cancer, pandemic influenza, tuberculosis and malaria, with the goal to improve methods for prevention and diagnostics and facilitate the development of effective therapeutics and vaccines.³⁹⁰

In a similar fashion, the UN Food and Agriculture Organisation (FAO) has highlighted the positive impact that biotechnology could have on the development of agriculture:

...biotechnology could be a major tool in the fight against hunger and poverty, especially in developing countries. Because it may deliver solutions where conventional breeding approaches have failed, it could greatly assist the development of crop varieties able to thrive in the difficult environments where many of the world's poor live and farm.³⁹¹

It is not difficult to see how those assertions have been translated into national policies and practical steps across the globe. The US NIH that provide the bulk financial support for medical and health-oriented R&D in the US spent over 30.9 billion dollars during the fiscal year 2012, about a third of which was allocated for funding biotechnology and bioengineering

³⁸⁹ WHO, *World Health Report*, 2013, available at http://www.who.int/whr/2013/main_messages/en/index.html (accessed 29/01/2014).

³⁹⁰ See the 'Infectious Diseases' section of the WHO website: http://www.who.int/topics/infectious_diseases/en/ (accessed 19/01/2014).

³⁹¹ UN FAO, *World Agriculture: Towards 2015/2030*, Summary Report, 2002, available at <ftp://ftp.fao.org/docrep/fao/004/y3557e/y3557e.pdf> (accessed 19/01/2014).

projects.³⁹² Within its Sixth Framework Programme for Research and Technological Development spanning the period 2002-2006 the European Union (EU) distributed more than 2.5 billion euro for projects under the theme 'Life Sciences, Genomics and Biotechnology for Health'.³⁹³ Developing countries, too, are increasingly investing in 'red' biotechnology as part of their efforts to address public health concerns. According to a recent WHO report, support for biotechnology and particularly, for cancer research, in Cuba has soared over the past 20 years, amounting to over one billion dollars.³⁹⁴ As a result, the Cuban biotechnology industry is burgeoning, holding around 1200 international patents and exporting vaccines and pharmaceuticals to more than 50 countries.

The prospect of climate change coupled with rising population numbers has compelled governments in the global North and South alike to explore 'green' biotechnology as a means of ensuring food security. The USA remains by far the largest commercial producer of GM crops. Several EU member states (France, Germany, Spain, Poland, Romania, Czech Republic, Portugal and Slovakia), Canada and Australia further feature in the list of industrialised nations that have embarked on growing GM plant breeds. More and more emerging economies are striving to expand their agrobiotechnology sector, most notably Brazil, India, Argentina, South Africa, Mexico, Burkina Faso, Myanmar and Chile.³⁹⁵ In 2008, the Chinese government launched a major R&D initiative worth 4 billion dollars to develop new plant varieties by 2020 that will enhance yields, have improved nutritional value and be resistant to pests.³⁹⁶

³⁹² For information on the NIH budget for 2012, see http://www.nih.gov/about/director/budgetrequest/NIH_BIB_020911.pdf (accessed 29/01/2014); on estimates of funding distributions for Various Research, Condition, and Disease Categories, 2011-2016 see http://report.nih.gov/categorical_spending.aspx (accessed 21/09/2015). For an overview of the NIH budget for 2015, see David Malakoff and Jeffrey Mervis, 'First Look: US Spending Deal a Mixed Bag for Science', *ScienceInsider*, 9 December 2014, available at <http://news.sciencemag.org/funding/2014/12/first-look-new-u-s-spending-deal-mixed-bag-science> (accessed 16/09/2015); Jocelyn Kaiser, 'Within NIH's Flat 2015 Budget, a Few Favourites', *ScienceInsider*, 10 December 2014, available at <http://news.sciencemag.org/funding/2014/12/within-nih-s-flat-2015-budget-few-favorites> (accessed 16/09/2015).

³⁹³ For information on the EU Sixth Framework Programme and the Activity Area of Life Sciences, Genomics and Biotechnology for Health, see <http://cordis.europa.eu/fp6/lifescihealth.htm> (accessed 29/01/2014).

³⁹⁴ See WHO, *Cuba – Battling Cancer with Biotechnology*, January 2013, available at http://www.who.int/features/2013/cuba_biotechnology/en/index.html (accessed 29/01/2014).

³⁹⁵ See Clive James, *Global Status of Commercialised Biotech/GM Crops: 2012*, Brief No.44, International Service for the Acquisition of Agri-Biotech Applications, 2012, available at <http://www.isaaa.org/resources/publications/briefs/44/executivesummary/pdf/Brief%2044%20-%20Executive%20Summary%20-%20English.pdf> (accessed 29/01/2014).

³⁹⁶ 'Plant Genetic Engineering: China Hesitates on the Brink', *GMO Safety*, 30 August 2011, available at

Synergies within and between Private and Public Sectors

Public-private partnerships underpinned by access to early-stage risk capital and strong linkages between business, universities and entrepreneurial support networks constitute an important vehicle for promoting innovation and fostering technology transfer and product development. For instance, the Chinese government has launched a major initiative mobilising 2.5 billion dollars in venture capital to support start-ups in the immense Zhangjiang science park outside Shanghai;³⁹⁷ Russia's Rusnano has entered a 760 million dollar partnership with the US venture capital firm Domain Associates to fund 'emerging life science technology companies and establish manufacturing facilities in Russia for production of advanced therapeutic products'; and Cleveland's University Hospital has allocated 250 million dollars for setting up a 'non-profit entity to fund and advise physician-scientists on transitional research and a related for-profit accelerator that will develop selected compounds to proof of concept.'³⁹⁸ The Kauffman Foundation in the USA, a wealthy philanthropic establishment dedicated exclusively to the goal of entrepreneurship has been particularly zealous in its quest for promoting university-based entrepreneurial activities nationwide. Its Kauffman Campuses Initiative launched in early 2003 enjoyed so much popularity among universities that following the initial round of grants totalling 25 million dollars, the Foundation announced its resolve to leverage a 100 million dollar investment for the creation of new interdisciplinary education programmes.³⁹⁹

University-industry partnerships, while not a novel phenomenon in the area of biotechnology, have considerably intensified over the past several decades, thus facilitating the widespread commercialisation of life science research. Indeed, 90 per cent of the companies in the US surveyed by Blumenthal et al. in 1996 had relationships with an academic institution in that year and in

http://www.gmo-safety.eu/news/1347_genetic-engineering-china.html (accessed 29/01/2014).

³⁹⁷ Charles Wessner and Alan Wolff ed., *Rising to the Challenge*, op cit, p.41.

³⁹⁸ Jennifer Levin, 'Government Academic, and Venture Firms Come Together in March to Fund Translational and Early-Stage Development', *FierceBiotech*, 4 April 2012, available at <http://www.fiercebiotech.com/press-releases/government-academic-and-venture-firms-come-together-march-fund-translational> (accessed 21/10/13).

³⁹⁹ Daniel Greenberg, *Science for Sale: The Perils, Rewards and Delusions of Campus Capitalism* (Chicago, IL: The University of Chicago Press, 2007), p.90.

more than half of those cases industry provided financial support for research in such institutions.⁴⁰⁰ According to another study, the total industry investment in academic life science research in the USA tripled between 1985 and 1998 reaching almost 2 billion dollars and has been growing ever since.⁴⁰¹ Against this backdrop, some commentators have put forward the 'Triple Helix' model, which serves both as a conceptual tool and a policy blueprint. In the former case, it is used to elucidate the academic-industry-government relationships that underpin the institutional arrangements and changing practices in the processes of production, transfer and application of knowledge in post-industrial societies; in the latter, it is promoted as a framework for economic development through state investment and knowledge sharing between academia and industry.⁴⁰²

Others, however, have remained sceptical of the close integration of universities and the private sector voicing concerns about the possible deleterious effects arising therefrom:

As in other activities, when big money flows fast, temptations and opportunities arise for risky behaviour and stealthy or even brazen wrongdoing in pursuit of personal or institutional advantage. The new world of academic-commercial dealings is characterised by some grey areas and evolving rules for permissible and impermissible conduct. The people who manage and conduct research in scientific organisations are not immune to the weaknesses and foibles so plentiful elsewhere, despite the accolades for probity that science bestows upon itself.⁴⁰³

⁴⁰⁰ David Blumenthal et al. 'Relationships between Academic Institutions and Industry in the Life Sciences – an Industry Survey', *The New England Journal of Medicine*, vol.334:6 (1996), pp.368-373; Jason Owen-Smith and Walter Powell, 'The Expanding Role of University Patenting in the Life Sciences: Assessing the Importance of Experience and Connectivity', *Research Policy*, vol.32 (2003), pp.1695-1711; Daniel Lee Kleinman, *Impure Cultures: University Biology and the World of Commerce*, (Madison: University of Wisconsin Press, 2003).

⁴⁰¹Hui Yang and Steven Buccola, 'University-Industry Relationships and the Design of Biotechnology Research', paper presented at the Annual Meeting of the American Agricultural Economics Association, Montreal, Canada, July 27-30 2000. Available at: <http://ageconsearch.umn.edu/handle/21985> (accessed 25/11/2013); see also Dorothy Nelkin et al. 'University-Industry Alliances', *Science, technology and Human Values*, vol. 12:1 (1987), pp.65-74.

⁴⁰² See, for example, Henry Etzkowitz, 'Entrepreneurial Science in the Academy: A Case of the Transformation of Norms', *Social Problems*, vol.36:1 (1989), pp.14-29; Loet Leydesdorff and Martin Meyer, 'The Triple Helix of University-Industry-Government Relations', *Scientometrics*, vol. 58:2 (2003), pp.191-203; Henry Etzkowitz, *The Triple Helix: University-Industry-Government Innovation In Action*, (London: Routledge, 2008); Henry Etzkowitz and Loet Leydesdorff, 'The Dynamics of Innovation: from National Systems and "Mode 2" to a Triple Helix of University-Industry-Government Relations', *Research Policy*, vol.29:2 (2000), pp.109-123.

⁴⁰³ Daniel Greenberg, *Science for Sale*, *op cit*, p.102; Mark Cooper, 'Commercialisation of the University and the Problem Choice by Academic Biological Scientists', *Science, Technology, and Human Values*, vol.34:5 (2009), pp.629-653.

With more and more universities joining the biotechnology 'gold rush' and corporate values and goals steadily penetrating the professional academic cultures, scholarship turns into a result-oriented activity subject to the priorities and interests of business partners and industrial sponsors. Strategy and careful planning deemed essential to the pursuit of for-profit knowledge can have a restraining effect on the spontaneous vigour characteristic of academic research, limiting the range of problems that could be studied to those defined by the market.⁴⁰⁴ At the same time, scientists often find themselves under tremendous pressure striving to satisfy the demands of their industrial clients without utterly neglecting their academic duties ranging from mentorship through filing grant applications to publishing. The extensive workload coupled with the bright prospects for securing long-term research funding and achieving some individual gain and prominence provide a favourable environment in which instances of dubious, sometimes fraudulent, behaviour, conflicts of interest and lack of transparency, unless too severe, are unlikely to encounter widespread opprobrium and may even go unnoticed.⁴⁰⁵ In the race for patents and venture capital, the business mentality dulls scientific rigour and the ethics threshold appears not too difficult to cross.

Governments Tend to Favour Strategic, Political and Economic Interests at the Expense of Precaution

Given the tremendous benefits that biotechnology is expected to generate in virtually any sphere of human activity, it is not difficult to understand why its progress is predominantly viewed through an explicitly positive lens by policy-makers. Since the opportunities for achieving public betterment and enhancing state prestige and international standing are too tempting and too abundant, there is a powerful urge to dedicate both will and resources to

⁴⁰⁴ Ken Auletta, 'Get Rich U', *The New Yorker*, 30 April 2012, available at http://www.newyorker.com/reporting/2012/04/30/120430fa_fact_auletta (accessed 25/11/2013). See also Dina Biscotti et al, 'The "Independent Investigator": How Academic Researchers Construct Their Professional Identity in University-Industry Agricultural Biotechnology Research Collaborations' in Nina Bandelj (ed.), 'Economic Sociology of Work', *Research in the Sociology of Work Series*, vol.18 (2009), pp.261-285; Mathias Kaiser, 'Toward More Secrecy in Science: Comments on Some Structural Changes in Science – and on Their Implications for an Ethics of Science', *Perspectives on Science*, vol.4:2 (1996), pp.207-230.

⁴⁰⁵ Ibid; see also Daniel Greenberg *Science, Money and Politics: Political Triumph and Ethical Erosion* (Chicago, IL: The University of Chicago Press, 2001).

promoting the large-scale expansion of the life sciences. For one thing, the prospect of conquering disease and maximising human wellbeing provides solid justification for a deliberate and sustained investment in fostering scientific and technological prowess. Lack of commitment and reluctance to support R&D in the life sciences then becomes an unfavourable option in the political calculations of states regardless of their level of economic development and international status. Within the context of political calculus pervaded by realist fears, competition and power, the perceived risks of inaction with regard to scientific and technological development justify vast expenditure, lower regulatory barriers to innovation and product development. Political choices concerning biotechnology support are therefore frequently made at the expense of calls for caution and potential social, environmental and ethical concerns.

The regulation of genetic engineering is a case in point. As discussed in the previous chapter, from the outset, the attempts of governments to impose strict controls on research involving rDNA faced a severe backlash from academic scientists and business executives alike. By the 1980s, the various legislative initiatives put forward in the USA were abandoned in favour of the regime established by the NIH Guidelines, which virtually exempted the biotechnology industry from formal regulation. While the leading US-based companies pledged to 'voluntarily comply' with the Guidelines, behind the scenes they craftily continued to push for a system that would insulate them from governmental and public scrutiny.⁴⁰⁶ Indeed, during the 1990s when the States Parties to the BTWC strived to strengthen the treaty by negotiating a binding verification mechanism corporate interests proved too big and too important to be ignored. Both the Pharmaceutical Research and Manufacturers of America (PhRMA) which represented the country's major research-based pharmaceutical and biotechnology companies, and the Biotechnology Industry Organisation (BIO) which at that time represented some 1400 biotechnology firms, became vocal opponents of any measures designed to promote international arms control which seemed to hinder in

⁴⁰⁶ Susan Wright and David Wallace, 'Varieties of Secrets and Secret Varieties: The Case of Biotechnology', *op cit.*

any way the protection of proprietary information and intellectual property.⁴⁰⁷ In the period between 1994 and 2001 the associations invested considerable effort, time and ingenuity in lobbying the US government and influencing the diplomatic talks in Geneva to secure an outcome that was in line with the demands of their constituencies. Of course, it would be naive to ascribe the US resolve to reject in 2001 both the text of the protocol and its utility in general for providing adequate verification and enhancing confidence among States Parties solely to the activity of the biotechnology industry; nevertheless, it would be equally naive to suppose that corporate interests played no significant role in the process.⁴⁰⁸

Besides economic priorities, national security and military calculations can also provide a compelling rationale for downplaying the potential risks associated with biotechnology expansion. Following the 'Anthrax letters' attack in October 2001, the US government embarked on a massive financial investment to boost its bioterrorism preparedness and enable the prevention, early detection, monitoring and emergency response to biological threats. As outlined in *Biodefense for the 21st Century*, a presidential directive that set out a comprehensive framework for national biodefence policy, between 2001 and 2005 the federal government provided roughly 6 billion dollars 'to state and local health systems to bolster their ability to respond to bioterrorism and major public health crises'.⁴⁰⁹ Along with the highly controversial vaccination programme that the government envisaged,⁴¹⁰ another important development designed to enhance America's biodefence preparedness and capability was the drastic increase both in the number of high-containment labs (BSL-3 and BSL-4) and the number of researchers with access to some of the most dangerous pathogens known to mankind, including the causative agents of Ebola, plague and Q fever. Some commentators have questioned the logic behind this policy highlighting the

⁴⁰⁷ Ibid, p.53-54.

⁴⁰⁸ For a detailed analysis on the US decision to reject the draft BTWC Protocol, see Malcolm Dando, *Preventing Biological Warfare: The Failure of American Leadership*, (Basingstoke: Palgrave, 2002).

⁴⁰⁹ Office of Press Secretary, *Fact Sheet: President Bush Signs Biodefence for the 21st Century*, 28 April 2008, The White House, Washington DC, available at [http://www.nrt.org/production/NRT/NRTWeb.nsf/AllAttachmentsByTitle/A-21HSPD_10/\\$File/HSPD%2010.pdf?OpenElement](http://www.nrt.org/production/NRT/NRTWeb.nsf/AllAttachmentsByTitle/A-21HSPD_10/$File/HSPD%2010.pdf?OpenElement) (accessed 2/01/2014).

⁴¹⁰ Hillel Cohen, 'The Pitfalls of Bioterrorism Preparedness: The Anthrax and Smallpox Experiences', *American Journal of Public Health*, vol.94:10 (2004), pp.1667-1671; Michael Selgelid, 'Bioterrorism and Smallpox Planning: Information and Voluntary Vaccination', *Journal of Medical Ethics*, vol.30 (2004), pp.558-560.

heightened risk of accidental or deliberate release of pathogens.⁴¹¹ Far from being ill-founded or hypothetical, such fears stemmed from a range of high-profile cases that occurred after 2001 across the US in which the lack of proper training and professional negligence resulted in scientists being exposed to or infected with deadly microbes.⁴¹² Real-life horror stories about vials of plague being transported in the hand-luggage of researchers on passenger aircraft without the required authorisation, and deadly cultures gone missing from what appeared to be secure laboratories further fuelled the criticism toward the US biodefence policy raising difficult questions about its appropriateness and actual goals even before the 'Anthrax letter' investigation revealed that the attack was 'insider's business'.⁴¹³

Biotechnology Regulations Seek to Promote rather than Restrict Technological Advancement

Life science research, just as any other sphere of professional activity, is subject to a range of institutional, national and international regulations. Along with the more general rules such as those related to occupational health and safety, fair pay and job competition, conflict of interests, labour rights, and professional liability, there are also specific ones addressing particular aspects of the research process including project clearing (e.g. review by local biosafety committees), safe laboratory practice and transport of pathogens (e.g. 2005 International Health Regulations), exchange of viral strains (e.g. Pandemic Influenza Preparedness Framework, 2011), handling of dangerous pathogens (e.g. US Select Agent Programme) and ethical treatment of human subjects and samples obtained therefrom (e.g. The 2004

⁴¹¹ See Susan Wright, 'Taking Biodefence Too Far', *Bulletin of Atomic Scientists*, vol.60:6 (2004), pp.58-66; Eileen Choffnes, 'New Labs, More Terror', *Bulletin of Atomic Scientist*, vol. 58:5 (2002), pp.29-32.

⁴¹² Nick Schwellenbach, 'A Plague of Researchers', *Bulletin of Atomic Scientists*, vol.61:3 (2005), pp.14-16; Marylia Kelley and Jay Coghlan, 'Mixing Bugs and Bombs', *Bulletin of Atomic Scientists*, vol.59:5 (2003), pp.24-31; Roxanne Khamsi, 'Lab Loses Trio of Plague Mice', *Nature News*, 16 September 2005, available at <http://www.nature.com/news/2005/050912/full/news050912-13.html> (accessed 2/01/2014).

⁴¹³ Martin Enserink and David Malakoff, 'The Trials of Thomas Butler', *Science*, vol. 302:5663 (19 December 2003), pp.2054-2063; for a detailed account of the 'Anthrax letters' attack and the controversy of the US biodefence programme see Jeanne Guillemin, *American Anthrax: Fear, Crime, and the Investigation of the Nation's Deadliest Bioterror Attack*, (New York: Henry Hol and Co, 2011); Scott Shane, 'Army Suspends Germ Research at Maryland Lab', *New York Times*, 9 February 2009, available at http://www.nytimes.com/2009/02/10/washington/10germs.html?_r=0 (accessed 2/01/2014); Mark Wheelis and Malcolm Dando, 'Back to Bioweapons?', *Bulletin of Atomic Scientists*, vol.59:1 (2003), pp.40-46.

Human Tissue Act in the UK).⁴¹⁴ While hardly exhaustive, this list suffices to convey the idea that the regulatory regime governing the practice of life science research is dense and comprehensive. With more than 30 international organisations overseeing biotechnology from various perspectives,⁴¹⁵ there is a *prima facie* reason to assume that the regime in its current form is sufficiently flexible to accommodate novel advances and hold any potential risks, which they may pose, at bay. Yet in reality over the past decade the opposite trend has prevailed, that is, the existing governance mechanisms have struggled to respond adequately to the proliferation of new scientific developments with multiple adaptive uses and the multiplicity of cutting-edge developments posing profound ethical quandaries. How to account for this discrepancy?

Part of the problem stems from the fact that since at least the late 1970s the regulation of biotechnology has been streamlined so as to become compatible with and not a restriction on continued technological change and economic growth.⁴¹⁶ As such, it rests upon the barely questioned assumption that the progress of biotechnology is inherently good and needs to be harnessed and vigorously promoted. Needless to say, any measures that seem to slow down or restrain its advancement are deemed undesirable and even detrimental to socio-economic development. Hence, when developing

⁴¹⁴ See, for example, International Health Regulations (WHO, 2005), specifically section 'Laboratory', available at <http://www.who.int/ihr/publications/9789241596664/en/index.html> (accessed 3/01/2014); Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits, (WHO, 2011), available at http://www.who.int/influenza/resources/pip_framework/en/index.html (accessed 3/01/2014); Select Agent Programme (US, 2002), available at <http://www.cdc.gov/phpr/dsat.htm> (accessed 3/01/2014); Human Tissue Act of 2004, see <http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/legislation/humantissueact.cfm> (accessed 3/01/2014). For further discussion on the implementation of biotechnology regulations, see Bo Sundqvist et al. 'Harmonisation of European Laboratory Response Networks by Implementing CWA 15793: Use of Gap Analysis and an "Insider" Exercise as Tools', *Biosecurity and Bioterrorism: Biodefence Strategy, Practice, and Science*, vol.11:S1 (2013), pp.36-44; Julie Fisher and Rebecca Katz, 'Moving Forward to 2014: Global IHR (2005) Implementation', *Biosecurity and Bioterrorism: Biodefence Strategy, Practice, and Science*, vol.11:2 (2013), pp.153-156. On the development of health and safety regulations on the use of nanotechnology, see Eileen Kuempel et al. 'Risk Assessment and Risk Management of Nanoparticles in the Workplace: Translating research into Practice', *Annals of Occupational Hygiene*, vol.56:5 (2012), pp.491-505.

⁴¹⁵ See Catherine Rhodes, *International Governance of Biotechnology*, *op cit.*

⁴¹⁶ David Dickson, *The New Politics of Science*, *op cit.* p.268. There is a debate on whether the 'American model' of science-policy making underpinned by neoliberal ideology is fully embraced in Europe. See, for example, Gabriele Abels, 'The Long and Winding Road from Asilomar to Brussels: Science, Policy and the Public in Biotechnology Regulation', *Science as Culture*, vol.14:4 (2005), pp.339-353; Herbert Gottweis, 'Transnationalising Recombinant-DNA Regulation: Between Asilomar, EMBO, the OECD, and the European Community', *Science as Culture*, vol.14:4 (2005), pp.325-338. Further, a Policy Paper issued by a Business Taskforce appointed by the UK Government issued a Policy Paper in late 2013 demanding the liberalization of the existing EU legislation which, in their view, 'places restrictions on products and technologies without adequate evidence of risk'. See Department for Business, Innovation & Skills and the Prime Minister's Office, *Cut the EU Red Tape: Report from the Business Task Force*, Policy Paper October 2013, available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/249969/TaskForce-report-15-October.pdf (accessed 29/01/2014).

regulations, policy-makers have generally pursued a two-fold objective: first, to promote the safe practice of life science research by reducing any risks arising therefrom both to scientists and the general public; and second, to ensure that any issues that may hinder the expansion of biotechnology are not subject to restrictive legislation.

A vivid manifestation of this approach is the way in which the ongoing debate on 'dual use research of concern' – benignly-intended research that seeks to maximise human welfare by responding to health, societal and environmental ills but could also facilitate the development of more sophisticated and potent biological weapons and enable bioterrorism⁴¹⁷ – has been handled. For more than a decade, researchers, journal editors, security experts and policy-makers have strived to devise oversight mechanisms and governance initiatives that could adequately tackle the challenge of dual use without stifling innovation. Unfortunately, to date their efforts have met with little success, as a result of which virtually each experiment of dual use concern is dealt with separately on a case-by-case basis. This is not to say that there are no similarities across the studies of this kind. On the contrary, a few of the most notable examples follow a similar paradigm, including the creation of a vaccine-resistant strain of the Mousepox virus, the artificial synthesis of the Polio virus, the recreation of the 1918 Spanish Influenza virus and, most recently, the production of a mammalian-transmissible H5N1 Avian Influenza virus (see Box 4.1).⁴¹⁸ All four of them were performed in strict compliance

⁴¹⁷ See, for example, National Science Advisory Board for Biosecurity (NSABB), *Proposed Framework for the Oversight of Dual Use Life Science Research: Strategies for Minimising the Potential Misuse of Research Information*, June 2007, available at http://oba.od.nih.gov/biosecurity/biosecurity_documents.html (accessed 6/01/2014). On the potential for misuse of novel scientific developments, see James Petro et al. 'Biotechnology: Impact on Biological Warfare and Biodefence', *Biosecurity and Bioterrorism: Biodefence Strategy, Practice, and Science*, vol.1:3 (2003), pp.161-168; Gregory Koblenz, 'Biosecurity Reconsidered: Calibrating Biological Threats and Responses', *International Security*, vol.34:4 (2010), pp.96-132; Christian Enemark and Ian Ramshaw, 'Gene Technology, Biological Weapons, and the Security of Science', *Security Studies*, vol.18 (2009), pp.624-641. Some commentators have expressed scepticism toward the claim that scientific and technological advancement poses serious threats underscoring the importance of other factors, such as socio-economic and socio-technic contexts. See, for example, Kathleen Vogel, 'Intelligent Assessment: Putting Emerging Biotechnology Threats in Context', *Bulletin of Atomic Scientists*, vol.69:1 (2013), pp.43-52; Sonia Ben Ouagrham-Gormley, 'Barriers to Bioweapons: Intangible Obstacles to Proliferation', *International Security*, vol.36:4 (2012), pp.80-114. Others, however, argue that advances in modern biology and medicine have implications for the evolution of biological weapon programmes. See Malcolm Dando, 'The Impact of the Development of Modern Biology and Medicine on the Evolution of Offensive Biological Warfare Programmes in the Twentieth Century', *Defence Analysis*, vol.15:1 (1999), pp.43-62; Kathryn Nixdorff and Wolfgang Bender, 'Ethics of University Research, Biotechnology and Potential Military Spin-Off', *Minerva*, vol.40 (2002), pp.15-35.

⁴¹⁸ See Ronald Jackson et al. 'Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox', *Journal of Virology*, vol.75:3 (2001), pp.1205-1210; Samatha Robins et al. 'The Efficacy of Cidofovir Treatment of Mice Infected with Ectromelia (Mousepox) Virus Encoding Interleukin-4', *Antiviral Research*, vol.66:1 (2005), pp.1-7; Rachel Nowak, 'Disaster in

with the rules and procedures in place for laboratory biosafety, biosecurity and biorisk management and under appropriate physical containment conditions; all had passed thorough review by the respective local biosafety and bioethics committees; and all of them were deemed essential in terms of public health benefits. Above all, the ethical and security concerns that the studies have raised go far beyond the laboratory door, posing fundamental questions about how life science research is reviewed, conducted and communicated.

Box 4.1: Examples of Experiments of Concern

The Australian Mousepox Virus Study

In early 2001, the *Journal of Virology* published a report of the creation of a highly-virulent strain of the *Ectromelia virus*, the causative agent of mousepox. The work described in the report was carried out by a group of Australian scientists based in Canberra. Its original goal was the development of an infectious immunocontraceptive that could be used against wild mice for the purpose of pest-control. To achieve this, the group drew upon previously published work. During the course of the experiment, the researchers unexpectedly discovered that the newly-engineered strain of the Mousepox virus, which they created, killed 60 per cent more mice than the parent virus, including mice that had been vaccinated or that had natural immunity. When the research was published, concerns were raised that it could potentially be misapplied for hostile purposes, or even that the same technique could be utilised for creating a more virulent strain of the *Variola virus*, which causes smallpox in humans.

The Artificial Synthesis of the Polio Virus

In 2002, a team of scientists led by Dr Eckard Wimmer from the University of New York at Stony Brook announced that they had successfully created a polio virus 'from scratch'. To carry out the research, the scientists 'followed a recipe they downloaded from the internet and used gene sequences from a mail-order supplier'.⁴¹⁹ Once the virus created, it was tested on mice, as a

the Making', *The New Scientist*, vol.2273, 13 January 2001; Arno Mullbacher and Mario Lobigs, 'Creation of Killer Poxvirus Could Have Been Predicted', *Journal of Virology*, vol.75:18 (2001), pp.8353-8355; Jeronimo Cello et al. 'Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template', *op cit*; Steve Connor, 'Fears of Bioterrorism as Scientists Create Deadly Polio Virus', *The Independent*, 12 July 2002; Michael Selgelid, 'A Tale of Two Studies: Ethics, Bioterrorism and the Censorship of Science', *The Hasting Centre Report*, vol. 37:3 (2007), pp.35-43; David Whitehouse, 'First Synthetic Virus Created', *BBC News*, 11 July 2002, available at <http://news.bbc.co.uk/2/hi/2122619.stm> (accessed 6/01/2014); Terrence Tumpey et al. 'Characterisation of the Reconstructed 1918 Spanish Influenza Pandemic Virus', *Science*, vol. 310:5745, (2005), pp.77-80.

⁴¹⁹ David Whitehouse, 'First Synthetic Virus Created', *BBC News*, 11 July 2002, available at <http://news.bbc.co.uk/1/hi/sci/tech/2122619.stm> (accessed 1/02/16).

result of which the infected animals became paralysed and died. The study spurred a wide-ranging debate, not least because it drew attention to the possibility of using synthetic biology for constructing de novo viruses for the purposes of bioterrorism.

The Recreation of 1918 Spanish Influenza Virus

In 2005, it was announced that CDC scientists together with colleagues from several research institutions across the USA had successfully re-created the influenza virus, that was responsible for the 1918 pandemic, which killed between 20 and 50 million people worldwide. Using DNA from a tissue of a flu victim buried in the permafrost in Alaska, the researchers managed to reconstruct the influenza virus and thus study its pathogenesis and properties that contributed to its virulence. Despite the scientific justification that was put forward, critics have argued that the study is 'a recipe for disaster', not least because the availability of the virus' full-genome sequence and detailed method for its reconstruction on the Internet may facilitate its synthesis by a rogue scientist.⁴²⁰

Yet none of the high-profile experiments of concern has proved critical enough to provoke a radical change in the way dual-use research is governed.⁴²¹ Three points merit consideration in this regard. The first pertains to the manner in which the dominant discourse on dual use is framed, that is, in purely ethical terms as a dilemma. While bioethics undoubtedly has a role to play in the discussions on dual use, the language of 'dual-use dilemmas' is too abstract to offer appropriate analytical tools for dealing with the issues at play. As discussed above, the questions that dual-use research poses such as data sharing, research funding and project planning are far from hypothetical but they feature explicitly in everyday professional practice.

⁴²⁰ Jan van Aken, 'Ethics of Reconstructing Spanish Flu: Is It Wise to Resurrect a Deadly Virus?', *Heredity*, vol.98 (2007), pp.1-2.

⁴²¹ On the governance of dual-use research, see Christine Uhlenhaut et al. 'Protecting Society: Biological Security and Dual-Use Dilemma in the Life Sciences – Status Quo and Options for the Future', *EMBO Reports*, vol.14:1 (2013), pp.25-30; Catriona McLeish and Ralf Trapp, 'The Life Sciences Revolution and the BWC: Reconsidering the Science and Technology Review Process in a Post-Proliferation world', *The Non-Proliferation Review*, vol.18:3 (2011), pp.527-543. Some novel developments related to the way in which dual-use research is governed are worth of note. For instance, the Robert Koch Institute, the central federal institution responsible for disease control and prevention in Germany, has recently implemented an Internal Directive on Dual-Use Potential of Life Sciences Research featuring a Code of Conduct for risk Assessment and Risk Mitigation. Article 5 of the Code lists a number of activities in place for the purpose of raising awareness among the Institute staff of dual-use issues. The full text of the Code is available at http://www.rki.de/EN/Content/Institute/Dual_Use/code_of_conduct.html?nn=4005636 (accessed 27/01/2014); another example is the licensing programme run by the Danish Centre for Biosecurity and Biopreparedness, the national authority that controls the use of dual-use materials, which features an education and outreach component. A full description of the programme is available at <http://www.biosikring.dk/eng> (accessed 27/01/2014). For a proposal on how to improve the governance of emerging technologies with far-reaching implications, see Kenneth Oye et al. 'Regulating Gene Drives', *Science*, vol.345:6197 (2014), pp.626-628.

However, the 'dilemma framework' automatically strips them of the complex socio-technical arenas in which they have actually presented themselves by laying an emphasis on what action should ideally be taken, rather than what is practically feasible given the circumstances.⁴²² Moreover, such issues are typically structural in nature for they constitute fundamental elements of the life sciences professional culture, and as such, could hardly be adequately addressed solely at the level of individual researchers. Yet framing social, legal and security concerns in terms of moral dilemmas allows for structural issues to be omitted from the discussion, rendering life scientists the chief, if not the only, moral agents expected to reach what is deemed to be the 'right' answer.⁴²³ Assigning abstract duties then comes to be regarded as an appropriate 'solution', even if those are virtually impossible to fulfil given the complexities of the working environment within which researchers operate.

The second point is related to the reductionist view that dominates the discourse of what counts as a risk in life science research. Perhaps one of the most significant legacies of the Asilomar Conference on rDNA (see Chapter 3) is the emphasis on laboratory risk that could be effectively managed by dint of physical containment and rules and procedures for safe laboratory practice.⁴²⁴ It suffices to mention that the bulk of guidelines and formal regulations published by the WHO focus exclusively on promoting and refining measures that aim to maximise laboratory biosafety and prevent the accidental release of pathogens. Hence, it is hardly surprising that the concept of dual use and the idea of risks *beyond the laboratory door* implicit in it seem alien to the majority of practising researchers. Striking as it may appear, even though dual use research has been debated for more than a

⁴²² Daniel Chambliss, *Beyond Caring: Hospitals, Nurses and the Social Organisation of Ethics* (Chicago, IL: University of Chicago Press, 1996), p.6. See also Jim Whitman, *When Dual-Use Issues Are so Abundant, Why Are Dual-Use Dilemmas so Rare*, Research Report for the Wellcome Trust Project on 'Building Sustainable Capacity in Dual-Use Bioethics', University of Bradford, 2010, available at <http://www.brad.ac.uk/bioethics/media/sss/bioethics/docs/monograph-7-JW.pdf> (accessed 29/01/2014). On the limitations of the risk-benefit framework for assessing life science research of concern, see Brian Rappert, 'Why Has Not There Been More Research of Concern', *Frontiers in Public Health*, vol.2:74 (2014), pp.1-14.

⁴²³ Daniel Chambliss, *Beyond Caring op cit*, p.92.

⁴²⁴ See Marcia Barinaga, 'Asilomar Revisited: Lessons for Today?', *Science*, vol.287:5458 (2000), pp.1584-1585; Sheldon Krinsky, 'From Asilomar to Industrial Biotechnology: Risks, Reductionism and Regulation', *Science as Culture*, vol.14:4 (2005), pp.309-323.

decade now, the level of awareness among life scientists of the broader social, security and legal implications of their work remains low.⁴²⁵

The third point deals with the way in which risks in life science research are assessed and mitigated. Given the narrow definition of risk encompassing technical particulars, physical containment and biosafety, risk assessment is considered an appropriate and reliable tool for ensuring research safety. The heavy reliance upon risk assessing tools is underpinned by two underlying assumptions. One is that it is possible to foresee and calculate most, if not all, things that could potentially go wrong both during the development phase of the project and after its completion. The other is that it is possible then to use the produced data as a basis for devising measures and strategies for eradicating, or at least, mitigating the risks likely to occur. Attractive as it may seem, this 'new alchemy where body counting replaces social and cultural values' presupposes a clear distinction between the risk assessment 'experts' and the general public, whereby the former are granted a licence to make decisions about the risks that the latter cannot do without.⁴²⁶ Likewise, cost-benefit analysis on the basis of which research proposals are screened for potentials risks and security concerns has attracted some serious criticism. In the view of some commentators, besides being sometimes deeply inaccurate, the cost-benefit analysis is 'ethically wrong' since 'applying narrow quantitative criteria to human health and human life' is

⁴²⁵ See Malcolm Dando and Brian Rappert, 'Codes of Conduct for Life Sciences: Some Insights from UK Academia', Briefing Paper no.16 (2nd series: 2005), University of Bradford, available at www.brad.ac.uk/acad/sbtwc (accessed 8/03/2013). See also German Ethics Council, *Biosecurity – Freedom and Responsibility of Research*, (Berlin: Deutscher Ethikrat, 2014), available at <http://www.ethikrat.org/files/opinion-biosecurity.pdf> (accessed 17/09/2015).

⁴²⁶ Charles Perrow, *Normal Accidents: Living with High-Risk Technologies*, *op cit*, p.12. On the framing of risk in biotechnology, see Geert van Calster, 'Risk Regulation, EU Law and Emerging Technologies: Smother or Smooth?', *Nanoethics*, vol.2 (2008), pp.61-71; Jenifer Kuzma and John Besley, 'Ethics of Risk Analysis and Regulatory Review: From Bio- to Nanotechnology', *Nanoethics*, vol.2 (2008), pp.149-162; Les Levidow et al. 'European Biotechnology Regulation: Framing the Risk Assessment of a Herbicide Tolerant Crop', *Science, Technology, and Human Values*, vol.22:4 (1997), pp.472-505; Lisa Clark, 'Framing the Uncertainty of Risk: Models of Governance for Genetically Modified Crops', *Science and Public Policy*, vol.40 (2013), pp.479-491; Jesper Toft, 'Denmark's Regulation of Agri-Biotechnology: Co-Existence Bypassing Risk Issues', *Science and Public Policy*, vol.32:4 (2005), pp.293-300; Ereck Chakaayaa et al. 'Riding the Tide of Biopharming in Africa: Considerations for Risk Assessment', *South African Journal of Science*, vol.102 (2006), pp.284-288; Jean-Michel Marcoux and Lyne Le'tourneau, 'A Distorted Regulatory Landscape: Genetically Modified Wheat and the Influence of Non-Safety Issues in Canada', *Science and Public Policy*, vol.40 (2013), pp.514-532; Shawn Harmon et al. 'Governing Risk, Engaging Public an Endangering Trust: New Horizons for Law and Social Science', *Science and Public Policy*, vol.40 (2013), pp.25-33; Maaïke van Tuyl, 'Dealing with Future Risks in the Netherlands', *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, vol.11: S1 (2013), pp.555-563. On the shortcomings of the existing models for public deliberation on the risks of biotechnology, see Les Levidow, 'European Public Participation as Risk Governance: Enhancing Democratic Accountability for Agrobiotech Policy', *East Asian Science, technology and Society: an International Journal*, vol.1 (2007), pp.19-51.

unacceptable.⁴²⁷ But there are other problems, too. As pointed out by Dickson, the cost-benefit analysis distorts political decision-making by omitting any factors that cannot be quantified, thus obscuring questions of equity, justice, power and social welfare behind a technocratic haze of numbers.⁴²⁸ As a result, complex and politically charged decisions are reduced to a form that fits neatly into the technocratic ways of making regulatory decisions, whereby calculations and approximations made by the few substitute for the judgements of many.⁴²⁹

The wide-ranging controversy that unraveled in late 2011 when two teams of scientists working independently in the Netherlands and the USA managed to produce an air-borne strain of the H5N1 Avian Influenza virus, a highly pathogenic and lethal microbe with over 60 per cent mortality rate in humans arguably constituted the pinnacle of the deliberation on dual use research. Both studies set alarm bells ringing for the security community who almost immediately jumped in the debate voicing concerns over the possibility of biological proliferation and bioterrorism. Some commentators even argued that the experiments ran counter to the spirit if not to the letter of the 1975 BTWC.⁴³⁰ Against this backdrop, the resultant controversy was deemed at least initially to offer a timely opportunity to evaluate the existing governance mechanisms, determine their gaps and weaknesses and broaden the scope of deliberation inviting participation of a wide range of stakeholders. Unfortunately, the outcome of the debate proved far more moderate, signalling preference for preserving the *status quo* without disrupting the established systems for governance and oversight. Despite the extensive mass media coverage of the controversy, only few public consultations were held and none of those was designed as a platform for making policy proposals or developing action plans. Moreover, the densely-packed agenda prepared duly in advance left very limited scope for posing 'tricky' questions which the participating 'experts' might have struggled to answer. Needless to

⁴²⁷ David Dickson, *The New Politics of Science*, *op cit*, p. 285. For critique of cost-benefit analysis, see also Brian Rappert, 'The Benefits, Risks and Threats of Biotechnology', *Science and Public Policy*, vol.35:1 (2008), pp.1-7.

⁴²⁸ *Ibid*, 286.

⁴²⁹ *Ibid*.

⁴³⁰ See Tatyana Novossiolova et al. 'The Creation of Contagious H5N1 Avian Influenza Virus: Implications for the Education of Life Scientists', *Journal of Terrorism Research*, vol.3:1 (2012), pp.39-51.

say, all consequential decisions were made behind closed doors away from public scrutiny and on some occasions the people with the greatest vested interest in the publication of the studies were also the ones with the greatest say in the process.⁴³¹ There were no significant changes in terms of governance initiatives, either. Far from being ground-breaking developments, the US Government Policy for Oversight of Life Sciences Dual Use Research of Concern⁴³² and the decision of the Dutch government to invoke export control legislation before allowing the publication of the study conducted within its jurisdiction were little more than desperate moves that aimed to obscure the inadequacy and shortcomings of the measures already in place.⁴³³ Overall, the manner in which the H5N1 debate was handled could be treated as a missed opportunity, whereby those in charge of the decision-making process did little to address or even acknowledge the broader issues underpinning dual-use research of concern but simply 'kicked the can down the road to the next manuscript' waiting for the next controversy to erupt.⁴³⁴

Reliance on Technical Fixes

Technology seems to play a significant role in the governance of life science research. High-containment laboratories, well-equipped biosafety cabinets, sophisticated waste management systems, enhanced personal protective equipment and secure containers for the safe storage and transportation of biohazard materials are just a few of the tools and systems in place that allow the safe handling of dangerous pathogens and toxins and, at the same time,

⁴³¹ All meetings of the US National Science Advisory Board for Biosecurity (NSABB) convened to discuss the manuscripts were restricted to selected individuals and full proceedings were never published. Moreover, the consequential Consultation Meeting organised by the World Health Organisation (WHO) in February 2012 which rejected the NSABB recommendation for a redacted publication of the manuscripts featured the lead scientists who conducted the experiments and representatives of the US National Institutes of Health, the primary funding body of both studies. See Gretchen Vogel, 'Flu Experts – and One Ethicist – Debate Controversial H5N1 Papers', *ScienceInsider*, 16 February 2012, available at <http://news.sciencemag.org/2012/02/flu-experts%E2%80%94and-one-ethicist%E2%80%94debate-controversial-h5n1-papers> (accessed 27/01/2014). The full list of participants and final report of the Meeting are available at http://www.who.int/influenza/human_animal_interface/list_participants/en/index.html (accessed 27/01/2014).

⁴³² For more information, see <http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern> (accessed 16/09/2015); Martin Enserink, 'Fight Over Dutch H5N1 Paper Enters Endgame', *ScienceInsider*, 24 April 2012, available at <http://news.sciencemag.org/2012/04/fight-over-dutch-h5n1-paper-enters-endgame> (accessed 6/01/2014).

⁴³³ See Martin Enserink, 'Fight Over Dutch H5N1 Paper Enters Endgame', *ScienceInsider*, 24 April 2012, available at <http://news.sciencemag.org/2012/04/fight-over-dutch-h5n1-paper-enters-endgame> (accessed 17/09/2015); Martin Enserink, 'Dutch Appeals Court Dodges Decision on Hotly Debated H5N1 Papers', *ScienceInsider*, 16 July 2015, available at <http://news.sciencemag.org/europe/2015/07/dutch-appeals-court-dodges-decision-hotly-debated-h5n1-papers> (accessed 17/09/2015).

⁴³⁴ Letter from Michael Osterholm to Amy Patterson, 12 April 2012; see also Brendan Maher, 'Bias Accusation Rattles US Biosecurity Board', *Nature News*, 14 April 2012, available at <http://www.nature.com/news/bias-accusation-rattles-us-biosecurity-board-1.10454> (accessed 6/01/2014).

protect both laboratory personnel and the general public from exposure to deadly microbes. That said, the effectiveness of technical solutions should not be overstated if only for the fact that ‘problems’ of governance are barely technical matters *per se* but rather constitute complex issues of human relatedness. Nevertheless, the attractiveness of technological fixes as offering reliable risk mitigation and reassurance in the safety of biotechnology is ever growing. It suffices to mention that the H5N1 controversy discussed above was in part resolved after the lead researchers in the Netherlands and the USA respectively agreed to add a detailed section on the technical specificities and laboratory biosafety and biosecurity measures taken during the experiments.⁴³⁵ The strategy has proved effective in diverting attention from the rather inconvenient questions regarding the utility and significant potential for hostile misuse of the so called ‘gain-of-function’ (GOF) research and concentrating it on more mundane issues dealing with in-house precautions and safety procedures. Once the latter were deemed adequately resolved, the former were effectively forgotten.

Still, the value of technical means in ensuring reliable risk management should not be taken for granted. For one thing, laboratory biosafety precautions, however sophisticated, are far from perfect and accidents do occur. Such is the case with the Pirbright site in the UK which was at the centre of a major outbreak of foot-and-mouth disease in 2007, as a result of which over 2100 animals were slaughtered.⁴³⁶ In 2012 the bioterrorism BSL-3 laboratory at the US CDC in Atlanta suffered repeated problems with airflow systems designed to help prevent the release of infectious agents.⁴³⁷ The faulty system could perhaps be regarded as an exception had it not been for the authoritative investigation report of the US Government Accountability Office (GAO) released in March 2013. According to the report, the cost of building and maintaining high-containment laboratories, coupled with the

⁴³⁵ See Masaki Imai et al. ‘Experimental Adaptation of an Influenza H5 HA Confers Respiratory Droplet Transmission to a Reassortant H5 HA/H1N1 Virus in Ferrets’, *Nature*, vol.486 (2012), pp.420-430; Sander Herfst et al. ‘Airborne Transmission of Influenza A/H5N1 Virus between Ferrets: Materials/Methods, Supporting Text, Tables, Figures, and/or References’, *Science*, vol. 336:6088, (2012), pp.1534-1541. Supplementary materials are available at <http://www.sciencemag.org/content/suppl/2012/06/20/336.6088.1534.DC1/1213362.Herfst.SM.pdf> (accessed 27/01/2014).

⁴³⁶ Pallab Ghosh, “Safety Incidents” at Animal Lab’, *BBC News*, 26 May 2011, available at <http://www.bbc.co.uk/news/science-environment-13566593> (accessed 8/01/2014).

⁴³⁷ Alison Young, ‘Airflow Problems Plague CDC Bioterror Lab’, *USA Today*, 12 June 2012, available at <http://usatoday30.usatoday.com/news/nation/story/2012-06-13/cdc-bioterror-lab/55557704/1> (accessed 8/01/2014).

absence of national standards for their design, construction, operation, and maintenance ‘exposes the nation to risk’.⁴³⁸ Far more critical is the situation in the developing world and emerging economies where lax regulations and technical failures have significantly heightened the risk of accidental release of pathogens, as demonstrated by the numerous ‘escapes’ of the Severe Acute Respiratory Syndrome (SARS).⁴³⁹

But even if technology functions impeccably, this hardly reduces the likelihood for a human error or inappropriate behaviour. Unlocked doors in high-containment facilities hosting deadly pathogens, eating and drinking in laboratories and poor waste disposal practices are just a small part of the otherwise long list of mundane mishaps that may result in severe consequences. It is worth mentioning that the US CDC came under the spotlight after internal e-mail correspondence revealed that doors in the BSL-3 block where experiments involving the causative agents of anthrax, SARS and influenza were performed were left unlocked on numerous occasions, thus increasing the risk of unauthorised access or theft.⁴⁴⁰ Given the chance of technical flaw and the potential for human error, some life scientists have begun to question the reliability of existing laboratory precautions and demand thorough review and evaluation. In a recent letter to the European

⁴³⁸ US Government Accountability Office, *High-Containment Laboratories: Assessment of the Nation’s Need Is Missing*, 25 February 2013, available at <http://www.documentcloud.org/documents/627140-gao-report-on-high-containment-labs-february-2013.html> (accessed 8/01/2014).

⁴³⁹ Robert Walgate, ‘SARS Escaped Beijing Lab Twice’, *The Scientist*, 26 April 2004, available at <http://www.the-scientist.com/?articles.view/articleNo/22811/title/SARS-escaped-Beijing-lab-twice/> (accessed 8/01/2014); Lawrence Altman, ‘Lab Infection Blamed for Singapore SARS Case’, *New York Times*, 24 September 2003, available at <http://www.nytimes.com/2003/09/24/world/lab-infection-blamed-for-singapore-sars-case.html> (accessed 8/01/2014);

⁴⁴⁰ Alison Young, ‘Security Lapses Found at CDC Bioterror Lab’, *US Today*, 27 June 2012, available at <http://usatoday30.usatoday.com/news/nation/story/2012-06-27/cdc-lab-security/55870990/1> (accessed 8/01/2014).

Between 2014 and 2015, several high-containment facilities in the US have experienced serious biosafety lapses. Accidents involving dangerous pathogens such as the causative agents of anthrax and bird flu were reported. See Centers for Disease Control and Prevention, *Report on the Potential Exposure to Anthrax*, 7 November 2014, available at http://www.cdc.gov/about/pdf/lab-safety/Final_Anthrax_Report.pdf (accessed 17/09/2015); Editorial, ‘Biosafety in the Balance’, *Nature*, 25 June 2014. Available at

<http://www.nature.com/news/biosafety-in-the-balance-1.15447> (accessed 17/09/2015); Marc Lipsitch, ‘Anthrax? That’s Not the Real Worry’, *New York Times*, 29 June 2014, http://www.nytimes.com/2014/06/30/opinion/anthrax-thats-not-the-real-worry.html?_r=0 (accessed 17/09/2015); Donald McNeil, ‘CDC Closes Anthrax and Flu Labs After Accidents’, *New York Times*, 11 July 2014, <http://www.nytimes.com/2014/07/12/science/cdc-closes-anthrax-and-flu-labs-after-accidents.html> (accessed 17/09/2015); Ian Sample, ‘From Anthrax to Bird Flu – the Dangers of Lax Security in Disease-Control Labs’, *The Guardian*, 18 July 2014, <http://www.theguardian.com/world/2014/jul/18/anthrax-bird-flu-dangers-lax-security-disease-control-labs> (accessed 17/09/2015).

About the same time, there were also reports about smallpox vials being retrieved after having been left unaccounted for over 50 years. See AP, ‘Forgotten Vials of Smallpox Found in Storage Room’, *New York Times*, 8 July 2014, http://www.nytimes.com/aponline/2014/07/08/health/ap-us-med-forgotten-smallpox.html?hp&action=click&pgtype=Homepage&version=HpHeadline&module=first-column-region®ion=top-news&WT.nav=top-news&_r=0 (accessed 17/09/2015). Most recently in 2015 there have been reports about live anthrax being shipped from US military research facilities worldwide. See Nicky Woolf, ‘Anthrax Shipment from Pentagon the result of a “Massive Institutional Failure”’, *The Guardian*, 23 July 2015, <http://www.theguardian.com/us-news/2015/jul/23/anthrax-shipment-pentagon-institutional-failure> (accessed 17/09/2015).

Commission the Foundation for Vaccine Research has asked for ‘a rigorous, comprehensive risk-benefit assessment’ of GOF research that ‘could help determine whether the unique risks posed by these sorts of experiments are balanced by unique public health benefits which could not be achieved by alternative, safe scientific approaches’.⁴⁴¹

Engines that Drive Biotechnology Momentum

By and large, the ongoing progress of biotechnology is largely viewed and assessed through an explicitly positive lens which allows focusing almost exclusively on the benefits likely to be accrued notwithstanding the risks, actual and potential. The resultant distorted image is problematic, not least because it precludes any comprehensive discussion on the potential side effects and negative implications of novel life science advances. Above all, it sustains the barely questioned assumption that the existing governance mechanisms are adequate and sufficient to cope with the stresses and strains of the rapidly evolving biotechnology landscape. Yet given the complex and multifaceted dynamics shaping the life science enterprise, the rapid pace of innovation and the limits to predicting the synergistic and cumulative effects of the proliferation of new technologies, the uncritical acceptance of such assumptions is at best naïve and at worst dangerous.

Integration of Biology with Other Disciplines

Arguably the advancement of the life sciences has greatly benefited from the fascinating breakthroughs made in other areas of study, such as chemistry, engineering, computing, informatics, robotics, mathematics and physics. Some commentators even talk about a Third Revolution in Biotechnology underpinned by scientific and technological convergence:

Convergence does not simply involve a transfer of
tools sets from one science to another;

⁴⁴¹ Letter from the Foundation for Vaccine Research to the European Commission, *Response to Letter by the European Society for Virology on ‘Gain-of-Function’ Influenza Research and Proposal to Organise a Scientific Briefing for the European Commission and Conduct Comprehensive Risk-Benefit Assessment*, 18 December 2013, available at http://www.nature.com/polopoly_fs/7.14586!/file/vaccine%20foundation%20letter.pdf (accessed 8/01/2014). On the ongoing debate on GOF, see National Research Council, *Potential Risks and Benefits of Gain-of-Function Research: Summary of a Workshop*, (Washington DC: National Academies Press, 2015).

fundamentally different conceptual approaches from physical science and engineering are imported into biological research, while life science's understanding of complex evolutionary systems is reciprocally influencing physical science and engineering. Convergence is the result of true intellectual cross-pollination.⁴⁴²

The resultant 'New Biology' has opened up a range of marvellous possibilities enabling the manipulation of living matter at the full range of scales, as well as the application of biological systems principles for the development of novel materials, processes and devices.⁴⁴³ As such, it has been largely hailed as possessing the 'capacity to tackle a broad range of scientific and societal problems.'⁴⁴⁴ This is not an exaggeration. As noted by a recent report of the US NAS, the precipitous decline in the cost of genome sequencing would not have been possible without a combination of engineering of equipment, robotics for automation, and chemistry and biochemistry to make the sequencing accurate.⁴⁴⁵ Likewise, it is the combination of expertise from fields as diverse as evolutionary biology, computer science, mathematics, and statistics that has allowed both the analysis of raw genomic data and the subsequent use of these data to other fields.⁴⁴⁶ At the same time, advances in nanoscience and nanotechnology have considerably enhanced drug delivery making it more accurate by targeting specific parts of the body.⁴⁴⁷

Yet the transformative potential of scientific and technological convergence comes at a price, not least because parallel to the benefits it offers there are risks the effects of which could be truly devastating.⁴⁴⁸ Take drug delivery, for

⁴⁴² Philip Sharp et al. *The Third Revolution: The Convergence of the Life Sciences, Physical Sciences and Engineering*, MIT White Paper, January 2011, Cambridge MA.

⁴⁴³ See Committee on Biomolecular Materials and Processes, National Research Council, *Inspired by Biology: From Molecules to Materials to Machines*, (Washington, DC: National Academies Press, 2008).

⁴⁴⁴ National Research Council, *A New Biology for the 21st Century* (Washington DC: The National Academies Press, 2009), p.3.

⁴⁴⁵ *Ibid.*, p.42.

⁴⁴⁶ *Ibid.*

⁴⁴⁷ See Kinam Park, 'Nanotechnology: What It Can Do for Drug Delivery', *Journal of Control Release*, vol. 120:1-2 (2008), pp.1-3; Kinam Park, 'Facing the Truth about Nanotechnology in Drug Delivery', *ACS Nano*, vol.7:9, (2013), pp.7442-7447; Suwussa Bamrungsap et al, 'Nanotechnology in Therapeutics', *Nanomedicine*, vol.7:8 (2012), pp.1253-1271; 'Carbon Nanotubes – Bullets in the Fight against Cancer', *Community Research and Development Information Service*, 10 September 2013, available at http://cordis.europa.eu/news/rcn/36049_en.html (accessed 13/01/2014).

⁴⁴⁸ On the governance challenges brought about by the convergence between biology and other fields of science, see Francis Fukuyama and Caroline Wagner, *Information and Biological Revolutions: Global Governance Challenges – Summary of a Study Group* (Washington DC: RAND Corporation, 2000), available at

instance. Thanks to the technological breakthroughs over the past decade, doctors have gained unprecedented access to the human body which, in turn, has facilitated the treatment of previously incurable disease and conditions (e.g. some forms of cancer). Nanoparticles and aerosols are now utilised for delivering a precise dose of therapeutics to tissues and cells via novel pathways circumventing body's natural defences and evading immune response. It is not difficult to imagine how such knowledge could be misapplied for malicious ends, including incapacitating and killing. Research on bioregulators is a case in point. Bioregulators are natural chemicals in the human body that play a vital role in the maintenance of the homeostasis but when administered in large quantities or in healthy individuals could be toxic and lead to serious disorders, even death. Given their properties, bioregulators constitute the perfect bioweapon: efficient and virtually impossible to detect. And if in the past, security analysts discounted the risk of their weaponisation due to the instability of the compounds when released in the atmosphere, the emergence of novel drug delivery techniques has significantly altered the security calculus.⁴⁴⁹ This is just but one example of the challenges that the increasing convergence between biology and chemistry poses to the integrity of the international biological and chemical non-proliferation regimes.⁴⁵⁰ Even though some effort has been made over the recent years to address those and other areas of concern and strengthen the international prohibition against biological and chemical warfare, in practical terms little has been achieved, as a result of which the risk of the hostile exploitation of novel scientific developments remains far from hypothetical.

Along with the risk of misuse of new knowledge, there is the risk posed by the lack of sufficient scientific knowledge. Cross-disciplinary convergence opens a multitude of opportunities for manipulation and modification of living

http://www.rand.org/content/dam/rand/pubs/monograph_reports/2007/MR1139.pdf (accessed 29/01/2014); Spiez Convergence, *Report of the First Workshop*, 6-9 October 2014, available at http://www.labor-spiez.ch/en/akt/pdf/Spiez_Convergence_2014_web.pdf (accessed 17/09/2015).

⁴⁴⁹ See Jonathan Tucker, 'The Body's Own Bioweapons', *The Bulletin of Atomic Scientists*, vol.64:1 (2008), pp.16-22.

⁴⁵⁰ See Jonathan Tucker (ed.), *Innovation, Dual Use, and Security: Managing the Risks of Emerging Biological and Chemical Technologies* (Cambridge MA: MIT Press, 2012); US National Academy of Science, *Life Sciences and Related Fields: Trends Relevant to the Biological Weapons Convention* (Washington DC: National Academies Press, 2011).

matter but, at the same time, it precludes almost any sensible assessment of the potential interactions likely to occur in the process. Nano-based medicine is but one area that has attracted criticism in this regard. Since some elements behave differently at nano-scale, it becomes extremely difficult to assess their level of toxicity or other negative side effects that they may exert. Such is the case with long carbon nanotubes, which having been initially praised for their potential to improve implant development⁴⁵¹ were later blamed for exhibiting asbestos-like behaviour that could lead to cancer.⁴⁵²

Another area of converging science with far-reaching implications is synthetic biology, a cross-disciplinary field that draws upon strategies and techniques from molecular biology, chemistry, engineering, genomics and nanotechnology and thus enables the design and modification of biological systems at a fundamental level. Empowered by the tools of synthetic biology, in 2002 scientists managed to assemble a polio virus 'from scratch' in the absence of a natural template. And in 2010 Craig Venter and his team announced the construction of the first self-replicating synthetic cell which, in their view, was 'a proof of the principle that genomes can be designed in the computer, chemically made in the laboratory and transplanted into a recipient cell to produce a new self-replicating cell controlled only by the synthetic genome.'⁴⁵³ The controversial work has attracted criticism on several grounds, including the potential negative effects of the accidental or deliberate release of the novel organism in the environment and the arrogance of scientists to 'play God'.⁴⁵⁴ More broadly, both the polio and synthetic cell studies have exposed the obstacles to the regulation of

⁴⁵¹ Katherine Gammon, 'Building Better Implants', *MIT Technology Review*, 28 September 2007, available at <http://www.technologyreview.com/news/408759/building-better-implants/> (accessed 14/01/2014).

⁴⁵² Kevin Bullis, 'Some Nanotubes Could Cause Cancer', *MIT Technology Review*, 22 May 2008, available at <http://www.technologyreview.com/news/410172/some-nanotubes-could-cause-cancer/> (accessed 14/01/2014).

⁴⁵³ 'First Self-Replicating Synthetic Bacterial Cell', *Press Release*, J. Craig Venter Institute, 20 May 2010, available at <http://www.jcvi.org/cms/press/press-releases/full-text/article/first-self-replicating-synthetic-bacterial-cell-constructed-by-j-craig-venter-institute-researcher/home/> (accessed 14/01/2014).

⁴⁵⁴ Ian Sample, 'Craig Venter Creates Synthetic Life Form', *The Guardian*, 20 May 2010, available at <http://www.theguardian.com/science/2010/may/20/craig-venter-synthetic-life-form> (accessed 14/01/2014); ETC Group, 'Synthia is Alive...and Breeding: Panacea or Pandora's Box?', *News Release*, 20 May 2010, available at <http://www.etcgroup.org/content/synthia-alive-%E2%80%A6-and-breeding-panacea-or-pandoras-box> (accessed 29/01/2014).

synthetic biology.⁴⁵⁵ While some commentators dismiss the risk of bioterrorism, underscoring the key role of tacit skills and knowledge and the difficulties that the lack thereof poses to the replication of the experiments,⁴⁵⁶ other issues still merit attention. Consider the question of access to commercially available genomic sequences. Even though the oversight system for screening base pair orders has improved since the 2006 *Guardian* report that exposed the lax regulations under which virtually anyone could order gene sequences,⁴⁵⁷ gaps still remain leaving scope for abuse by those with malign intent. For example, Schmidt and Giersch have outlined at least three areas of emerging challenges that the existing governance regimes would struggle to accommodate, including ‘split orders’, ‘outsourcing’ and the potential for non-natural biological systems.⁴⁵⁸

Biology as a Predictive rather than Descriptive Science

The Human Genome Project completed in 2003 lasted over ten years and cost close to 3 billion dollars; by contrast, about a decade later, whole-

⁴⁵⁵ On the security implications of synthetic biology, see International Council for the Life Sciences, *Security Aspects of Synthetic Biology*, report of a Meeting, 5-7 2012, Heidelberg, Germany; International Council for the Life Sciences, *Security Aspects of Synthetic Biology*, report of a Meeting, 7-8 March 2013, Hong Kong, both available at <http://iclscharter.org/our-work/synthetic-biology/> (accessed 28/01/2014); Alexander Kelle, *Synthetic Biology and Biosecurity Awareness in Europe*, Bradford Science and Technology Report No.9, November 2007, available at http://www.synbiosafe.eu/uploads/pdf/Synbiosafe-Biosecurity_awareness_in_Europe_Kelle.pdf (accessed 28/01/2014); UNICRI, *Security Implications of Synthetic Biology and Nanobiotechnology: A Risk and Response Assessment of Advances in Biotechnology* (Turin: UNICRI, 2012), available at http://www.unicri.it/in_focus/files/UNICRI%202012%20Security%20Implications%20of%20Synthetic%20Biology%20and%20Nanobiotechnology%20Final%20Public-1.pdf (accessed 28/01/2014). On the social and ethical aspects of synthetic biology, see Presidential Commission for the Study of Bioethical Issues, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*, December 2010, available at <http://bioethics.gov/synthetic-biology-report> (accessed 28/01/2014); Andrew Balmer and Paul Martin, *Synthetic Biology: Social and Ethical Challenges*, May 2008, Institute for Science and Society, University of Nottingham, available at http://www.bbsrc.ac.uk/web/files/reviews/0806_synthetic_biology.pdf (accessed 28/01/2014).

⁴⁵⁶ See Kathleen Vogel, ‘Framing Biosecurity: An alternative to the Biotech Revolution Model’, *Science and Public Policy*, vol.35:1 (2008), pp.45-54; James Revill and Catherine Jefferson, ‘Tacit Knowledge and the Biological Weapons Regime’, *Science and Public Policy*, (2013), pp.1-14. Vogel’s view are contested in Jonathan Tucker ‘Could Terrorists Exploit Synthetic Biology’, *The New Atlantis*, No.31 (Spring 2011), pp.69-81.

⁴⁵⁷ James Randerson, ‘Lax Laws, Virus DNA and Potential for Terror’, *The Guardian*, 14 June 2006, available at <http://www.theguardian.com/science/2006/jun/14/weaponstechnology.uk> (accessed 14/01/2014). On the issue of commercial order screenings, see Stephen Maurer et al. *Making Commercial Biology Safer: What the Gene Synthesis Industry Has Learned about Screening Customers and Orders*, Working Paper, 17 September 2009, available at http://gspp.berkeley.edu/assets/uploads/page/Maurer_IASB_Screening.pdf (accessed 28/01/2014); Michele Garfinkel et al. *Synthetic Genomics: Options for Governance*, October 2007, available at <http://www.synbiosafe.eu/uploads/pdf/Synthetic%20Genomics%20Options%20for%20Governance.pdf> (accessed 28/01/2014). On the governance of synthetic biology, see Catherine Lyall, ‘Governing Genomics: New Governance Tools for New Technologies’, *Technology Analysis and Strategic Management*, vol.19:3 (2007), pp.369-386; Hans Bugl et al. ‘DNA Synthesis and Biological Security’, *Nature Biotechnology*, vol.25:6 (2007), pp.627-629; Stephen Maurer and Sebastian von Engelhardt, ‘Industry Self-Governance: A New Way to Manage Dangerous Technologies’, *Bulletin of the Atomic Scientists*, vol.69:3 (2013), pp.53-62; Jennifer Kuzma and Todd Tanji, ‘Unpacking Synthetic Biology: Identification of Oversight Policy Problems and Options’, *Regulation and Governance*, vol.4 (2010), pp.92-112; Filippa Lentzos, ‘Synthetic Biology, Security and Governance’, *BioSocieties*, vol.7:4 (2012), pp.339-351.

⁴⁵⁸ Markus Schmidt and Gregor Giersch, ‘DNA Synthesis and Security’, in Marissa Campbell (ed.), *DNA Microarrays, Synthesis and Synthetic DNA* (Nova Science Publishers, 2012), p.296.

genome sequencing can be performed within hours at a price of roughly 1000 dollars or less.⁴⁵⁹ While still in its infancy, personalised medicine and individual genetic testing are steadily gaining popularity. Indeed, 'up to 100 000 people in England are expected to have their entire genetic makeup mapped in the first stage of an ambitious public health programme' launched by the National Health Service in 2012 that aims to 'revolutionise the treatment and prevention of cancer and other disease.'⁴⁶⁰ According to its proponents, genomic testing offers numerous advantages *vis-à-vis* traditional evidence-based medicine, including the possibility of early diagnostics of disease, of individually-tailored treatment and, perhaps most importantly, of disease prevention, as illustrated in the resolve of the Hollywood actress Angelina Jolie to undergo double mastectomy after discovering she has an inherited genetic mutation that puts her at high risk of breast and ovarian cancer.⁴⁶¹ But this is just the beginning. In 2012 scientists managed to sequence a foetus's entire genome using a blood sample from the mother and a saliva specimen from the father, a development that could potentially allow for a range of genetic disease conditions to be detected prenatally.⁴⁶² And laboratory experiments have already demonstrated the efficacy of genetic therapy to cure mitochondrial disease by creating an embryo with genetic material from both parents and a third person acting as a donor.⁴⁶³

⁴⁵⁹ See Paul Rincon, 'Science Enters \$1,000 Genome Era', *BBC News*, 15 January 2014, available at <http://www.bbc.co.uk/news/science-environment-25751958> (accessed 27/01/2014); Carole Cadwalladr, 'What Happened When I Had My Genome Sequenced', *The Observer*, 8 June 2013, available at <http://www.theguardian.com/science/2013/jun/08/genome-sequenced> (accessed 9/01/2014); Julia Kollowe, 'DNA Machine Can Sequence Human Genomes in Hours', *The Guardian*, 17 February 2012, available at <http://www.theguardian.com/science/2012/feb/17/dna-machine-human-sequencing> (accessed 9/01/2014). For information on the Human Genome Project, see <http://www.genome.gov/10001772> (accessed 9/01/2014). For information about commercial companies offering full-genome sequencing, see <http://www.illumina.com/> (accessed 9/01/2014). For an overview of the developments in genome-based therapy, see Steve Olson and Adam Berger, *Genome-Based Diagnostics: Clarifying Pathways to Clinical Use: Workshop Summary*, (Washington DC: National Academies Press, 2012); Adam Berger and Steve Olson, *Genome-Based Therapeutics: Targeted Drug Discovery and Development: Workshop Summary*, (Washington DC: National Academies Press, 2012).

⁴⁶⁰ Peter Walker, 'DNA of 100,000 People to be Mapped for NHS', *The Guardian*, 10 December 2012, available at <http://www.theguardian.com/science/2012/dec/10/1000000-peoples-dna-mapped> (accessed 9/01/2014).

⁴⁶¹ See Q. Tian et al, 'Systems Cancer Medicine: Towards Realisation of Predictive, Preventive, Personalised and Participatory (P4) Medicine', *Journal of Internal Medicine*, vol. 271 (2012), pp.111-121; Ben Quinn, 'Angelina Jolie "Grateful and Moved" by Reaction to Her Mastectomy Decision', *The Guardian*, 2 June 2013, available at <http://www.theguardian.com/film/2013/jun/02/angelina-jolie-mastectomy-grateful-reaction> (accessed 9/01/2014).

⁴⁶² Andrew Pollack, 'DNA Blueprint for Fetus Built Using Tests of Parents', *New York Times*, 6 June 2012, available at http://www.nytimes.com/2012/06/07/health/tests-of-parents-are-used-to-map-genes-of-a-fetus.html?pagewanted=1&_r=5 (accessed 9/01/2014).

⁴⁶³ Ian Sample, "'Three-Parent Babies" Cure for Illness Raises Ethical Fear', *The Guardian*, 5 June 2012, available at <http://www.theguardian.com/science/2012/jun/05/mitochondrial-genetic-disease-ethical-doubts> (accessed 9/01/2014).

While truly breathtaking, the advances outlined above raise a host of thorny issues of ethical, social and legal concern that merit public scrutiny and extensive deliberation before decisions regarding their widespread application are made. At a very basic level, there is the question of whether and to what extent we as individuals are capable of assimilating the information that our own genetic makeup may reveal. Are we sufficiently resilient to cope with the emotional distress, anxiety, shame, stigma and guilt that the awareness of severe medical conditions that we or our closed ones are suffering or likely to develop? Far from hypothetical, this question has prompted the establishment of a novel profession, that of the genetics counsellor whose task is to help patients overcome any negative effects, stress, or psychological trauma that the disclosure of their genomic map may create.⁴⁶⁴ This is just a partial solution though, for the crux of the matter lies in finding a way to deal effectively with risk and probabilities and we as humans are yet to demonstrate a capacity for understanding or relating them to our own lives.⁴⁶⁵

Individual emotional turmoil, however significant, constitutes only the tip of the iceberg. According to Daniel Kevles, the torrent of new genetic information has already begun to fundamentally reconfigure social practices and inter-personal relations:

It has been rightly emphasised that employers and medical or life insurers may seek to learn the genetic profiles of, respectively, prospective employees or clients. Employers might wish to identify workers likely to contract disorders that allegedly affect job performance while both employers and insurers might wish to identify people likely to fall victim to diseases that result in costly medical or disability payouts. Whatever the purpose, such genetic identification would brand people with what an American union official has called a life-long “genetic scarlet letter” or what some Europeans term a “genetic passport”.⁴⁶⁶

⁴⁶⁴ See Carole Cadwalladr, ‘What Happened When I Had My Genome Sequenced’, *op cit*.

⁴⁶⁵ *Ibid*. Another point that Cadwalladr raises is the danger of a negative placebo effect whereby doubts about certain genetic disorder may lead to psychosomatic symptoms.

⁴⁶⁶ Daniel Kevles, ‘From Eugenics to Patents: Genetics, Law, and Human Rights’, *Annals of Human Genetics*, vol.75:3 (2011), p.330.

Linking genetic makeup with human identity would ultimately set the scene for the proliferation of technologies aimed at human enhancement: after all, if a gene therapy could allow one to stand a chance in a job competition, boosting one's capabilities would potentially make them a more desirable candidate. Other issues of more immediate concern are also likely to arise. One is privacy. Gene-sequencing companies usually hold the genetic data of their clients in digital format on online platforms, which automatically creates a risk that personal information may be leaked, hacked or stolen.⁴⁶⁷ Further, there is the question of ownership. Consider, for instance, the controversial issue of human gene patenting, whereby patented genes are treated as research tools and, as such, are controlled by the patent holder who may restrict and charge for their use.⁴⁶⁸ Thus created, the system often operates to the detriment of patients by hindering research practice, elevating diagnostics prices and denying access to second and independent medical opinion.⁴⁶⁹ Gene identification alone has a potential 'dark side' too, for it could enable the development of weapons targeted at group-specific gene markers (e.g. ethnicity).⁴⁷⁰

Pre-natal genetic testing is yet another significant bone of contention, not least because it evokes notions of state-mandated eugenic programmes and assaults on human rights and dignity. While a Nazi-like campaign for a superior race seems improbable in the twentieth-first century, this is not to say that other forms of eugenics may not be encouraged. Indeed, some commentators have highlighted the rise of 'homemade eugenics',⁴⁷¹ whereby individual families can make decisions on the attributes of their progeny:

⁴⁶⁷ See Abdul-Karrem Ahmed, 'Unhidden Traits: Genomic Data Privacy Debates Heat Up', *Scientific American*, 14 August 2013, available at <http://www.scientificamerican.com/article/unhidden-traits-genomic-data-privacy-debates-heat-up/> (accessed 27/01/2014).

⁴⁶⁸ Daniel Kevles, 'From Eugenics to Patents', *op cit*, p.330.

⁴⁶⁹ *Ibid*, p.331. See also Harriet Washington, *Deadly Monopolies: The Shocking Corporate Takeover of Life Itself – and the Consequences for Your Health and Our Medical Future* (New York: Doubleday, 2011); Sheila Jasanoff 'Taking Life: Private Rights in Public Nature' in Kaushik Sunder Rajan ed. *Lively Capital: Biotechnologies, Ethics, and Governance in Global Markets* (Duke University Press, 2012), pp.155-184.

⁴⁷⁰ See National Research Council, *Globalization, Biosecurity, and the Future of the Life Sciences*, *op cit*; Malcolm Dando, 'Benefits and Threats of Developments in Biotechnology and Genetic Engineering' in SIPRI Yearbook, *Armaments, Disarmament and International Security* (Oxford: Oxford University Press, 1999). On Ethnic gene markers, see Alice Roberts, *The Incredible Human Journey: The Story of How We Colonised the Planet* (London: Bloomsbury, 2009); Mark Shriver et al. 'Ethnic-Affiliation Estimation by Use of Population-Specific DNA Markers', *American Journal of Human Genetics*, vol.60, (1997), pp.957-964; Alastair Wood, 'Racial Differences in the Response to Drugs – Pointers to Genetic Differences', *New England Journal of Medicine*, vol.344:18 (2001), pp.1393-1395.

⁴⁷¹ Robert Wright, 'The Achilles' Helix', *New Republic*, vol.203:2-3 (1990), pp. 21-26.

The lure of biologically improving the human race, having tantalised brilliant scientists in the past, could equally seduce them in the future, even though the expression of the imperatives may differ in language and sophistication. Objective, socially unprejudiced knowledge is not *ipso facto* inconsistent with eugenic goals of some type. Such knowledge may, indeed, assist in seeking them, especially in the consumer-oriented, commercially driven enterprise of contemporary biomedicine.⁴⁷²

It is plausible to assume that when presented with the opportunity of having their future child tested for genetic disorders, many parents would barely hesitate to accept. Such a resolve could have far-reaching implications though. For instance, some genetic therapies entail the use of donor DNA different from that of the parents, whereby any genetic modifications in the embryo will pass down to future generations.⁴⁷³ Despite the government support for the ‘three-parent babies’ in the UK, local religious organisations have protested vociferously against the legalisation of the technique.⁴⁷⁴ At the same time, there are certain genetic disorders that can be diagnosed at an early stage but, as of yet, cannot be cured, which inevitably poses the tough choice between raising an unhealthy child and abortion. To be sure, such questions constitute more than individual parents’ dilemmas, for they touch upon established social and cultural values, something evident in the profound differences across national reproductive policies. More broadly, there are concerns that reproductive genomics may remain a prerogative of those affluent enough to afford it, thus further exacerbating the divide between the global rich and the global poor.⁴⁷⁵

⁴⁷² Daniel Kevles, ‘From Eugenics to Patents’, *op cit*, p.330.

⁴⁷³ Ian Sample, ‘Britain Ponders “Three-Person” Embryos to Combat Genetic Disease’, *The Guardian*, 20 March 2013, available at <http://www.theguardian.com/science/2013/mar/20/britain-three-person-embryos-genetic> (accessed 10/01/2014).

⁴⁷⁴ See Department of Health and Human Fertilisation and Embryology Authority, *Innovative Genetic Treatment to Prevent Mitochondrial Disease*, Press Release, 28 June 2013, available at <https://www.gov.uk/government/news/innovative-genetic-treatment-to-prevent-mitochondrial-disease> (accessed 10/01/2014); Peter Saunders, ‘Three-Parent Embryos for Mitochondrial Disease? Twelve Reasons for Caution’, *LifeSiteNews*, 28 June 2013, available at <http://www.lifesitenews.com/blog/three-parent-embryos-for-mitochondrial-disease-twelve-reasons-for-caution> (accessed 10/01/2014); Ian Sample, ‘“Three-Parent” Babies Explained: What Are the Concerns and Are They Justified?’, *The Guardian*, 2 February 2015, available at <http://www.theguardian.com/science/2015/feb/02/three-parent-babies-explained> (accessed 22/09/2015). In February 2015, the UK passed legislation allowing the use of the technique. See James Gallagher, ‘UK Approves Three-Person Babies’, *BBC News*, 24 February 2015, available at <http://www.bbc.co.uk/news/health-31594856> (accessed 22/09/2015).

⁴⁷⁵ See Ronald Green, ‘Building Baby from the Genes Up’, *The Washington Post*, 13 April 2008, available at <http://www.washingtonpost.com/wp-dyn/content/article/2008/04/11/AR2008041103330.html> (accessed 10/01/2014).

Diffusion of Life Science Expertise: International Collaboration, De-Skilling and Amateur Biology

The growth of life science capacity over the past few decades across the globe has been truly astonishing, leading to the emergence of a vibrant research community that brings together researchers from various parts of the world. Indeed, a 2011 NAS report highlights the extension of both North-South and South-South partnerships, which has played a key role in synergising strengths and maximising competitiveness by improving the quality and effectiveness of research and facilitating data sharing.⁴⁷⁶ At the same time, increasing collaboration in the realm of biotechnology industry has offered companies situated in emerging economies access to the global market, thus contributing to economic development and growth.⁴⁷⁷

Recent advances in technology and laboratory and experimental equipment have further impacted on the practice of life science research in profound ways. Improvements in DNA sequencing technology have significantly shortened the time required for the preparation of nucleic base-lines, thus relieving scientists of the burden of completing the task themselves and allowing them to focus on their actual project instead. Studies and experiments once performed by senior researchers with extensive experience are now carried out by Masters students. Aided by specially designed genetic engineering toolkits, children as young as the age of ten start exploring the realm of biology in an interactive and engaging manner. Needless to say, their notion of science and the world in general would differ significantly from that of their parents whose primary sources of knowledge used to be textbooks and encyclopaedias. Indeed, the increasing commercialisation of synthetic biology offers anyone curious enough to fiddle with biological systems the chance of doing so in the comfort of their own

⁴⁷⁶ US National Academy of Science, *Life Sciences and Related Fields*, *op cit*, p.63. One commentator distinguishes between 'Big Science' which was 'to-down, hierarchical, vertical' and 'networked science' characterised by 'open systems, open software, open participation'. See Diane Rhoten, 'The Dawn of Networked Science', *Chronicle of Higher Education*, vol.54:2, (2007), pp.78-90. On the changing patterns of science collaboration, see James Porter, 'Changing Dynamics of Collaboration in Life Sciences', *Science as Culture*, vol.22:3 (2013), pp.388-393.

⁴⁷⁷ *Ibid.*

home.⁴⁷⁸ Such modern gene hackers often lack formal background in biology and come from various walks of life. Driven by an insatiable appetite for knowledge and the vision of a ground-breaking discovery that could be turned into a multi-million dollar profit, they take up the rather unusual hobby of biohacking which entails the redesign of existing and the creation of novel biological systems. For just few hundred dollars bio enthusiasts set up laboratories easily obtaining all essential requisites and equipment from online sales. And if to some biohacking equates to little more than an unusual hobby, others highlight its potential to generate substantial revenue and fuel economic development.⁴⁷⁹

Contrary to popular expectation, biohackers are not just eccentric individuals who work in solitude away from public attention. Rather, they are members of a wide global movement dedicated to the ideal of Do-It-Yourself Biology (DIY), which has branches in 45 locations on four continents.⁴⁸⁰ The movement has been partially institutionalised through the establishment of the BioBricks⁴⁸¹ and International Genetically Engineered Machine (iGEM) Foundations, which seek to promote the open and ethical conduct of biological engineering and stimulate innovation and creativity. To this end, iGEM holds an annual competition open to high school students, university undergraduates and entrepreneurs from all over the world. With more than 200 participating teams, the competition constitutes the premiere forum at which biohackers can showcase their skills through project presentation.

Exciting as it may seem, the ongoing diffusion of life science expertise poses an array of governance conundrums. At the level of professional practice, the proliferation of research facilities around the world has exposed the urgent need for laboratory biosafety and biosecurity training, especially in developing states where a tradition of handling dangerous pathogens is

⁴⁷⁸ See, for example, Marcus Wohlsen, *Biopunk: Solving Biotech's Biggest Problems in Kitchens and Garages* (New York: Penguin, 2011); Heidi Ledford, 'Life Hackers', *Nature*, vol.467 (2010), pp.650-652; Editorial, 'Garage Biology' *Nature*, vol.467 (2010), p.634.

⁴⁷⁹ Robert Carlson, *Biology Is Technology: The Promise, Peril, and New Business of Engineering Life* (Cambridge MA: Harvard University Press, 2010).

⁴⁸⁰ For more information, see <http://diybio.org/> (accessed 14/01/2014).

⁴⁸¹ For more information, see <http://biobricks.org/about-foundation/> (accessed 14/02/2014); http://igem.org/Main_Page (accessed 14/02/2014).

lacking. The issue is further complicated, for such countries often lack the required legal and institutional infrastructure to ensure that professional practice is in compliance with relevant international regulations. Foreign aid has gone some way in helping overcome those deficiencies but it has given rise to new problems, too. For instance, it is far from unlikely for a donor state to provide material support for the construction of a state-of-the-art laboratory eventually leaving its maintenance to the local government, which can hardly afford the subsequent costs. A similar trend is observed in the area of capacity building and human resource development. Most projects that aim to promote biorisk management and a biological security culture tend to be severely constrained in terms of time and funding and overly ambitious in terms of agenda and expected outcomes. Lack of adequate mechanisms for quality assessment hinders progress evaluation and sometimes leads to duplication of effort and resources.

The emergence of the DIY biologists in the life science arena has further added to the challenge of ensuring that novel scientific and technological developments are utilised in a safe and ethical manner. Even at the level of everyday practice, difficulties still persist. For instance, many amateur scientists have complained of the lack of manuals and guidelines regarding the safe operation and maintenance of home laboratories. Issues such as waste disposal, safe handling and storage of biological material and prevention of contamination pervade the work of biohackers who unlike professional researchers conduct experiments in a much more volatile environment.⁴⁸² Potential security concerns are also present. With more and more individuals gaining access to biological engineering technologies, ensuring appropriate oversight of what goes on in garage laboratories becomes increasingly difficult. The experience of the US FBI is a case in point. Back in 2004 the FBI arrested Steven Kurtz, a professor at the University of Buffalo under the suspicion of plotting a bioterrorist attack.⁴⁸³

⁴⁸² See, for example, Markus Schmidt, 'Diffusion of Synthetic Biology: A Challenge to Biosafety', *Systems and Synthetic Biology*, vol.2:1-1 (2008), pp.1-6; Markus Schmidt, 'Do I Understand What I Can Create: Biosafety Issues in synthetic Biology' in Markus Schmidt et al. (ed.), *Synthetic Biology: The Technoscience and Its Societal Consequences* (Dordrecht: Springer, 2010).

⁴⁸³ 'Charge Dropped against Artist in a Terror Case', *The Associated Press*, 22 April 2008, available at http://www.nytimes.com/2008/04/22/nyregion/22bioart.html?_r=2& (accessed 14/02/2014).

The subsequent investigation revealed that all laboratory and DNA extraction equipment found in Kurtz's house was legitimately obtained and used in his artwork. In an attempt to avoid mistakes of this kind, the FBI has drastically changed its approach to dealing with the DIY movement launching a series of outreach activities that seek to raise awareness of the potential security implications of biohacking.⁴⁸⁴ While undoubtedly necessary, such initiatives may well be seen as too little, too late in light of the wide spread of materials, tools and devices that could facilitate the malign misuse of the life sciences. Indeed, it is worth noting that as early as the late 1990s the US Defence Threat Reduction Agency (DTRA) managed to build a research facility that simulated the manufacture of weaponised anthrax using only commercially available materials and equipment.⁴⁸⁵

The Role of States: Both a Poacher and Gamekeeper

Structural factors have an important bearing on the development and growth of biotechnology. Economic considerations, power interests and realist fears generate potent dynamics that shape and influence and sometimes direct the life science trajectory. Within this context, states assume a dual role. On the one hand, they are expected to act as gamekeepers and regulate, monitor and control the process of life science research and the dissemination of novel technologies. On the other hand, though, they also have powerful incentives to act as 'poachers', not least because of the fascinating opportunities for enhancing their prosperity, prestige and security that

⁴⁸⁴ See Edward Lempinen, 'FBI, AAAS Collaborate on Ambitious Outreach to Biotech Researchers and DIY Biologists', *AAAS News*, 1 April 2011, available at <http://www.aaas.org/news/fbi-aaas-collaborate-ambitious-outreach-biotech-researchers-and-diy-biologists> (accessed 28/02/2014). Alternative governance frameworks include: National Science Advisory Board for Biosecurity (NSABB), *Strategies to Educate Amateur Biologists and Scientists in Non-Life Science Disciplines About Dual Use Research in the Life Sciences*, June 2011, available at http://oba.od.nih.gov/biosecurity/pdf/FinalNSABBReport-AmateurBiologist-NonlifeScientists_June-2011.pdf (accessed 28/02/2014); Catherine Jefferson, *Governing Amateur Biology: Extending Responsible Research and Innovation in Synthetic Biology to New Actors*, Research Report for the Wellcome Trust Project 'Building Sustainable Capacity in Dual Use Bioethics', 2013, available at http://www.brad.ac.uk/bioethics/media/ssis/bioethics/docs/Jefferson_Governing_Amateur_Biology.pdf (accessed 28/02/2014).

⁴⁸⁵ See Jerry Seper, 'Secret Project Manufactured Mock Anthrax', *The Washington Times*, 26 October 2001, available at <http://www.washingtontimes.com/news/2001/oct/26/20011026-030448-2429/> (accessed 28/02/2014); Judith Miller et al. *Germs: Biological Weapons and America's Secret War* (New York: Simon & Schuster, 2001), pp.297-299.

scientific and technological development open up.⁴⁸⁶ The following passage effectively outlines states' dual function:

Government has an important role in setting long-term priorities and in making sure a national environment exists in which beneficial innovations will be developed. There must be a free and rational debate about the ethical and social aspects of potential uses of technology, and government must provide an arena for these debates that is most conducive to results that benefit humans. At the same time, government must ensure economic conditions that facilitate the rapid invention and deployment of beneficial technologies, thereby encouraging entrepreneurs and venture capitalists to promote innovation.⁴⁸⁷

Given that the agent (i.e. state governments) in charge of initiating ethical debates on the progress of biotechnology is also the one expected to provide the conditions that would allow this progress to generate outcomes likely to contribute to economic growth and political superiority, it is hardly surprising that any issues likely to slow down or otherwise hinder the enormous momentum of the life sciences are omitted from public discussion. This duality further informs how risks are perceived, framed and addressed. For instance, even though most of the developing countries lack capacity to manage dual use research of concern, they do not see this as an immediate priority and prefer to invest effort and resources in improving their laboratory biosafety and laboratory biosecurity infrastructure and capacity.⁴⁸⁸ In the view of their governments, the dangers of naturally occurring and circulating diseases constitute a far greater worry than the potential for misuse of cutting-edge research. By contrast, some developed countries, most notably the USA, have embarked on building their biological defence systems highlighting the grave threat posed by the potential use of bioweapons by non-state actors. Their activities have encountered severe opprobrium as

⁴⁸⁶ Jim Whitman, 'Global Governance and the Twenty-First Century Technology' in Brian Rappert (ed.), *Technology and Security: Governing Threats in the New Millennium*, (Basingstoke: Palgrave, 2007), p.96.

⁴⁸⁷ Mihail Roco and William Sims Bainbridge, *Converging technologies for Improving Human Performance: Nanotechnology, Biotechnology, Information technology and Cognitive Science*, (Washington, DC: National Science Foundation, 2002), p.30.

⁴⁸⁸ *Report of the WHO Informal Consultation on Dual Use Research of Concern*, 26-28 February 2013, Geneva Switzerland, available at http://www.who.int/csr/durc/durc_feb2013_full_mtg_report.pdf (accessed 28/01/2014).

some analysts see them as a contravention of the norms embedded in the BTWC.⁴⁸⁹

The evolution of the chemical and biological non-proliferation regime epitomises the attempts of states to avert the hostile exploitation of the life sciences whilst promoting their use for ‘peaceful, prophylactic and protective purposes’. The entry into force of the BTWC and the Chemical Weapons Convention (CWC) in 1975 and 1997, respectively, is indicative both of states’ renunciation of chemical, biological and toxin weapons and of their commitment to the goals of arms control and disarmament. That said, the imperfections and shortcomings of these treaties signify the influence of realist fears and political calculations that pervade international negotiations. In the case of the BTWC, two points merit attention. The first pertains to the lack of verification mechanism when the treaty was first agreed back in the early 1970s. Subsequent revelations of secret state-led offensive biological programmes in the former Soviet Union, South Africa and Iraq up until the early 1990s have significantly undermined the Convention. Second, the failure to negotiate a binding protocol in 2001 has further dimmed the prospects for strengthening the regime and thus ensuring universal compliance with its prescriptions. Less acute but just as worrying is the situation regarding the CWC. Even though the Convention is exemplary in many respects, not least because of its verification system, almost universal membership and implementing body – Organisation for the Prohibition of Chemical Weapons (OPCW) – it still faces serious challenges that need to be considered. For instance, while the treaty bans the development, production, acquisition and retention of chemical weapons, the definition of ‘purposes not prohibited under th[e] Convention’ entails ‘law enforcement including domestic riot control purposes’ (Article II.9d). Some commentators have argued that given the lack of a universally agreed definition what kind of activities count as ‘law enforcement’, this text opens a major loophole in the

⁴⁸⁹ Alexander Kelle et al. *Preventing a Biochemical Arms Race* (Stanford: Stanford University Press, 2013), chapter 5; Jonathan Tucker, ‘Biological Threat Assessment: Is the Cure Worse than the Disease?’, *Arms Control Today*, vol.34 (October 2004), available at http://www.armscontrol.org/act/2004_10/Tucker (accessed 20/01/2014).

Convention.⁴⁹⁰ Several States Parties of the Convention have voiced concerns in this regard. Australia has noted that:

The weaponisation of [Central Nervous System] acting chemicals for law enforcement purposes is of concern to Australia due to the health and safety risks and the possibility of their deliberate misuse, both of which have the potential to undermine the global norm against the use of toxic chemicals for purposes prohibited by the Convention. [...] Australia's position is that it is not possible for a State Party to disseminate anaesthetics, sedatives or analgesics by aerial dispersion in an effective and safe manner for law enforcement purposes.⁴⁹¹

Critics highlight the possibility for the deployment of novel chemical weapons for the purposes of countering terrorism, something evident in the 2002 Moscow theatre siege (Dubrovka) when the Russian security forces used a fentanyl-derivative agent, as a result of which about a sixth of the hostages and all of the terrorists involved died.⁴⁹² In 2011 the European Court of Human Rights ruled with regard to the Dubrovka operation that:

there had been no violation of Article 2 (right to life) of the European Convention on Human Rights concerning the decision to resolve the hostage crisis by force and use of gas.⁴⁹³

The Court, nonetheless, noted that:

Even if the gas had not been a "lethal force" but rather a "non-lethal incapacitating weapon", it had been dangerous and even potentially fatal for a weakened person [...].⁴⁹⁴

The Court further confirmed some of the earlier criticisms that were levelled against the Government, particularly in terms of preparedness and provision

⁴⁹⁰ Julian Perry Robinson, 'Difficulties Facing the Chemical Weapons Convention', *International Affairs*, vol.84:2 (2008), p.228; Michael Crowley, *Dangerous Ambiguities: Regulation of Riot Control Agents and Incapacitants under the Chemical Weapons Convention*, Bradford Non-Lethal Weapons Research Project, October 2009, University of Bradford. Available at <http://www.brad.ac.uk/bioethics/monographs/> (accessed 21/07/2015).

⁴⁹¹ Statement By Australia, *Weaponisation of Central Nervous System Acting Chemicals for Law Enforcement Purposes*, XIX Session of the Conference of the States Parties, 1-5 December 2014, OPCW, the Hague, the Netherlands. Available at <https://www.opcw.org/index.php?id=2520> (accessed 21/07/15).

⁴⁹² Artem Krechetnikov, 'Moscow Theatre Siege: Questions Remain Unanswered', *BBC News*, 24 October 2012, available at <http://www.bbc.co.uk/news/world-europe-20067384> (accessed 28/01/2014).

⁴⁹³ Registry of the European Court of Human Rights, *Press Release: Use of Gas against Terrorists during the Moscow Theatre Siege Was Justified, but the Rescue Operation afterwards Was Poorly Planned and Implemented*, ECHR 295 (2011), 20 December 2011.

⁴⁹⁴ *Ibid.*

of medical assistance.⁴⁹⁵ According to the ruling, Russia had to pay damages to all the 64 applicants – representatives of siege victims. To date, Russian officials have withheld information concerning the exact formula of the gas, which was used during the Dubrovka operation, on security grounds.⁴⁹⁶ Given the lack of an internationally agreed definition of what constitutes ‘terrorism’ on the one hand, and the rise of irregular/asymmetric warfare and sporadic conflicts, on the other, some commentators have warned against the possibility of a ‘grey area’ which may enable states to utilise non-traditional methods of war to gain advantage.⁴⁹⁷

Speed Differential between Scientific Advancement and the Pace of Deliberative Systems

Deliberative systems encompass a vast array of practices, processes and mechanisms, both formal and informal, whereby a polity considers the ‘acceptability, appropriateness and control of novel developments in or impacting on, shared social and physical arenas’.⁴⁹⁸ By design, they reflect and are informed by the values, beliefs and standards shared among the group, or in other words, by the prevalent culture. As such, deliberative systems vary across societies with their intensity, inclusiveness and structure depending on the established political and social norms. Yet their chief purpose and function remain virtually the same, namely to help societies adapt to the changing circumstance of their milieu in a way that ensures stability, sustainability and safety.

Public deliberation requires time; and wide-ranging life science advances, current and planned, offer profound challenges to shared ideas and ideals about the foundations of human relatedness and of social coherence, justice,

⁴⁹⁵ See [in Russian] ‘Chto eto bylo? Spasenie zalozhnikov ili unichtozhenie terroristov?’, *Novaya Gazeta*, No.86, 21 November 2002, available at <http://www.novayagazeta.ru/society/14856.html> (accessed 6/02/16); John Dunlop, *The 2002 Dubrovka and 2004 Beslan Hostage Crises: A Critique of Russian Counter-Terrorism* (Stuttgart: Ibidem-Verlag, 2006).

⁴⁹⁶ [in Russian] Vladimir Bogdanov, ‘Sekretov bol’she net’, *Rossiskaya Gazeta*, No. 5917, 23 October 2012, available at <http://www.rg.ru/2012/10/22/pamyat-site.html> (accessed 6/02/16).

⁴⁹⁷ Julian Perry Robinson, ‘Difficulties Facing the Chemical Weapons Convention’, *op cit*, p.226-227. See also National Research Council, *Avoiding Surprise in an Era of Global Technology Advances*, (Washington DC: National Academies Press, 2005), particularly Chapter 6.

⁴⁹⁸ Jim Whitman, ‘The Challenge to Deliberative Systems of Technological Systems Convergence’, *Innovation: The European Journal of Social Science Research*, vol.20:4 (2007), p.330.

human dignity and many other norms, both formal and informal.⁴⁹⁹ Yet given the ruminative nature of deliberative processes, on the one hand, and the fast speed at which biotechnology innovation is evolving on the other, the danger of the former being steadily outpaced and overburdened by the latter is far from hypothetical. Consider the following passage sketching the scale of social changes likely to arise from the increasing convergence between nanotechnology, biotechnology, cognitive neuroscience and information technology:

In the foreseeable future, we will be inundated with new inventions, new discoveries, new start-ups, and new entrepreneurs. These will create new goods and new services. [...] As expectations change, the process of politics and government will change. People's lives will be more complex and inevitably overwhelming. Keeping up with the changes that affect them and their loved ones exhausts most people. They focus most of their time and energy on tasks of everyday life. In the future, when they achieve success in their daily tasks, people will turn to the goods and services, the new job and investment opportunities, and the new ideas inherent in the entrepreneurial creativity of the Age of Transitions. No individual and no country will fully understand all of the changes as they occur or be able to adapt to them flawlessly during this time.⁵⁰⁰

This vision of a 'brave new world' merits attention on two important grounds. First, it implies that the changes likely to occur in the not too distant future as a result of the rapid progress of science and technology are imminent and unavoidable in the sense that their advent hardly depends on or even requires extensive public deliberation. Second, given that our capacity for adaptation to and grasp of those changes will be considerably impaired, the Age of Transitions leaves little space for public deliberation. To add to this gloomy picture, there is already some evidence that the progress in the life sciences is overwhelming the existing deliberative mechanisms. For instance, Kelle et al. argue that the rapidity of biotechnology advancement coupled with the immensity and complexity of the knowledge accumulated

⁴⁹⁹ Ibid, p.336.

⁵⁰⁰ Mihail Roco and William Sims Bainbridge, *Converging technologies for Improving Human Performance*, *op cit*, p.39-40.

therefrom complicates efforts to deal with potential risks, something evident in the regulatory gap that the convergence of chemistry and biology has created in the area of arms control.⁵⁰¹ This is problematic, for the reduced resilience of deliberative systems provides favourable conditions in which scientific and technological innovation can continue unabated. A vicious circle is thus created in which the inability of deliberative systems to cope with the strain exerted by biotechnology advancement fuels the latter turning it into a self-propelling force. The proliferation of contentious ‘gain-of-function’ research is a case in point. Even though the H5N1 controversy discussed in the preceding sections exposed the limitations of existing governance mechanisms for addressing the potential security, ethical and legal implications arising from such studies, it hardly precluded scientists from conducting similar experiments. Indeed, less than four months after the moratorium on research involving contagious H5N1 virus was lifted, a team of Chinese researchers announced the creation of a hybrid of the H5N1 strain and the H1N1 virus that caused the 2009 flu pandemic.⁵⁰² And it was not long until the newly-emerged H7N9 influenza virus became airborne, as well.⁵⁰³ If anything, those examples indicate that in light of the rapid pace of life science progress, addressing governance concerns on a case-by-case basis is not only self-defeating but given the number and variety of conundrums, it is likely to become unsustainable in the long run.

Runaway Biotechnology?

Given the significant potential of biotechnology to bring about multifaceted changes in different spheres of life and generate considerable benefits in the form of new products, enhancement of public and private capital and alleviation of social ills, there is a powerful urge to allow the ongoing expansion of the life sciences to proceed largely unfettered. Risks are carefully calculated and, where possible, downplayed as hypothetical at the

⁵⁰¹ See Alexander Kelle et al. *Preventing a Biochemical Arms Race*, *op cit*, p.60; Julian Perry Robinson, ‘Bringing the BWC Conventions Closer Together’, *The CBW Conventions Bulletin*, Issue 80 (2008), pp.1-4, available at <http://www.sussex.ac.uk/Units/spru/hsp/documents/cbwcb80.pdf> (accessed 20/01/2014).

⁵⁰² See Ying Zhang et al. ‘H5N1 Hybrid Viruses Bearing 2009/H1N1 Virus Genes Transmit in Guinea Pigs by Respiratory Droplet’, *Science*, vol. 340:6139, pp.1459-1463.

⁵⁰³ Maria Zhu et al. ‘Infectivity, Transmission, and Pathology of Human-Isolated H7N9 Influenza Virus in Ferrets and Pigs’, *Science*, vol.34:6142 (2013), pp.183-186; Mathilde Richard et al. ‘Limited Airborne Transmission of H7N9 Influenza A Virus between Ferrets’, *Nature*, vol.501 (2013), pp.560-563.

expense of comprehensive deliberation. And even when proposals for risk mitigation measures are entertained, preference is usually given to those unlikely to hinder the progress of life sciences. By and large, there is a genuine belief that the existing governance mechanisms in the area of biotechnology can accommodate and cope with the wide-ranging pressures exerted by scientific innovation and the rapid diffusion of technologies with multiple uses, by offering 'solutions' and handling concerns on a case-by-case basis. In particular, the technology of safety is still 'celebrated as an unadulterated improvement for society as a whole'.⁵⁰⁴

Yet there are reasons for scepticism toward the adequacy and effectiveness of the governance approaches currently in place. Much of the discussion in the preceding sections has focused on the ways in which the increasing pace, growth and global diffusion of biotechnology advances are beginning to expose the limits of the existing measures for control and risk management by challenging accepted values and beliefs and redefining established norms of practice. As the multifaceted dynamics driving the biotechnology momentum continue to intensify and multiply, it becomes more and more difficult to comprehend, let alone foresee, the various impacts that the large-scale deployment and proliferation of novel scientific and technological advances have both on our social systems and the environment. Given the tight coupling between human-made and natural systems and their complex, often unanticipated interactions with catastrophic potential, the existing narrow definitions of risk are rendered inadequate.⁵⁰⁵ At the same time, the advent of new technologies with multiple adaptive applications opens up an array of possibilities for hostile exploitation thus compelling governments to make tough decisions in an attempt to reconcile the benefits of biotechnology with the potential security concerns arising therefrom. While the advancement of biotechnology promises tremendous public health benefits, it also holds a considerable catastrophic potential, as the case of 'gain-of-function' experiments illustrate. As scientific capabilities and work involving dangerous pathogens proliferate globally, so do risks and the prospects of

⁵⁰⁴ Nan Goodman, *Shifting the Blame: Literature, Law, and the Theory of Accidents in Nineteenth-Century America*, (Princeton, NJ: Princeton University Press, 1998), p. 145.

⁵⁰⁵ Charles Perrow, *Normal Accidents*, *op cit*.

failures, whether technical or arising from human error. Indeed, assessing the rapidly evolving life science landscape some security commentators argue that 'current genetic engineering technology and the practices of the community that sustains it have definitively displaced the potential threat of biological warfare beyond the risks posed by naturally occurring epidemics'. Laboratories, however well equipped, do not exist in isolation but are an integral part of a larger ecological system. As such, they constitute a 'buffer zone' between the activities carried out inside and the wider environment. And despite being technically advanced and designed to ensure safety, this 'buffer zone', just as other safety systems is far from infallible. For one thing, mechanical controls leave room for human error and personal judgement, both of which are factors that could be highly consequential but which could hardly be modelled or predicted with exact certainty.⁵⁰⁶

The speed at which the transformation of the life sciences is taking place is yet another factor that adds to the complexity of life science governance. Stability is a fundamental condition for the development and preservation of human and natural systems alike. In social systems, culture is the primary source of stability, for it determines what values, beliefs, practices and modes of behaviour are deemed acceptable and, as such, lays the foundations of order (Chapter 1). All forms of governance therefore are cultural artefacts and manifestations of culture. Culture also provides the tacit standards whereby change is assessed and treated as acceptable or unacceptable. Hence, any state of affairs in which the rate of change precludes regulation disrupts the ordinary functioning of the system and jeopardises its preservation:

The breakdown of human regulation does not extinguish regulation of a simpler sort. [...] The system formed by men and the rest of the natural world will continue to regulate itself after a fashion, even if human regulation wholly fails at all levels above the primary group. But the resulting 'order' would exclude all those levels of human order which man-made stability makes possible.⁵⁰⁷

⁵⁰⁶ See Nan Goodman, *Shifting the Blame*, *op cit*, p. 147.

⁵⁰⁷ Geoffrey Vickers, *Freedom in a Rocking Boat: Changing Values in an Unstable Society* (London: Penguin Press, 1970), p.127.

To be sure, a world characterised by a runaway biotechnology would be far different from the one we know. The main challenge to averting this prospect lies in ensuring that the systems of governance are in sync with the progress of life sciences. History has shown that even highly developed, long-standing systems of governance can fail for reasons as diverse as disasters; loss of authority/legitimacy of governing bodies; and pervasive corruption. One further source of failure includes the inability of a society to adapt to its changing milieu:

Men are adaptable; they can learn to live even in harsh and hostile environments – so long as the environment remains constant enough to give them time to learn. [...] If they form the habit of adapting by constantly changing that to which they are trying to adapt, they build uncertainty into the very structure of their lives. They institutionalise cluelessness.⁵⁰⁸

The process of adaptation is closely connected to cultural patterns and any serious disruptions in the latter could have detrimental effects and impair it severely. The extent to which change is taking place within the framework of the prevalent culture defines the borderline between system evolution and system disintegration. The governance mechanisms currently in place, both formal and informal, are all a function of historical, cultural and socio-political contingencies. As such, their capacity for adaptation largely depends on our ability to comprehend and assimilate the complex changes that the progress of biotechnology brings about. They can only evolve as fast as our shared standards, values, routines and perceptions allow them to. And that is why governance can hardly be reduced to a technocratic exercise; on the contrary, to be effective, it requires extensive deliberation and full appreciation of the far-reaching implications of novel life science advances.

⁵⁰⁸ Geoffrey Vickers, *Human Systems Are Different*, *op cit.*, p.146; on the deleterious effects of rapid change that precludes the preservation of culture, see Helena Norberg-Hodge, 'Learning from Ladakh: A Passionate Appeal for 'Counter-Development'', *Earth Island Journal*, Vol.7:2 (1992), Jared Diamond, *Collapse: How Societies Choose to Fail or Survive*, (London: Penguin Books, 2005). Some commentators have critiqued the work of Diamond on the grounds of simplicity. For a summary of some of the criticisms levelled at his work, see Eric Powell, 'Do Civilisations Really Collapse', *Archaeology*, vol.61:2 (2008).

Chapter 5: Biotechnology Governance: The Case of Russia

The Governance of Biotechnology as Shaped by History, Politics, and Culture

The twentieth century witnessed a tremendous transformation in the attitude toward the role of science *vis-à-vis* society and the state. Rapid technological innovation manifested in the advent of new and more sophisticated modes of production, means of transport and communication, systems for energy supply, and wide-ranging consumer products attracted considerable public attention demonstrating the far-reaching implications of science for social progress and economic prosperity. At the same time, the military applications of cutting-edge technology resulted in the development weapons systems with enhanced accuracy and lethal capability endowing states with enormous destructive potential. From the electric light bulb and the telephone to mechanised manufacturing plants and mills; from the internal combustion engine to long-range missiles; and from rifles and machine guns to chemical weapons it was evident that science and technology were gradually beginning to have a bearing on everyday socio-economic and political life on a scale unprecedented before in history. The zeal of the Enlightenment that once embodied the pursuit of ultimate truth championing the values of reason, rigor, and scientific method was no longer an abstract domain limited to a chosen few but had evolved into an established profession enjoying social recognition and prestige. And just as with other professions, it paid substantial dividends by serving as a driver of innovation and technological advancement, a trend that has become particularly vivid in the aftermath of the Second World War.

By 1945 it had already been demonstrated that the high-level coordination, organisation, and facilitation of science could yield significant socio-political, economic, and military benefits. Examples outlined in some detail in the preceding chapters feature the rise of the German chemical industry from the late 1800s onwards and the subsequent development of the German chemical weapons programme, as well as the establishment of the NRC in

the USA during the First World War and the organisation of war-related research under the Office of Scientific Research and Development (OSRD) which coordinated all military-oriented scientific endeavours during the Second World War, including the Manhattan Project. Nonetheless, for the most part of the first four decades of the twentieth century, large-scale state-supported science programmes remained the exception rather than the rule. Indeed, few of the industrialised states at the time invested in science, with the bulk of money for research and innovation coming from private foundations, charities, and industry. A notable exception in this regard was the Soviet Union where from the 1920s the Bolshevik government, driven by both practical and ideological considerations, assumed full responsibility for financing science activities. It was not long before other countries adopted a similar pattern in their dealings with scientists. When accounting for governments' growing interest in allocating a designated budget line for science and technology as part of public expenditure, several aspects merit attention. One is the enormous psychological impact of the role of science and technology in the Second World War. Guided ballistic missiles, radar, and proximity fuses highlighted the crucial advantage that a state could gain through an organised scientific effort even before the use of the A-bomb formally put an end on the hostilities. But physics was hardly the only area of science that found wide-ranging applications at the time. Advances in medicine contributed to saving lives and ameliorating the negative consequences of war. The discovery and mass production of penicillin is a case in point. Equally, the prospects for the hostile misuse of cutting-edge biological research were also revealed as evidenced in the Nazi concentration camps and the Japanese Unit 731. Second, if back in 1918 the prevalent perception among state leaders was that another total war seemed impossible, or at least, possible to prevent, in the late 1940s the situation drastically changed. With the ideological and political differences between the former allies steadily exacerbating and Europe divided into spheres of influence, the iron curtain acquired a material dimension. Once the US nuclear monopoly was broken, the world plunged into yet another war – the Cold War. Third, given the lasting union fostered between science and war,

scientific and technological innovation came to be regarded as an essential requirement for ensuring states' national security:

In a world where the prosecution of war or the avoidance of war demands that we be in the forefront in the applications of science to public health, industry, and preparations for fighting effectively in a modern sense, we can no longer afford to drift with a slow current. It is essential that we provide equality of opportunity of higher education in the full sense, [...] so that highly endowed youngsters [...] may come forward with full educational equipment to attack the great problems of the future, [...].⁵⁰⁹

If a state-coordinated scientific effort in war-time was capable of procuring sophisticated weapon systems and thus making an invaluable contribution to boosting states' military potential and political influence, using this model for organising research in peace-time appeared key to long-term prosperity, economic stability, and reliable defence. The net result was a marriage of convenience between the 'national security state' and science, whereby the former could tap the vast technical expertise available at its disposal, and the latter could enjoy both regular, lavish financial support and an unprecedented access to decision-making power.

Against the backdrop of the battle for ideological superiority in which the East and West strived both to demonstrate political resilience and economic might, and take the upper hand in the intensive arms race, scientific progress was elevated to the status of a social value and deemed an important source of public good. Within this context, the advancement of science and technology was to a considerable degree subordinated to the goals and interests of the state and shaped by economic, socio-political, and military considerations, which in turn gave rise to a distinct professional culture that readily adapted to the altered environment. Practical utility thus became a central criterion for assessing the value of research underscoring an underlying feature of the new role which scientists had taken up – that of being in service of society and the state.

⁵⁰⁹ Vannevar Bush, *Modern Arms and Free Men* (London: William Heinemann Ltd, 1950), p.264.

During the second half of the twentieth century the life sciences underwent a significant expansion. Equipped with modern, more accurate tools, scientists were able to study and manipulate living matter at a scale unimaginable before. The discovery of the DNA structure and later, the advent of genetic engineering captured public attention, highlighting the wide gamut of potential applications and fascinating opportunities that promised to revolutionise virtually every aspect of life. Public health benefits, improved foodstuffs, and mitigation of environment concerns were just few of the expected positive uses of the novel advances. Complex problems for once appeared to have easy, affordable, and attainable solutions. And it was not long before the emerging bio-industry demonstrated its economic viability convincing governments to promote measures and policies aimed at fostering favourable conditions for the growth of biotechnology. The choice of regulatory mechanisms largely reflected the dominant mentality of the day and, as such, was primarily informed by national security considerations and a strong interest in gaining advantage in the Cold War rivalry. To this end, regulations were designed in a way that allowed scientific advancement to continue uninhibited taking a narrow definition of 'risk' limited mainly to the technical aspects of scientific practice within laboratories. Broader issues related to the ethical, legal, and social implications of novel developments more often than not remained unacknowledged. Life scientists were granted almost exclusive decision-making powers in assessing the safety of emerging technologies and in providing expert advice on how best to address any potential questions that might pose an obstacle to the expansion of research. Insulated from public scrutiny and liberated from abstract constraints, biotechnology has continued to advance with its breakthroughs hardly safeguarded against potential malign intent.

The Challenges Posed by 21st Century Biotechnology

Following the end of the Cold War, world affairs have been increasingly shaped by the multifaceted forces of globalisation. Growing interconnectedness in the social, political, security, and economic realm has underscored both the changing character of challenges whereby local

concerns are no longer spatially limited but could have global repercussions, and the increasing need for international cooperation as individual states appear ill-placed to address potential threats on their own. From financial crunches to infectious diseases, from climate change to terrorism, and from political instability to the spread of weapons of mass destruction (WMD), the list of risks that can quickly become global in their reach or extent is now a key feature of the altered conditions in which states operate in the twentieth-first century. Against this backdrop, the rapid advancement of biotechnology over the past few decades seems both promising and daunting. On the one hand, its wide-ranging applications have the potential to facilitate the development of new medicines, vaccines and therapeutics, environmental-friendly technologies, improved foodstuffs, and forensic methods; on the other, they raise profound social, ethical, legal, and security concerns that cut across different religious and cultural norms and beliefs, hinder the verification of compliance with established rules and procedures, and expose the limitations of the existing regulatory mechanisms currently in place. The case of dual-use life science research is indicative in this regard. As the spectre of possible positive applications of biotechnology continues to expand, so do the prospects for its hostile misuse. Back in the late 1980s not long after gene splicing had become a reality, Commander Stephen Rose of the US Navy observed that:

A key aspect of [biotechnology] is that weapons of mass destruction threaten to become commonplace. We are crossing into an era when tiny nations and terrorist groups can arm themselves with biological and chemical weapons of great destructiveness – the equivalent of the ‘poor man’s atomic bomb’ [...];

and that:

[t]he outlook for biological weapons is grimly interesting. Weaponers have only just begun to explore the potential of the biotechnological revolution. It is sobering to realize that far more development lies ahead than behind.⁵¹⁰

⁵¹⁰ Stephen Rose, ‘The Coming Explosion of Silent Weapons’, *Naval War College Review*, vol.42:3 (summer 1989), p.7,p.21.

Ominous as they are, his remarks offered only a foretaste of the type of challenges and security risks that were likely to arise from biotechnology in the near future. Two decades later, the future has arrived and the issues science policy-makers and security officials alike are grappling with remain as acute as ever. Dual-use life science research – peacefully-intended research which ‘can be reasonably anticipated to produce knowledge, information, products, or technologies that could directly be misapplied to pose a significant threat’ to public, animal, or plant health, infrastructure, the environment, or national security⁵¹¹ – strikes right at the heart of the established international regime prohibiting the development, acquisition, stockpiling, and retention of biological weapons. Given its legitimate uses, such research is not subject to restrictive regulation and its results are openly disseminated. The issue is further exacerbated by the lack of an international mechanisms for ensuring that any related ethical, social, legal, and security concerns are tackled, or at least, taken into account before experimental work commences, something evident during the 2011 H5N1 controversy outlined in the preceding chapter. During that debate it also became apparent that limiting data sharing once the research had been completed and ready for publication was both infeasible from a practical and undesirable from an ethical point of view. Attempts to mitigate the potential security challenges posed by dual use research through technical means, biosafety procedures, and sophisticated laboratory equipment, whilst certainly an attractive solution, are already beginning to prove counterproductive hindering studies on highly dangerous pathogens and reducing public health benefits.⁵¹² And even if Asilomar-style consensus on dual-use research is reached, implementing international regulations or guidelines would be far from a straightforward task:

[T]he research community is far larger, far more broadly international, and far more influenced by commercial pressures. Whatever regulations are imposed, on prudential or ethical grounds, they

⁵¹¹ See National Institutes of Health, *Biosecurity*, available at <http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern> (accessed 14/07/15).

⁵¹² See Stephen Morse, ‘Pathogen Security – Help or Hindrance’, *Frontiers in Bioengineering and Biotechnology*, vol.2 (2015), pp.1-12; Amy Shurtleff et al. ‘The Impact of Regulations, Safety Considerations and Physical Limitations on Research Progress at Maximum Biocontainment’, *Viruses*, vol.4 (2012), pp.3932-3951; N Wurtz et al. ‘Negative Laws Regarding Biosecurity and Bioterrorism on Real Diseases’, *Clinical Microbiology and Infection*, vol.20:6 (2014), pp.507-515; Christian Devaux, ‘The Hidden Face of Academic Researches on Classified Highly Pathogenic Microorganisms’, *Infection, Genetics, and Evolution*, vol.29 (2015), pp.26-34.

could never be enforced worldwide – any more than the drug laws can. Whatever can be done will be done by someone, somewhere. [...] The global village will have its village idiots and they'll have global range.⁵¹³

Yet the dual use conundrum is only one aspect of modern biotechnology. The wide-spread diffusion of capabilities and expertise, coupled with the closer integration of biology with other disciplines such as computing, chemistry, and engineering have redefined the established loci in which the life sciences are traditionally found and significantly increased the number of individuals with access to manipulating living matter. The advent of garage biology and biohackers reflects both the democratisation and deskilling enabled by the progress of biotechnology. It is also symptomatic of the availability and accessibility of the materials and equipment necessary for setting up a laboratory in the comfort of one's home. Nevertheless, a critical analysis of this trend highlights its potential 'dark side'. A recent report has revealed the 'disruptive effect' that biotechnology e-commerce has had on arms control agreements in the area of biological disarmament.⁵¹⁴ Using the Australia Group rules on export control, the authors of the report demonstrate the range of dual-use products, tools, and devices that could be bought online for the purpose of illicit development of biological weapons:

Transactions serving BW programs can be carried out openly, in effect hiding in plain sight amongst lawful transactions. Compounding these issues, we found that online vendors routinely offered payment options that could be utilized by unscrupulous buyers to hide their identities and to launder funds.⁵¹⁵

As the highly heterogeneous and segmented landscape of biotechnology research unlocks an extensive gamut of opportunities open to various actors including those seeking to cause harm, the need for re-thinking the existing controls and regulatory barriers and adapting them to the new reality looms

⁵¹³ Martin Rees, 'The World in 2050 and Beyond', *New Statesman*, 26 November 2014, available at <http://www.newstatesman.com/sci-tech/2014/11/martin-rees-world-2050-and-beyond> (accessed 14/07/15).

⁵¹⁴ Raymond Zilinskas and Philippe Mauger, *Biotechnology E-Commerce: A Disruptive Challenge to Biological Arms Control*, CNS Occasional Paper No.21, Middlebury Institute of International Studies, 2015.

⁵¹⁵ *Ibid.*, p.2.

large. Adding to this challenge is the rapid pace of technological innovation which makes it virtually impossible to keep track of novel discoveries and emerging technologies. Advances in genomics, synthetic biology, systems biology, and nanotechnology offer tremendous prospects for treatment of serious disease and medical conditions. At the same time, many of those run counter to socially-accepted ethical, religious, and moral norms and as such, possess the potential to fuel clashes and public disputes. The controversy over GMOs and food, stem cell research, 'three-parent babies', the creation of a synthetic live cell, gene therapy, embryo screening, and nano-based medications demonstrates the resistance and sometimes even public outcry with which scientific breakthroughs could be met. The problem is at least in part due to the character of the existing systems for public deliberation which, unlike technological innovation, tend to operate at a much slower pace. With powerful commercial interests, political and defence considerations, and vigorous competition in the conditions of intense globalisation shaping research agendas, progress, profits, and benefits are more often than not prioritised at the expense of caution, careful evaluation of risks, and public engagement. As a result, any potential ethical, social, and legal issues likely to hinder the pace of innovation tend to be addressed superficially and in outline with the goal of fencing off instead of engaging constructively with public fears and concerns.

The challenges posed by modern biotechnology expose the shortcomings of the established governance mechanisms but equally, their complexity highlights the limits of easy fixes and readily available technical solutions. The systems, structures, power relations, regulations, professional norms, beliefs, and attitudes that shape and influence the development of the life science enterprise are products of historical, cultural, and political contingencies: whilst not static, they have evolved over time reflecting the prevalent world outlook and atmosphere of the day which in turn has made them stable and resilient. Resilience does not preclude change; rather it implies that sustainable change is achieved through adaptation since

there are limits to the possible rate at which human history can change without disintegration, since coherent change involves change in the whole set of cultural standards by which a society interprets its situation; and these standards are related to the life experience and hence the life span of individuals.⁵¹⁶

Inertia and Resistance to Change: The Case of Russia

In December 1991 the USSR officially ceased to exist with Russia inheriting much of its military arsenal, diplomatic prerogatives, and political standing. But from the outset, the new Russia pledged to follow a radically distinct course of development and part for good with the heritage of autocratic rule, suppression of freedom, and ubiquitous surveillance. The steps made toward liberalisation during Gorbachev's era galvanised the public into embracing what was once denounced as 'degrading imperialist influence'. From the jeans culture and the concerts of Pink Floyd and Scorpions through McDonald's to freedom of speech and recognition of the right to self-determination, the triumph of democracy appeared imminent. By the time of the fall of the Berlin Wall that marked the end of the Cold War, the old order was already showing signs of crumbling away. After gaining its independence, Russia underwent an extensive transformation with the goal of achieving a swift transition to liberal democracy and market economy. Under the leadership of the first democratically-elected president, Boris Yeltsin, a package of drastic reforms was introduced aimed at building a Western-style state. State control over industry was abolished, prices were liberalised, and private initiative was encouraged. The one-party system was replaced with political pluralism and free elections were organised on a regular basis, which allowed citizens to express their political preference and will and, at the same time, hold their political representatives accountable. Yet by the mid-1990s the initial optimism of a smooth transition to a freer and economically stable society began to fade. The storm of the White House in 1993,⁵¹⁷ the war in Chechnya from 1994, and the rise of the oligarchs and

⁵¹⁶ Geoffrey Vickers, *Human Systems Are Different* (London: Harper & Row Publishers, 1983, p. xv).

⁵¹⁷ This refers to the armed siege of the Russian Parliament in October 1993 – the first major political crisis in post-Soviet Russia. On 21 September 1993, President Yeltsin issued Decree No.1400, according to which the state legislature – the Congress of People's Deputies and its Supreme Council were to be dissolved. As the Decree was

resultant linkage of economic influence with politics demonstrated that past patterns, modes of behaviour, and power relations still persisted and played a crucial role in determining the course of Russia's development.

Besides economic and political restructuring, President Yeltsin faced another important task, namely the question of the enormous military complex, which Russia inherited following the Soviet Union's collapse. A particularly sensitive issue that merited immediate attention was the offensive biological weapons programme. Along with the UK and the US, the Soviet Union was a depository State-Party to the BTWC that entered into force in 1975. During the 1980s, Moscow came under suspicion of illicit biological activities largely as a result of the Sverdlovsk anthrax outbreak and the reports on the alleged use of 'yellow rain' by the Soviet troops in Afghanistan. Shortly before the disintegration of the USSR, two senior science administrators – Vladimir Pasechnik and Kanatzhan Alibekov (Ken Alibek) – defected to the UK and the USA, respectively, where they were debriefed by the local intelligence services. Based on their accounts, from the 1970s onwards the Soviet Union set out to expand and modernise its biological weapons programme. To this end, a special complex – 'Biopreparat' – was established. By design, Biopreparat was a civilian agency that served as a cover for the illicit research work carried out at research facilities and laboratories around the country. Along with the institutes under the auspices of the military, a large network of organisations associated with the Ministry of Health and the Academy of Sciences were also said to be involved in weapons development. Open-air trials were conducted on Resurrection Island in the Aral Sea. Amidst the leak of information, in 1992 President Yeltsin passed a decree announcing the termination of the biological weapons programme and issued a law in line with Russia's obligations under the BTWC. In the same

inherently anti-constitutional, parliament refused to obey to its provisions. The resultant crisis featured vigorous protests against the Decree with violent clashes and armed struggles escalating on 3-4 October 1993 when the President deployed heavy weaponry around the White House where the Congress was based (today the building houses the Government of the Russian Federation and parliament – the State Duma – is found on Manege Square in close proximity to the Kremlin. About 30 per cent of the total area of the White House was destroyed by tanks and machine guns which forced the deputies to surrender eventually. Key figures, including the first and last Vice-President of the Russian Federation, Aleksandr Rutskoy and the Chairman of the Supreme Council, Ruslan Khasbulatov were arrested. For a timeline of the events, see History in Real Time: Relieve the 1993 Russian Parliament Siege, *Russia Today*, 5 October 2013, available at <http://www.rt.com/news/parliament-siege-yeltsin-timeline-691/> (accessed 4/8/2015). For analysis, see Michael McFaul, *Russia's Unfinished Revolution: Political Change from Gorbachev to Putin* (Cornell University Press, 2001), particularly Chapter 5.

year, the Russian government reported its clandestine activities to the Convention.

Over the last few years, Russia has invested significant efforts and resources on technical and economic modernisation. In this regard, biotechnology is deemed a critical priority and, as such, has received considerable attention and support. The assimilation and implementation of cutting-edge life science advances in various fields of activity ranging from medicine and food production through drug development and agriculture to energy and environment protection are among the primary goals of both the public and the private sector. Against the backdrop of a shaky democratic transition highlighted in the persistence of a Soviet-style mentality and politico-economic elite comprising cadres closely associated with the old regime, and the legacy of the Soviet bioweapons programme, Russia is an excellent test case to examine the extent to which the Soviet normative and institutional inertia in the life sciences constitutes a governance challenge and whether it can be reconciled against the country's ongoing biotechnology expansion.

Research Hypotheses and Research Question

The dissertation advances two research hypotheses:

- It is argued that throughout the world, systems of life science governance carry historical, cultural, and political legacies that now confront the revolutionary and pervasive advances of the twenty-first century biotechnology. Nations' adaptability to the twin challenges of attempting to secure the benefits while reducing the risks and threats is a large and still burgeoning governance challenge.
- It is argued that the legacy of the Soviet Union is particularly important in this regard, since the history of a prolonged authoritarian rule and intense development of biological weapons in combination with the continuing scientific and technological prowess of Russia is a governance challenge, unprecedented in its nature and scale.

The primary research question that the dissertation seeks to examine is:

- To what extent and by what means is it possible for Russia to reconcile its on-going expansion in biotechnology with the institutional and normative inertia arising from its Soviet past?

Methodology

The primary object of the research is the professional life science culture in Russia, that is, the complex of shared beliefs, norms, routines, and practices prevalent within the life science community in that country. Since professional cultures do not exist in a vacuum but constantly interact with and are impacted upon by the surrounding larger cultures, any analysis of professional cultures could hardly be divorced from the context and the historical, political, and economic contingencies in which the latter develop and operate. The concept of culture is an abstraction that does not refer to a fixed structure or entity readily found in reality. Rather, cultures are products of human relatedness and people's shared perceptions of normal and abnormal, acceptable and unacceptable, right and wrong. They are intricate webs of delicate intangibles that delineate the scope of and ground rules for human interaction. The study of cultures therefore inevitably presupposes elements of interpretation and subjectivity, for an objective observation would preclude analysis and any attempt to critically engage with the language, jargon, and modes of behaviour encountered in an 'alien'⁵¹⁸ culture would entail an explanation informed, at least in part, by one's experience, world outlook, and choice of words.⁵¹⁹ Bias is one issue that merits attention in this regard. Some commentators have pointed out that the 'process of knowing involves the whole self'⁵²⁰ arguing against the need for fencing off personal

⁵¹⁸ Alien here is used to signify a culture to which an individual does not belong.

⁵¹⁹ On the issue of 'objectivity' and relativism, see Linda Alcoff, 'Objectivity and Its Politics', *New Literary History*, vol.32:4 (2001), pp.835-848; Richard Bernstein, *Beyond Objectivism and Relativism: Science, Hermeneutics, and Praxis* (Oxford: Basil Blackwell, 1983); Martin Hollis and Steven Lukes (ed.), *Rationality and Relativism* (Cambridge MA: MIT Press, 1982); Ian Hacking, *The Social Construction of What?* (Cambridge MA: Harvard University Press, 1999); Kenneth Gergen, 'Correspondence versus Autonomy in the Language of Understanding Human Action', in Donald Fiske and Richard Shweder (ed.), *Metatheory in Social Science: Pluralisms and Subjectivities* (Chicago IL: Chicago University Press, 1986), pp.136-163; Daniel Little, 'Evidence and Objectivity in the Social Sciences', *Social Research*, vol.60:2 (1993), pp.362-396; Eleonora Montuschi, 'Rethinking Objectivity in Social Science', *Social Epistemology*, vol.18:2-3 (2004), pp.109-122.

⁵²⁰ Renato Resaldo, 'Subjectivity in Social Analysis' in Steven Seidman (ed.), *The Postmodern Turn: New Perspectives on Social Theory* (Cambridge: Cambridge University Press, 1994), p.177.

bias and advocating for an attempt to incorporate one's assumptions and preconceptions into the research findings (phenomenological research).⁵²¹ Given the inherent risk of a too close researcher's involvement and resultant distortion of the data analysis, the present research has adopted a different approach, whereby personal bias is acknowledged and its potential impact recognised, but related personal reflections are nevertheless kept separate from the overall analysis.

Several factors have a bearing on the author's bias, including family background and professional experience. Being a native Russian who has spent most of her life living abroad, first in Bulgaria and more recently, in the United Kingdom, has influenced the lens through which she approaches the normative and institutional dimensions of life science research in Russia. At the same time, by dint of being a social scientist, she is an outsider to the professional setting that she studies which in turn leaves a scope for interpretation.

In order to engage with the structural, professional and behavioural aspects of life scientists' work in Russia and to begin to understand their meanings, the enquiry has used qualitative research methods. Those include qualitative analysis of primary and secondary sources such as government documents, official statements, reports, and academic publications, as well as semi-structured interviews with Russian practising life scientists, bioethicists, diplomatic representatives, and government officials. The overview of the evolution of professional life science culture in Russia from the late imperial period (second half of XIX century) until the present time has benefited from an extensive literature review using both English and original Russian sources. Being a Russian speaker has enabled the author to gain access to a wide range of relevant online materials, newspapers, video briefings and interviews, and documentary TV programmes, as well as follow social media discussions and open forums. Whenever quotes from original Russian publications have been used throughout the text, those have been subject to translation by the author. Likewise, while every effort has been made to

⁵²¹ See Colin Robson, *Real World Research*, 3 ed. (Chichester: John Wiley & Sons Ltd, 2011), p.151.

locate official English versions of government and policy documents available online, whenever this has not been possible, the author's translation has been used instead. The author's translations throughout the text are clearly marked. All materials originally produced in Russian, such as official documents, books, and journal articles have been cited with their original Russian titles following transliteration from Cyrillic into Latin script in accordance with the relevant rules in Russian language whereby only the first word in a title is spelled with a capital letter. Soft sign indicating vowel reduction in Russian is indicated throughout the text with an apostrophe (') following the consonant after which it occurs.

The fieldwork carried out as part of the research entailed two visits to Russia, interactions with representatives of the Russian Federation at the bi-annual meetings of the BTWC in Geneva, Switzerland, and participation in numerous seminars, conferences and workshops held across Former Soviet Union (FSU) countries, including Ukraine, the Republic of Moldova, Georgia, and Tajikistan. In addition, an extended fieldwork mission was undertaken between September 2014 and December 2014 at the BTWC Implementation Support Unit at the UN Office for Disarmament Affairs in Geneva, Switzerland. During the visits to Russia, focus was given to Moscow and Akademgorodok (Academy City) near Novosibirsk as leading science centres. These two cities were chosen because of their key strategic role in the development of life sciences both during the Cold War after the collapse the Soviet Union. The cities host many leading universities and research institutes, and also serve as important administrative science centres with the Russian Academy of Sciences and its Siberian branch, respectively. Semi-structured interviews were conducted with life scientists and ethics teaching staff from three universities and five research institutes and an on-site facility visit with a tour of a BSL-3 laboratory at one of the institutes was carried out. For the purpose of observing the principles of confidentiality, the identity of interviewees is not disclosed. Ethical approval for the fieldwork was granted by the University of Bradford's Ethics Committee in May 2013 and all research activities involving human participation were performed in compliance with the University's Research Ethics Policy. Interviews were

conducted in Russian and were not taped but field notes were taken instead. Whenever a direct quote from an interview has been used, the English translation has been subject to a prior agreement with the interviewee. In addition to the interviews, the extensive resource base of the Russian State Library was utilised allowing access to a wide range of relevant publications and documents.

Besides interactions with Russian life scientists and officials in Russia and Geneva, the research has benefited from insights gained through multiple interactions with life scientists working in FSU countries and experts involved in the implementation of relevant projects in the region. Among those, it is worth noting representatives of the Ukrainian Academy of Sciences, the Palladin Institute of Biochemistry (Kiev), the Ukrainian Biosafety Association, Agricultural University of Georgia (Tbilisi), the Georgian Biosafety Association, National Centre for Disease Control and the R. Lugar Centre for Public Health Research, Georgia, the National Centre for Public Health and Ministry of Defence (Republic of Moldova), the Anti-Plague Stations in Armenia, Azerbaijan, and Kyrgyzstan, the Biosecurity Association of Tajikistan, and the two intergovernmental organisations set up to promote the peaceful use of science in the region – the International Science and Technology Centre (based in Kazakhstan) and the Science and Technology Centre of Ukraine (based in Ukraine). The research has further benefited from the author's close involvement in the organisation of two international conferences held in Georgia (2014) and Tajikistan (2015), respectively.

Chapter 6: Organisation and Governance of Soviet Biotechnology

Science in the Soviet Union

Prior to the disintegration of the USSR in the early 1990s, the scientific community in the country ranked among the largest in the world, with the number of individuals employed as *nauchniye rabotniki* (scientific workers) effectively approaching the two million mark.⁵²² Yet what is so impressive about this figure is the fact that it obscures more than it reveals, which is why a careful analysis is needed in order to fully grasp its significance. For one thing, in the Russian language the concept of *nauka* (science) has a broad meaning encompassing all fields of study, theoretical and practical alike (e.g. the natural and social sciences, humanities, philosophy, medicine, engineering, technology). As such, it is semantically closer to the German concept *Wissenschaft* and its English equivalent, *knowledge* or *scholarship*. Following this logic, the term *nauchniy rabotnik* does not necessarily refer to a scientist as commonly understood in the West but, on the contrary, applies to virtually any individual involved in scientific activity of any stripe and in any type of specialised institution. Likewise, it does not presuppose a clear distinction between teaching and research; between fundamental and applied research; or between research and development. Revisiting the aforementioned statistics in light of the all-encompassing meaning of *nauka* and by extension of *nauchniy rabotnik* therefore offers invaluable insights not only into the structure and composition of the Soviet scientific community but also, and even more importantly, into the role and status assigned to science and its practitioners in the Soviet Union.

By the time of the Bolshevik Revolution Russian science had already achieved some prominence, even if the systems in place to support and encourage its promotion and development lagged behind the ones established in other European countries at the time. Two key factors account

⁵²² See [in Russian] *Narodnoe khozyaistvo SSSR v 1990: Statisticheskii ezhegodnik*, (Moscow: USSR State Statistics Commission, 1991).

for this trend. First, it was not until the 1860s that radical socio-economic reforms, such as the abolishment of serfdom, were introduced in an attempt to modernise the Russian Empire and overcome its deficiencies *vis-à-vis* the Great Powers in the West exposed in the Crimean War. The extensive divide between the nobility and the representatives of lower estates fuelled by pervasive illiteracy and limited social mobility forced the autocracy to take steps toward the emancipation of peasants by increasing the existing and creating new educational opportunities in the form of specialised technical schools and enhanced support for universities. In order to counterbalance the potential threat of growing revolutionary spirit among the expanding intelligentsia, the Imperial government retained strict control over universities, keeping their influence in check at the expense of the strengthened authority of the more conservative but close-to-the-court Academy of Sciences. The reforms, nevertheless, had a positive impact on science, as ‘admission to universities was broadened, class privileges were reduced [...], travel abroad for the purpose of study was again permitted, and the education of women on the secondary level was stimulated.’⁵²³ Likewise, during the same period, the Academy underwent a process of ‘domestication’ aimed to break with the long-standing legacy of employing foreigners by turning it into a truly national institution.⁵²⁴

The second factor worthy of note pertains to the prevalent economic situation in the Russian Empire. In the second half of the nineteenth century the country was still largely agrarian with the question of industrialisation subject to a heated debate. Cognizant of the need for fostering innovation and industrial development, the government was fearful of the potential political implications that the rise of an influential bourgeois class might have, as a result of which no significant measures were implemented for alleviating Russia’s economic backwardness. Adding to this deficiency was the fact that most of the existing pockets of industrial production were under the control of foreign capital and, as such, heavily dependent on the import of raw

⁵²³ Loren Graham, *Science in Russia and the Soviet Union: A Short History*, (Cambridge: Cambridge University Press, 1993), p.37.

⁵²⁴ Alexander Vucinich, *Science in Russian Culture 1861-1917*, (Stanford, CA: Stanford University Press, 1970), p.68-73.

materials and research knowledge from abroad. Thus, little progress was made to foster linkages between the academic and corporate sectors, leaving applied research in Russia practically undeveloped.⁵²⁵

During the late nineteenth and early twentieth century, the pursuit of science in the Russian Empire took place both at the universities and the Imperial Academy of Science. While the former typically were the source of major breakthroughs, it was the latter that enjoyed generous support and preferential treatment from the government. Besides Moscow and St Petersburg, strong university scholarship developed in Kazan, Khar'kov, Kiev, and Odessa. Alongside the already existing research facilities, including the Pulkovo Observatory, new laboratories, experimental stations and workshops were created which added fresh impetus to the growth of the natural sciences. Although much of the research effort was concentrated on theoretical issues, the participation of Russia in the First World War demanded the development of practically-oriented projects to meet the ever-increasing needs for manufacturing supplies, processing raw materials and supplying everyday goods. Notable examples in this regard are the War-Chemical Committee that grew out of the collaboration between the Russian Chemical Society and the military, and the Commission for the Study of Natural Resources (KEPS) established under the auspices of the Imperial Academy of Science to provide advice on war-related matters.

It is worth noting that the generation of Russian scholars that emerged in the second half of the nineteenth century differed significantly from their predecessors. Many of them received their education or worked abroad and had access to the works of their foreign peers; they fostered professional

⁵²⁵ See Alexei Kojevnikov, 'The Great War, the Russian Civil War, and the Invention of Big Science', *Science in Context*, vol.15:2 (2002), pp.239-275; Loren Graham, *The Soviet Academy of Sciences and the Communist Party 1927-1932*, (Princeton, NJ: Princeton University Press, 1967), p.8; Nathan Brooks, 'Chemistry in War, Revolution, and Upheaval: Russia and the Soviet Union, 1900-1929', *Centaurus*, vol.39 (1997), pp.349-367. On the mixed attitudes of scientists toward 'pure' and 'applied' research see, Alexei Kojevnikov, *Stalin's Great Science: The Times and Adventures of Soviet Physicists*, (London: Imperial College Press, 2006). On science in Tsarist Russia, see Michael Gordin, 'Points Critical: Russia, Ireland, and Science at the Boundary', *Osiris*, vol.24:1 (2009), pp.99-109; Elizabeth Hachten, 'In Service to Science and Society: Scientists and the Public in Late-Nineteenth-Century Russia', *Osiris*, vol.17 (2002), pp.171-209; Kirill Rossianov, 'Taming the Primitive: Elie Metchnikov and His Discovery of Immune Cells', *Osiris*, vol.23:1 (2008), pp.213-229; Andy Byford, 'Turning Pedagogy into a Science: Teachers and Psychologists in Late Imperial Russia (1897-1917)', *Osiris*, vol.23:1 (2008), pp.50-81; Michael Gordin, 'The Heidelberg Circle: German Inflections on the Professionalisation of Russian Chemistry in the 1860s', *Osiris*, vol.23 (2008), pp.23-49.

networks both domestically and internationally, published in journals and periodicals, and participated in conferences and congresses. Just like their European colleagues, Russian scientists praised rigor, truth and objectivity and were convinced that those could only be achieved through the proper use of approved scientific methods. And even though the majority of them were passionate critics of the autocracy, as professionals they always strived to affirm the apolitical nature of their activity: as science was synonymous with truth, it was above religion, above ideology, and above politics.⁵²⁶

As much as the Russian scientific community endorsed the February Revolution which overthrew the tsarist regime, the Bolsheviks' usurpation of power nine months later was met with deep suspicion. By and large, the scholars in the country subscribed to liberal ideals and were thus supportive of the provisional government formed in the aftermath of Nicolay II's abdication. Unsurprisingly, the opposing socialist faction (Petrograd Soviet), which sought to mobilise the masses of workers and peasants was at best, disdained and, at worst, deemed dangerous. Ironically, it was precisely the radical 'hard' Marxists led by Vladimir Ulyanov-Lenin that saw the future of Russia through the prism of scientific and technological progress and was eager to fully utilise the transformative potential that new knowledge could offer for achieving social welfare and maximising economic prosperity. Science was, in short, their 'closest revolutionary ally' and a key asset to the goal of building communism.⁵²⁷

From the outset, the Bolsheviks demonstrated deep commitment to science and its practitioners commonly summarised in the slogan 'Communism is the

⁵²⁶ Nikolai Kremmentsov, *Stalinist Science*, *op cit*.

⁵²⁷ Alexei Kojevnikov, 'The Phenomenon of Soviet Science', *op cit*, p.122. On the history of Soviet science, see Helena Sheehan, *Marxism and the Philosophy of Science: A Critical History*, (Humanities Press International, 1993); *The UNESCO Courier*, July 1970 (23rd year), pp.4-22, special issue on Lenin and Science, Education, and Culture; David Joravosky, *Soviet Marxism and Natural Science, 1917-1932* (London: Routledge and Kegan Paul, 1961); Stephen Fortescue, *The Communist Party and Soviet Science* (Basingstoke: Macmillan Press, 1986); Loren Graham (ed.) *Science and the Soviet Social Order* (Cambridge, MA: Harvard University Press, 1990); Hilary Rose and Steven Rose, *Science and Society*, (London: Penguin Press, 1969), especially pp.160-168; Paul Josephson, *Totalitarian Science and Technology*, *op cit*; Loren Graham, 'Big Science in the Last Years of the Big Soviet Union', *Osiris*, vol.7 (1992), pp.49-71; E.P. Strjukova, [in Russian] 'Istoriografiya Nauchno-Tekhnicheskoi Politiki v SSSR v 1950-1990', *Contemporary History Archive*, 2010, Ural Federal University, available at <http://elar.urfu.ru/handle/10995/19780?locale=en> (accessed 7/8/2015). On the appraisal of Soviet science, see V. Trapeznikov, 'Scientific Policy in the Soviet Union: The Efficiency of Science in the Soviet Union', *Minerva*, vol.5:4 (1967), pp.546-552; John Turkevich, 'Soviet Science Appraised', *Foreign Affairs*, vol.44:3 (1966), pp.489-500; Ivan London, 'Toward a Realistic Appraisal of Soviet Science', *Bulletin of the Atomic Scientists*, vol.13:5 (1957), pp.169-176;

Soviet power plus the electrification of the whole country.⁵²⁸ Having abandoned the doctrine of 'war communism', they embarked on the implementation of the New Economic Policy (NEP) as part of which the state retained its control over banking and key industries while, at the same time, allowing private ownership and initiative in trade and small-scale manufacturing.⁵²⁹ Along with the economic reforms, science and education were also vigorously promoted. The education system was expanded and new opportunities were created for the members of previously oppressed social strata through affirmative action policies and the establishment of special workers' departments at universities – *rabfaki* – to enable people with limited education to acquire advanced degrees and qualifications. New institutions, such as the Institute of Red Professors and the Communist Academy of Science were set up for the purpose of nurturing scientific elite of a proletarian stripe in order to overcome the regime's reliance on bourgeois expertise.

Fostering close relations with the techno-scientific community in the 1920s was a key priority for the Bolshevik government. The task was challenging in its own right. On the one hand, most scientists, at least initially, were reluctant to associate themselves with the Marxist leaders whom they treated with distrust. On the other hand, the state desperately needed scientists and engineers in order to fulfil its grand vision of an advanced modern society based on the principles of communism. The situation was further complicated by the fact that Russian scholars belonged to the despised bourgeois class and so allying with them, even in the name of communist ideals, threatened to erode the credibility of the Bolshevik leaders in the eyes of their constituencies. Still, pressed with the immediate socio-economic and health concerns following the Russian involvement in World War One, the government adopted an expedient solution. As the sole patron of science, the state offered generous support in the form of material resources, organisation of conferences and symposiums, and the creation of new institutions.

⁵²⁸ Vladimir Lenin, *Our Foreign and Domestic Position and Party Tasks*, Speech delivered to the Moscow Gubernia Conference of the R.C.P.(B), 21 November 1920, available at <https://www.marxists.org/archive/lenin/works/1920/nov/21.htm#fw01> (accessed 21/07/15).

⁵²⁹ Nikolai Kremmentsov, *Stalinist Science*, *op cit*, p.17.

Scientists were granted a wide range of privileges which sought to cajole them into contributing their skills and knowledge at the government's disposal.⁵³⁰ They could keep their property and status, had access to decision-making power, and enjoyed protection from arrest and other forms of high-level harassment.

In the aftermath of 'big Revolution' science experienced its own 'little revolution' characterised, above all, by the emergence of 'big science' as a state-sponsored establishment.⁵³¹ This trend vividly manifested itself in the formation of scientific institutes, a type of specialised research institution dedicated to innovation and knowledge-production. Contrary to the popular belief, the idea of scientific institutes dated back at least to the late Imperial period when the Moscow Society for a Research Institute was created (1914).⁵³² A few years later the chief of KEPS, Vladimir Vernadsky, envisioned the creation of new research institutions oriented toward utilitarian service and governed on the principles of centralism, planning and collectivism, effectively outlining the model of what later became the Soviet research institute.⁵³³ Under the Soviet regime, science was permanently transformed from an elitist activity confined largely to universities into 'a new mass profession and a branch of the civil service, recognised as socially important and supported in its own right, rather than indirectly via higher education, by generous public funds.'⁵³⁴

⁵³⁰ Ibid, p.19. On the relationship between science and the state in the Soviet Union in the years after the Revolution, see Paul Josephson, 'Soviet Scientists and the State: Politics, Ideology, and Fundamental Research from Stalin to Gorbachev', *Social Research*, vol.59:3 (1992), pp.589-614; Peter Kneen, *Soviet scientists and the State: An Examination of the Social and Political Aspects of Science in the USSR*, (Albany: State University of New York Press, 1984); Sheila Fitzpatrick, *The Cultural Front: Power and Culture in Revolutionary Russia*, (Ithaca, NY: Cornell University Press, 1992), especially Chapter 3.

⁵³¹ See Nikolai Kremensov, 'Big Revolution, Little Revolution: Science and Politics in Bolshevik Russia', *Social Research*, vol.73:4 (2006), pp.1173-1204. See also Raymond Hutchings, *Soviet Science, Technology, Design: Interaction and Convergence* (London: Oxford University Press, 1976), particularly Chapter 2; Loren Graham, *Science in Russia and the Soviet Union*, *op cit*;

⁵³² See Alexei Kojevnikov, 'The Great War, the Russian Civil War, and the Invention of Big Science', *op cit*.

⁵³³ Ibid. On the history of the Soviet research institute, see Boris Yudin, 'Istoriya sovetskoi nauki kak protsess vtorichnoi institutsionalizatsii', *Filosofskie issledovaniya*, No.3 (1993), pp.83-106; M.Bastrakova, 'Akademiya nauk i sozdanie issledovatel'skikh institutov: Dve zapiski V.I. Vernadskogo', *Voprosy istorii estestvoznaniya i tekhniki (VIET)*, No.1 (1991), pp.157-167; E.I.Kolchinsky, *Nauka i krizisy: Istoriko-sravnitel'nye ocherki*, (St Petersburg: Dmitrii Bulanin, 2003). For an alternative explanation of the origins of the Soviet institute, see Loren Graham, 'The Formation of Soviet Research Institutes: A Combination of Revolutionary Innovation and International Borrowing', *Social Studies of Science*, vol.5:3 (1975), pp.303-329. For the role of organisational culture in the development of the Soviet research institute, see Mark Adams, 'Science, ideology, and Structure: The Kol'tsov Institute, 1900-1970' in Linda Lubrano and Susan Gross Solomon (ed.) *The Social Context of Soviet Science* (Boulder CO: Westview Press, 1980), pp.173-199.

⁵³⁴ See Alexei Kojevnikov, 'The Phenomenon of Soviet Science', *op cit*. On the organisation of science in the Soviet Union, see Kendal Bailes, *Technology and Society under Lenin and Stalin: Origins of the Soviet Technical Intelligentsia, 1917-1941*, (Princeton, NJ: Princeton University Press, 1978); Susan Gross Solomon (ed.) *The Social*

But the institutional dimension was just one aspect of the ‘little revolution’. A much more fundamental change that occurred in the late 1920s and became deeply embedded in the Soviet science policy in the later years pertained to the dominant outlook on the role of science as a central ideology which surpassed philosophy and religion. Many of the early Bolshevik leaders were scientists and, as such, aligned themselves, to a greater or lesser extent, with the cult of rationality evident in Lenin’s writings. They further shared the conviction that the idea of a just and equal society was achievable through the proper implementation of the principles of science, rational division of labour, and bureaucracy, all of which transcended politics and class discrepancies.⁵³⁵ Within this context, science was considered not just a source of technological progress but a key doctrine for the organisation and conduct of socio-economic and political affairs. Yet the science in question – the science of ‘Marxism-Leninism-Stalinism’ – constituted a special type of science rooted in the tradition of dialectic materialism, whereby practicality was deemed a major criterion for evaluation of any and all activities in the Soviet Union.⁵³⁶ It was precisely this type of science and its nearly dogmatic character that determined which projects in any discipline were to be pursued and that in effect set the scene for the rise of Lysenkoism in the 1930s.

Context of Soviet Science (Boulder CO: Westview Press, 1980); Linda Lubrano, *Soviet Sociology of Science*, (Columbus OH: American Association for the Advancement of Slavic Studies, 1976); Zhores Medvedev, *Soviet Science* (Oxford: Oxford University Press, 1979); Mark Popovsky, *Science in Chains: The Crisis of Science and Scientists in the Soviet Union Today* (London: Collins and Harvill Press, 1980); Ronald Amann, ‘The Soviet Research and Development System: The Pressures of Academic Tradition and Rapid Industrialisation’, *Minerva*, vol.8:2 (1970), pp.217-241; Sonja Schmid, ‘Organisational Culture and Professional Identities in the Soviet Nuclear Power industry’, *Osiris*, vol.23 (2011), pp.82-111; Stephen Fortescue, ‘Project Planning in Soviet R&D’, *Research Policy*, vol.14 (1985), pp.267-282; Nicholas DeWitt, ‘Reorganisation of Science and Research in the USSR’ in Norman Kaplan (ed.) *Science and Society* (Chicago, IL: Rand McNally & Co, 1965), pp.303-321; Stephen Fortescue, *Science Policy in the Soviet Union* (London: Routledge, 1990); Alexander Korol, *Soviet Research and Development: Its Organisation, Personnel and Funds*, (Cambridge, MA: MIT Press, 1965); Lorem Graham, ‘The Development of Science Policy in the Soviet Union’ in T. Dixon Long and Christopher Wright (ed.), *Science Policies of Industrial Nations: Case Studies of the United States, Soviet Union, United Kingdom, France, Japan, and Sweden*, (London: Praeger, 1975), pp.12-58; Central Intelligence Agency, Office of Scientific Intelligence, *Long-Range Capabilities of the Soviet Union, 1962-72: Medical Sciences*, Scientific Intelligence Report, OSI-SR/62-24, 31 July 1962; W. Hosrley Gantt, ‘A Medical Review of Soviet Russia: V. The Medical Profession, Soviet Science, and Soviet Sanitation’, *The British Medical Journal*, vol.1:3450 (1927), pp.338-340; Michael Gordin and Karl Hall, ‘Introduction: Intelligentsia Science Inside and Outside Russia’, *Osiris*, vol.23 (2008), pp.1-19; Valentina Markusova and B.C Griffith, ‘Highly Cited Soviet Journals in the Physical and Life Sciences: A Study of the Function of Journals’, *Scientometrics*, vol.21:1 (1991), pp.99-113; Walter Grunden et al, ‘Laying the Foundation for Wartime Research: A Comparative Overview of Science Mobilisation in National Socialist Germany, Japan, and the Soviet Union’, *Osiris*, vol.20 (2005), pp.79-106.

⁵³⁵ See John Turkevich, ‘The Progress of Soviet Science’, *Foreign Affairs*, vol.32:3 (April 1954), pp.430-439.

⁵³⁶ See Nikolai Kremontsov, *A Martian Stranded on Earth: Alexander Bogdanov, Blood Transfusions, and Proletarian Science* (Chicago, IL: University of Chicago Press, 2011).

Some commentators have linked the science of 'Marxism-Leninism-Stalinism' described above to the concept of 'proletarian science'. The latter featured vividly in the works of one of the founders of the Bolshevik Party, Aleksandar Bogdanov, who was expelled from it some eight years before the Revolution. In his view, the proletariat bore unique values (e.g. collectivist spirit) that were not shared by other classes which in turn presupposed that a bourgeois culture (and by extension, bourgeois science) could not serve its interests. By the same token, bourgeois specialists could not contribute to the advancement of proletarian science and instead, a new intelligentsia of a proletarian stripe had to be nurtured for the purposes of the Soviet state.⁵³⁷ Whilst Lenin rejected Bogdanov's idea of 'proletarian science' as premature and dangerous, the Soviet science promulgated after Stalin's 'Great Break' and characterised by 'highly differentiated, strictly regulated, and thoroughly conventionalised activities' reflected many of the elements outlined in Bogdanov's vision.⁵³⁸

One point that merits special attention is the danger of overstating the extent to which 'proletarian science' took root and *developed* in the Soviet Union. True, it was vigorously *imposed* by dint of various measures, including funding policies and sometimes overtly oppressive means. Nonetheless, it is still important to appreciate that even such a tragic phenomenon as Lysenkoism constituted an exception rather than a rule, if only for the fact that it remained confined within the boundaries of a single discipline. It can be argued therefore that the interplay between the extensive Communist Party apparatus and various state agencies, on the one hand, and the Soviet scientific community, on the other, was far from straightforward but complex, multi-faceted and pervaded by power struggles and competing interests. Just as the Politburo sought to mobilise science to serve the needs of socialist

⁵³⁷ According to Bogdanov, the proletariat had to create a new culture of a strictly class character. The new 'proletarian culture' would assimilate everything in pre-existing culture that bore the imprint of common humanity but this material would be recast by the proletariat to reflect its own class consciousness. In order to promote the idea of 'proletarian culture', a movement called *Proletkult* was set up as early as 1918. See Helena Sheehan, *Marxism and the Philosophy of Science, op cit*, specifically Chapter 4. For its part, proletarian science had to be 'acceptable, understandable, and accountable to the proletariat's life mission, a science that is organised from the proletariat's point of view, one that is capable of leading [the proletariat's] forces to struggle for, attain, and implement its social ideals'. Its proponents maintained that the proletariat could apply, synthesise and produce scientific knowledge differently from other classes. By 1923 *Proletkult* lost support. On *Proletkult* and Proletarian science see Lynn Mally, *Culture of the Future: The Proletkult Movement in Revolutionary Russia*, (Berkeley, CA: University of California Press, 1990), p.162-163.

⁵³⁸ See Nikolai Kremensov, *A Martian Stranded on Earth, op cit*.

construction, scientists and engineers, for their own part aimed to adapt to the prevalent politico-ideological setting and exploit the generous resources available for advancing their own research agendas and boosting their career prospects. A case in point in this regard is the development of the biological sciences to be examined in the subsequent sections of this chapter.

Growth and Consolidation of Biotechnology Research in the Soviet Union

The development of biology as a separate scientific discipline had a long-standing tradition in Russia, the origins of which dated back at least to the reign of Peter the Great when the first serious comprehensive study of the Russian flora and fauna was conducted.⁵³⁹ The knowledge acquired through those surveys allowed Russian naturalists to undertake over the next one hundred and fifty years taxonomic investigations in botany and zoology, the latter of which laid the groundwork for fascinating discoveries in such areas as embryology, anatomy, and physiology. The refinement of the methodological apparatus for empirical studies facilitated by the emergence of new and improved tools and equipment in the late nineteenth century further contributed to the growth of cutting-edge scholarship, as evidenced in the work of Ivan Sechenov, Aleksandr Kovalevskii, Ilya Mechnikov, and Ivan Pavlov. Another dominant trend characteristic of the period and bearing far-reaching implications for the overall shaping and direction of the trajectory of biology, was the publication of Darwin's *On the Origins of Species*. Nowhere in the world did the theory of evolution receive such a warm welcome as it did from the Russian biological community. Or, so it seemed on the surface, not least because the main opponents of Darwinism in Russia largely came from the ranks of theology, even if a small group of trained biologists also levelled some vociferous criticism at it. Yet this is not to say that all of the remaining biology scholars readily embraced the theory of evolution to the extent that some of its most vocal supporters, such as Timiriazev and Menzbir did.⁵⁴⁰ Instead of trying to prove the ultimate supremacy of the principles outlined in

⁵³⁹ See Alexander Vucinich, *Science in Russian Culture*, *op cit*, especially Chapter 9.

⁵⁴⁰ *Ibid*, p.294-295.

Darwin's work, many Russian biologists embarked on the task of reconciling those with relevant competing theories, a trend that prominently manifested itself in the area of genetics, as Mendelism was gaining in popularity in the West.⁵⁴¹ Indeed, four of the eighteen founders of the synthetic theory of evolution, which sought to combine Mendel's laws on inheritance and Darwinism, were of Russian origin, including Sergei Chetverikov, Nikolay Timofeev-Ressovsky, Nikolay Dubinin, and Theodosius Dobzhansky. The list of renowned geneticists further features Aleksandr Serebrovskii who coined the concept of *genofond* known in English as 'gene pool' and the proponent of the centre of origin theory, Nikolai Vavilov.

Up until the early nineteenth century, virtually all medical affairs including the training of physicians and distribution of drugs were managed by the Medical Collegium, a St Petersburg-based state institution.⁵⁴² At that time it was only the Medical Faculty of Moscow State University created in 1755 that offered academic degrees in medicine.⁵⁴³ An Emperor's decree of 1798 laid the foundations for the establishment of the Imperial Medical-Surgical Academy and over the next two decades medicine was taught at four more universities across the country. For most part of the 1800s, medical practice in Russia focused on the prevention rather than the treatment of disease, a trend evident in the national public health policy and the measures implemented to address the spread of infectious diseases (e.g. plague), as well as in the activities of professional societies, such as the Pirogov Society and its preoccupation with *zemstvo* medicine.⁵⁴⁴ The relative effectiveness of such

⁵⁴¹ This trend was particularly popular among the Russian biologists of the younger generation at the time, including Nikolai Vavilov. In 1910, the Bureau of Applied Botany, a subsidiary of the Scientific Committee of the Central Administration of Land Tenure and Agriculture published an entire issue of its *Proceedings* dedicated to Mendel's *Experiments in Plant Hybridisation*. See Alexander Vucinich, *Science in Russian Culture, op cit*, Loren Graham, *Science in Russia and the Soviet Union, op cit*, p.241-242.

⁵⁴² See Loren Graham, *Science in Russia and the Soviet Union*, p. 245.

⁵⁴³ *Moscow State University Records* [in Russian: *Letopis' Moskovskogo universiteta*], available at <http://letopis.msu.ru/facultet/medicinskiy> (accessed 3/8/2015).

⁵⁴⁴ *Zemstvo* medicine refers to a state-supported programme of primary rural medical and clinical healthcare that emerged in the second half of the nineteenth century in Russia. It is named after the local organs of self-government introduced as part of the Great Reforms under Alexander II – *zemstva*. *Zemstvo* medicine focused chiefly on preventive practices including sanitation and community education. For further discussion, see Loren Graham, *Science in Russia and the Soviet Union, op cit*; Susan Gross Solomon and John Hutchinson, *Health and Society in Revolutionary Russia*, (Bloomington, IN: Indiana University Press, 1990); L.E. Gorelova and T.I. Surovtseva, 'Zemstvo District Medicine and Charity in Russia', *History of Medicine [Istoriya meditsiny]*, vol.4 (2014); Nancy Frieden, 'Physicians in Pre-Revolutionary Russia: Professionals or Servants of the State?', *Bulletin of the History of Medicine*, vol.49:1 (1975), pp.20-29; Terrence Emmons and Wayne Vucinich, *The Zemstvo in Russia: An Experiment in Local Self-Government*, (Cambridge: Cambridge University Press, 1982). During the pre-bacteriological age in Russia, two sets of measures were identified and implemented to combat epidemics and infectious diseases. The first one was defined by the Quarantine Charter (1866) under temporary such in those

preventive approaches in the fight against plague even led one professor from the Medical-Surgical Academy to acknowledge in 1874 that by then, a human would need to be either cattle or a pig to get infected with plague, for the prevalent culture had made *Homo Sapiens* lose his predisposition to the disease.⁵⁴⁵ The advances in basic science coupled with growing understanding of the role of pathogens in causing disease provided medical workers with incentives to direct their efforts to experimental studies with the goal of developing new cures and methods of prophylactics. To this end, the first research institute in Russia – the Institute of Experimental Medicine – was founded in 1890 in St Petersburg by Prince Oldenburg, who modelled it on the example of Louis Pasteur’s institute in Paris and Robert Koch’s institute in Berlin.⁵⁴⁶ The institute was initially divided into six departments specialising in physiology, chemistry, general bacteriology, pathoanatomy, syphilology, and epizootiology. In 1897, the institute acquired an additional research space – an anti-plague laboratory – which was established under the auspices of the State Anti-Plague Commission (KOMOChUM) at the former military fort, ‘Alexander I’. Besides plague, other dangerous pathogens studied at the laboratory included anthrax, cholera, and typhus.⁵⁴⁷ For over two decades, ‘Alexander I’ served as an important facility for the production of vaccine and sera and many of the medications developed there were sold on the international market. Following the Revolution, the laboratory was closed and anti-plague research was moved to Saratov on the Volga River.

Support and patronage for the life sciences in Tsarist Russia came from various sources.⁵⁴⁸ Apart from government subsidies, private donations played a key role in providing adequate facilities for the development of

places where they were considered necessary. The second set was defined by the Charter on Medical Police (1857) and entailed measures against the spread of disease through isolation and disinfection of sick people, their living areas and belongings. See Mikhail Supotnitskii and Nadezhda Supotnitskaia, [in Russian] *Ocherki Istorii Chumy*, (Moscow: 2006), in particular Ocherk XX, available at <http://www.supotnitskiy.ru/book/book3.htm> (accessed 2/2/2015).

⁵⁴⁵ Mikhail Supotnitskii and Nadezhda Supotnitskaia, *Ocherki Istorii Chumy*, *op cit*.

⁵⁴⁶ See [in Russian] *Istoriya Sozdaniya Instituta Eksperimental'noi Meditsiny*, available at <http://www.iemrams.spb.ru:8101/russian/hisiemru.htm> (accessed 2/2/2015).

⁵⁴⁷ T. Andriushkevich and T. Grekova, [in Russian] ‘Chumnoi Fort’, *Istoria Peterburga*, vol.5:15 (2003), pp.48-53; also see, *Chumnoi Fort: Osobaya Laboratoriya IEM*, available at <http://www.iemrams.spb.ru/russian/fort.htm> (accessed 2/2/2015); Alexander Melikishvili, ‘Genesis of the Anti-Plague System: Tsarist Period’, *Critical Reviews in Microbiology*, vol.32 (2006), pp.19-31.

⁵⁴⁸ See [in Russian] Elena Soboleva, *Organizatsiya nauki v poreformennoi Rossii*, (Leningrad: Nauka, 1983).

biology-related disciplines, as evidenced in the case of the Medical Faculty of Moscow State University and Shaniavskii University.⁵⁴⁹ The Ledentsov Society for the Advancement of the Exact Sciences and Their Practical Applications (1909) functioned as private endowment offering grants to deserving scholars (among whom was Ivan Pavlov), fostering ties with foreign scientific institutions, and commissioning research in areas of relevance to industry.⁵⁵⁰ Private sponsorship also facilitated the activities of learned and professional societies supplementing the funds raised through subscription fees and publication revenue. Besides the Pirogov Society described above, other prominent organisations of this type featured the Society of Russian Physicians, the Moscow Medical Society, the Moscow Surgical Society, the Russian Entomological Society, the Ural Society of Naturalists, and the Russian Microbiological Society.⁵⁵¹ Such entities sought to provide scholars with similar interests with a space for debate and exchange of ideas and experience. To this end, they hosted regular meetings, congresses, and symposia, disseminated information on relevant scientific topics, and some even provided free public services.⁵⁵² It is worth noting that under the Imperial regime the development of the life sciences depended almost exclusively on the initiative and motivation of individual researchers ready to show perseverance in finding sponsors, organising laboratories, and establishing new disciplines. The career of the renowned neurophysiologist Vladimir Bekhterev is indicative in this regard.⁵⁵³ During his term at Kazan University in the late 1880s, Bekhterev managed to embed psychiatry in the formal academic curriculum, along with which he founded a psychophysiological laboratory, set up the Kazan Society of Neuropathologists and Psychiatrists, and began publishing the first neuroscience journal in Russia, *Neurological Messenger* (1893). Upon his transfer to the Military-Surgical Academy, he continued to promote neuroscience by organising scientific societies and establishing two more

⁵⁴⁹ See Samuel Kassow, *Students, Professors, and the State in Tsarist Russia*, (Berkeley: University of California Press, 1989). On the development of research centres in biology-related disciplines in the later years, see Z.B. Shamina, 'Establishing the School for the Biology of Plant Cultured Cells and Biotechnology in the USSR', *Russian Journal of Plant Physiology*, vol.52:1 (2005), pp.137-140; M.V. Padkina and E.V. Sambuk, 'Biochemical Genetics in St. Petersburg University: From Gene –Enzyme Model to Medical Biotechnology', *Russian Journal of Genetics*, vol.43:10 (2007), pp.1135-1138.

⁵⁵⁰ Alexander Vucinich, *Science in Russian Culture, op cit*, p.210, 211.

⁵⁵¹ *Ibid*, p.91, 327.

⁵⁵² *Ibid*.

⁵⁵³ *Ibid*, p.321-322.

journals, *Review of Psychiatry, Neurology, and Psychology* (1895) and *Psychology of Criminal Anthropology and Hypnotism* (1904).

After the end of the Civil War in the early 1920s, the biological sciences underwent significant expansion, both in quantitative and qualitative terms. Some commentators have even pointed out that in no other area of science in Russia was the 'little revolution' as vivid as it was in the biological sciences.⁵⁵⁴ Indeed, there is some evidence that in the initial stages of the Soviet regime, biology and medicine-related disciplines were considered a resource of great national significance and, as such, were granted preferential treatment in terms of support and patronage.⁵⁵⁵ Several factors account for the Bolsheviks' inclination to promote the biological sciences. First, the advancement of biology held some promise to enhance human welfare which fit in the Bolsheviks' overall utilitarian conception of science as a means of building a new, improved society based on Marxist principles. In particular, what captured the attention of the Soviet leaders were the fascinating breakthroughs associated with the unfolding revolution in experimental medicine which coincided with their ascent to power. Mesmerised by the tremendous transformative potential that the application of biological knowledge seemed to possess, they demonstrated firm dedication to fund undertakings of various kinds with the goal of advancing their own political objectives. A second factor worth noting pertains to the socio-economic and health conditions prevalent in early Soviet Russia. The involvement in World War One and the two Revolutions and subsequent Civil War coupled with the negative impact of the attempts to implement war communism left the state economically and demographically crippled, pervaded by famine, disease, and low morale. Since addressing such urgent ills was of paramount importance, highlighting the benefits that biology could yield if managed in accordance with the principles of equity and collectivism became an indispensable element of the Bolshevik propaganda. The third factor that had bearing on the rapid institutionalisation of the biological

⁵⁵⁴ See Nikolai Kremmentsov, *Revolutionary Experiments: The Quest for Immortality in Bolshevik Science and Fiction* (Oxford: Oxford University Press, 2014); Nikolai Kremmentsov, *A Martian Stranded on Earth*, *op cit*.

⁵⁵⁵ The analysis on this point draws on the findings presented in Nikolai Kremmentsov, *Revolutionary Experiments*, *op cit*.

sciences was a matter of immediate concern to the Soviet leadership, namely the quality of their own health. Given the highly centralised government system, individual political figures enjoyed considerable influence. Yet being human and therefore susceptible to disease, their loss could pose some serious obstacles to the stability of the regime, not least in its initial stages. It suffices to mention that the high-rank Bolsheviks had access to healthcare and relevant facilities the quality of which far exceeded those available to the average Soviet citizen. Moreover, some disciplines, including endocrinology and the study of blood transfusion in part owed their establishment to their perceived utility to the top echelon of the Bolshevik Party.⁵⁵⁶

The cumulative effect of those three factors manifested itself in the growth of the institutional infrastructure that facilitated the promotion and development of the life sciences. Several state entities offered funding opportunities for biology-related disciplines, including the People's Commissariat of Public Health (*Narodniy komissariat zdravookhraneniya: NARKOMZDRAV*), People's Commissariat of Enlightenment (*Narodniy komissariat prosveshteniya: NARKOMPROS*), and People's Commissariat of Agriculture (*Narodniy komissariat zemedeliya: NARKOMZEM*). Research institutes specialising in a range of disciplines such as microbiology, infectious diseases, biochemistry, virology, zoology, palaeontology, morphology and genetics mushroomed from the 1920s onwards. One area that considerably flourished in the early days of the Soviet regime was social hygiene closely linked to the study of eugenics. Whilst the eugenics movement had its roots in Tsarist Russia, it was after the Bolshevik Revolution that the discipline was formally institutionalised and began to feature in formal medical curricula.⁵⁵⁷ Unlike some of their foreign peers, Soviet social hygienists rejected racial discrimination, denouncing forced sterilisation and segregation, and instead focused on using the knowledge acquired on the principles of inheritance of

⁵⁵⁶ Ibid.

⁵⁵⁷ Nikolai Kremntsov, 'From "Beastly Philosophy" to Medical Genetics: Eugenics in Russia and the Soviet Union', *Annals of Science*, vol.68:1 (2011), pp. 61-92; Nikolai Kremntsov, 'Eugenics in Russia and the Soviet Union' in Alison Bashford and Philippa Levine, *The Oxford Handbook on the History of Eugenics*, *op cit*, pp.413-429. On social hygiene, see Susan Gross Solomon, 'Social Hygiene in Soviet Medical Education, 1922-1930', *Journal of the History of Medicine and Allied Sciences*, vol.45 (1990), pp.607-643; Mark Adams et al. 'Human Heredity and Politics: A Comparative Institutional Study of the Eugenics Record Office at Cold Spring Harbour (United States), the Kaiser Wilhelm Institute for Anthropology, Human Heredity, and Eugenics (Germany), and the Maxim Gorky Medical Genetics Institute (USSR)', *Osiris*, vol.20 (2005), pp.232-262.

traits to finding appropriate methods for improving the genetic quality of future generations.⁵⁵⁸ This trend was hardly surprising though since any policies based on racial, ethnic, let alone, socio-economic discrimination did not sit comfortably with the ideal of building a classless multinational state vigorously pursued by the Bolshevik leaders. At the same time, any measures directed at the eradication of disease and social degradation and overall human betterment were warmly welcomed, which in turn created favourable conditions for the promotion of eugenics both as a research and policy agenda. Spearheaded by prominent geneticists, including Nikolai Kol'tsov and Yurii Filipchenko, the social hygiene movement grew exponentially. In 1920 the Russian Eugenics Society (RES) was set up in Moscow and over the following years, similar research groups cropped up in provincial centres nation-wide. New journals, such as the *Russian Eugenics Journal* and the *Herald of the Bureau of Eugenics* were founded, and a massive propaganda campaign aimed at sensitising the general public on the value of social hygiene for the purposes of state-building and social welfare was launched. A direct implication of the convergence of interests and agendas pursued by the life scientists, on the one hand, and the Soviet leadership, on the other was the increasingly greater role that medical and public health officials came to play in social policy-making and implementation, effectively using eugenics to 'bolster their claims as government experts and advisers in a variety of fields, ranging from family and marriage policies to pedagogy and demography.'⁵⁵⁹ It was precisely this legacy that continued to pervade decision-making on certain social policy issues in the Soviet Union even after eugenics was formally 'abolished' with the advent of Stalinism, mainly on politico-ideological grounds.⁵⁶⁰

It would be naïve to assume therefore that the rapid expansion of the biological sciences in early Soviet Russia was solely state-driven. Indeed, as the government emerged as the sole patron and provider of material support for science, scientists eagerly sought to exploit the Bolsheviks' preoccupation with the value of knowledge production for advancing their own agenda of

⁵⁵⁸ Nikolai Kremmentsov, 'From "Beastly Philosophy" to Medical Genetics, *op cit*, p.72.

⁵⁵⁹ *Ibid*, p.90.

⁵⁶⁰ *Ibid*, p.91.

sustaining and further enhancing the momentum of scientific progress. While initially reluctant to cooperate with the new leadership, life scientists, similarly to their counterparts in other fields, took full advantage of the opportunities made available adopting various tactics to highlight the practical benefits of their work and thus secure funding and acquire prominence.⁵⁶¹ The net result of the synergy between the science-oriented policy of state agencies and the inclination of the life science community to excel and remain competitive with their international peers was the development of an extensive network of schools, faculties, experimental stations, laboratories, institutes, and universities dedicated to furthering teaching, research and development in biology-related fields.

Besides the Academy of Sciences of the USSR, the supreme all-Union scientific organisation, two other high-standing entities were established specifically for managing the work performed in the life sciences, namely the Lenin All-Union Academy of Agricultural Sciences (*Vsesoyuznaya akademiya sel'sko-khozyaistvenyi nauk imeni Lenina: VASKhNIL*) founded in 1929 and the Academy of Medical Sciences of the USSR (*Akademiya meditsinskikh nauk: AMN*) founded in 1944. The Cold War and resultant arms race underpinned by the vigorous quest for scientific and technical superiority further intensified the efforts to promote research and development, something evident in the creation of 'science cities' such as Pushchino and Obolensk near Moscow, and Academgorodok and Kol'tsovo near Novosibirsk which housed some of the largest biological research complexes. A unique feature of the Soviet life science research infrastructure was the Anti-Plague (AP) System, a nation-wide network of institutes and stations designed to ensure adequate public health protection by serving multiple objectives including disease diagnostics and surveillance, development of therapeutics, and training and preparation of cadres. The scope of research carried out within the facilities of the AP System was broad, encompassing work on various highly dangerous infections (*osobo opasnykh infektsii: OOI*) caused by bacteria and viruses alike, regardless of whether their prime target was

⁵⁶¹ See Linda Lubrano and Susan Gross Solomon (ed.), *The Social Context of Soviet Science* (Boulder CO: Westview Press, 1980).

humans, plants, or animals. At the heart of the AP System was the 'Microbe' Institute in Saratov where the research on infectious diseases was transferred after the closure of Fort Alexander I. Five more research institutes formed the backbone of the System – Irkutsk, Rostov-on-Don, Alma-Ata, Volgograd, and Stavropol. In addition, more than twenty anti-plague stations were created across the USSR, for example, in Tbilisi, Baku, Dushanbe, Bishkek, Tashkent, Kishinev, Simferopol, and Odessa. From the 1960s onwards, all of the AP institutes and many of the stations were equipped with mobile units – specialised anti-epidemic brigades (*spetsialnyi protivoepidemicheskie brigadiy: SPEBiy*) – to be rapidly deployed in case of a disease outbreak to isolate the epidemic perimeter, conduct tests and diagnostics, and offer clinical support and assistance.⁵⁶²

Research and teaching units had a different standing within the Soviet ranking system. According to the classification adopted in 1951, there were three categories of scientific entities and it was this categorisation that determined the status of the organisation, its employment and equipment quota, and the amount of funding it was entitled to. The research and educational units under the auspices of the Academy of Sciences of the USSR and those dealing with military-oriented projects fell in the first and most privileged group; those associated with the Academy of the Medical Sciences, VASKhNIL, and the academies in the provincial Soviet Republics were divided between the first and second group; and the facilities related with ministries and those specialising in industrial and agricultural matters of local significance comprised the third group.⁵⁶³

Besides the principle of institutional differentiation, the life science community was further organised on the basis of individual academic credentials. The latter had an enormous impact on scientists' careers, since it determined the

⁵⁶² The special anti-epidemic teams (brigades) still exist in Russia today, see Federal Service for Surveillance in the Sphere of Consumers Rights Protection and Human Welfare, *Modernized Specialized Anti-Epidemic Teams of the ROSPOTREBNADZOR* (Saratov: FGIH RusRAPI 'Microbe', 2014).

⁵⁶³ See Zhores Medvedev, *Soviet Science* (Oxford: Oxford University Press, 1979), p.68-70. On research institutes, see also Alexander Korol, *Soviet Research and Development: Its Organisation, Personnel, and Funds* (Cambridge MA: MIT Press, 1965), particularly Chapter 5; Stephen Fortescue, *Science Policy in the Soviet Union*, (London: Routledge, 1990), particularly Chapter 6.

salary rate irrespective of the particular job position.⁵⁶⁴ A postgraduate research degree was thus a precondition both for a higher income and brighter career prospects, not to mention that the lack thereof virtually precluded independent research. There were two types of research degrees in the Soviet system: a 'candidate of science' approximately equal to a PhD, and a 'doctor of science' (*doctor nauk*) awarded as a result of a significant contribution to a specific field. Both degrees were granted upon a successful defence of an original written thesis in front of a specialised committee, with the final decision being made by the Highest Central Attestation Commission for Scientific Degrees and Titles at the Ministry of Education (*Viyshaya attestatsionnaya komissiya: VAK*). A 'candidate' degree constituted an essential requirement for applying for the 'doctor' one. Academic titles varied, as well and given the lack of a clear divide between research and teaching it was far from uncommon that individuals with a higher research degree would also hold an academic title, such as 'docent' (equivalent to associate professor), 'professor', 'corresponding member of the Academy', and 'full academician'.

Academic and professional merit was valued and awarded formal recognition at a national level. Established in 1925, the Lenin Prize (*Leninskaya premiya*) was the highest state acknowledgement of scientific achievement. Its award was suspended between 1935 and 1957, and in 1941 the Stalin Prize (*Stalinskaya premiya*) was introduced instead. There were three degrees of Stalin Prize granted in various areas of science, including separate categories for medicine, biology, and agriculture. During the Khrushchev era, the Stalin Prize was renamed State Prize (*Gosudarstvennaya premiya*) and the Lenin Prize was re-established in 1957 with a broader scope covering such areas as science, art, technology, literature, and journalism. Internationally, the Russian life sciences yielded two Nobel Prizes in medicine: one earned by Pavlov in 1904 and the other by Mechnikov in 1908.

⁵⁶⁴ See Zhores Medvedev, *Soviet Science, op cit.* p.78-79.

Features of Soviet Biotechnology Governance

The Soviet science system constituted a 'carefully charted administrative pyramid':⁵⁶⁵ it was 'a huge, centralised, hierarchical institutional structure'⁵⁶⁶ under the strict control of the Communist Party. To be sure, many of those features are to be observed as far as the governance of the life sciences is concerned. Yet rather than presenting a detailed historiographic account of the evolution of the institutional infrastructure tasked with the administration, coordination and control of Soviet biotechnology, the purpose of this section is to sketch the prevalent dynamics that shaped and impacted on the biotechnology enterprise until 1991. And those dynamics were hardly one-sided. On the contrary, along with the top-down forces that directed life science practice, there were much more subtle in character but just as powerful in magnitude bottom-up pressures arising from within the life science community, as the latter strived to adapt to and in turn influence the formation and execution of policy. The resultant professional culture thus constituted a complex amalgamation of the norms of scientific research and the internalised artefacts of Soviet politics and ideology.

Centralised Hierarchical Bureaucracies

In the immediate aftermath of the Bolshevik Revolution, several arms of the newly-established central government organ, the Council of People's Commissars (*Sovet Narodnykh Komissarov: SNK*) assumed responsibility for the administration and financing of the biological sciences. General science policy was supervised by the Main Administration of Scientific Institutions (Glavnauka) established under NARKOMPROS. The role of Glavnauka was especially prominent as far as universities were concerned, not least because from the outset teaching institutions were subject to much stricter state control than the ones specialising chiefly in research.⁵⁶⁷ Research relevant to the needs and purposes of agriculture was governed by the

⁵⁶⁵ Nicholas De Witt, 'Reorganization of Science and Research in the U.S.S.R' in Norman Kaplan ed. *Science and Society*, (Chicago, IL: Rand McNally & Company, 1965), p.303.

⁵⁶⁶ Nikolai Kremenstov, *Stalinist Science*, p. 54.

⁵⁶⁷ By design, the science system in the Soviet Union was conceived in a way whereby teaching and research were separated. Universities remained, as they were in Tsarist Russia, institutions focusing primarily on teaching, whilst research was concentrated in specialized research institutes.

Scientific Council created under NARKOMZEM. Medically-oriented research was primarily consolidated under the auspices of NARKOMZDRAV with two key institutions being in charge of its organisation and management, namely the Main Scientific Medical Council (*Glavnyi Uchenyi Meditsinskii Sovet: GUMS*) and the Pasteur State Institute of Healthcare (*Gosudarstvennyi nauchnyi institute narodnogo zdravoohraneniya imeni Pastera: GINZ*). Officially founded in 1920, GINZ was tasked with the 'consolidation of scientific forces and the governance of relevant scientific research with clear practical application'.⁵⁶⁸ In terms of structure, GINZ constituted a centralised entity unifying eight large research institutes in a wide range of scientific enquiry, including biochemistry, microbiology, epidemiology, and nutrition physiology. Besides GINZ, other institutes, such as the State Institute of Social Hygiene, the Academy of Psycho-neurology and Clinical Institutes of Functional Diagnostics and Experimental Therapy, despite being much smaller in comparison, also contributed to the development of life science research in the early years of the new regime. A common underlying feature of the way in which the majority of those institutions were governed was the explicitly fundamental role played by individual directors which in turn accounts, at least in part, for the fact that many of them disintegrated following a change in leadership.⁵⁶⁹

The science system underwent tremendous restructuring under Stalin's rule and it was during this period that many of its key and long-lasting elements came into being. Starting in the late 1920s, the government embarked on a massive campaign for ensuring total control over each and every aspect of social life in the USSR. As a result, the Academy of Sciences, which until then enjoyed relative autonomy over its own affairs was brought under the stringent supervision of the Communist Party.⁵⁷⁰ In the area of life sciences two new state institutions were established under the command of SNK

⁵⁶⁸ See (in Russian) Irina Karneeva, *Istoria Formirovaniya i Dinamika Struktury Rossiiskoi Akademii Meditsinskikh Nauk*, Doctoral Thesis, Nauchno-issledovatel'skii Centr "Meditsinskii Musei", Russian Academy of Medical Sciences (RAMN), 1994, Moscow, p.34.

⁵⁶⁹ *Ibid.*, p.38.

⁵⁷⁰ On the relationship between the Soviet Academy of Sciences and political power in the early days of the Soviet Union, see Loren Graham, *The Soviet Academy of Sciences and the Communist Party, 1927-1932*, (Princeton, NJ: Princeton University Press, 1967). A detailed account of the development of the Soviet Academy of Sciences is presented in Alexander Vucinich, *Empire of Knowledge: The Academy of Sciences of the USSR (1917-1970)*, (Berkeley, CA: University of California Press, 1984). For a detailed overview on the development of the Academy, see Jack Cross, *A Guide to the Russian Academy of Sciences*, 2nd edition (Austin, Texas: Cross Associates, 1997).

(later, *Sovet ministrov: SOVMIN*), namely VASKhNIL and VIEM (All-Union Institute of Experimental Medicine, *Vsesoyuznyi institute eksperimental'naya meditsina*). The former was charged with overseeing the development of agricultural research and would in the later years become notorious as a bastion of Lysenkoism; the latter, founded in 1933, took over the coordination of biomedical research following the disintegration of GINZ three years earlier. Both VASKhNIL and VIEM were patterned on the bureaucratic structure of the USSR Academy of Science, that is, their main governing body, usually a presidium, comprised a range of designated sections and departments which dealt with personnel selection, planning, administration, enrolment, and student affairs.⁵⁷¹ Since all members of the presidium had to be formally approved by the Party's Central Committee, the government could exercise *de facto* control over the practice of scientific institutions.⁵⁷² By design, VIEM constituted a scientific complex with each department and its subordinate entities playing an essential role in the overall coordination and management of research. In 1944 following a decision (*postanovlenie*) of the SNK, it was officially transformed into the USSR AMN. According to that *postanovlenie*, AMN had three departments: Medico-Biological Sciences; Hygiene, Microbiology, and Epidemiology; and Clinical Medicine. The first president elect was academician Nikolay Burdenko, surgeon-in-chief of the Red Army during the Second World War and one of the founders of neuroscience in the USSR. From the outset, it became abundantly clear that AMN would conduct its affairs under the close supervision of the government, in particular, the Ministry of Healthcare (*Ministerstvo zdravookhraneniya: MINZDRAV*)⁵⁷³ and later, also the State Committee of Science and Technology (*Gosudarstvennyi komitet po nauke i tekhnike: GKNT*). For instance, when in 1947 MINZDRAV resolved to take steps toward regaining its administrative powers over a number of institutes and laboratories which after 1944 came under the auspices of AMN, the Academy's presidium simply approved the resolution which it had been presented with.⁵⁷⁴ In a

⁵⁷¹ Nikolai Kremontsov, *Stalinist Science, op cit*, p.38.

⁵⁷² *Ibid.*

⁵⁷³ In 1946 Soviet commissariats became ministries.

⁵⁷⁴ The report still requested MINZDRAV to reconsider their decision with regard to the Institute of Malaria, Medical Parasitology and Helminthology. In the end, all institutions initially named in the resolutions were transferred under the MINZDRAV, apart from the antibiotics laboratory of the Institute of Malaria and the neuropharmacology

similar fashion, in 1970 GKNT was tasked to consider MINZDRAV's proposal for the establishment of an AMN affiliate in Novosibirsk, which the AMN's presidium subsequently affirmed a year later.

Besides VASKhNIL and AMN, at least two more entities featured prominently in the governance of biological research in the Soviet Union. One was the USSR Academy of Sciences through its Department of Chemical and Biological Sciences. Following the reforms in the 1960s and the emergence of GKNT as the 'highest administrative-coordinating agency in the country', the Academy effectively was turned into 'its main arm in the field of basic research' and so, 'acquired the authority to make decisions mandatory for the republic academies.'⁵⁷⁵ As already noted MINZDRAV exercised direct control over a number of research establishments. The AP System outlined in the preceding section is a case in point. Placed under the direct oversight of the Main Sanitary Epidemiological Directorate (*Glavnoe sanitarno-epidemiologicheskoe upravlenie: GSEU*) and later moved under the auspices of the Directorate of Quarantine Infections (*Glavnoe upravlenie karantinnykh infektsii: GUKI*), the AP System constituted a rigidly organised hierarchical structure comprising three main components: field stations,⁵⁷⁶ AP regional and observation stations, and AP institutes. Both the regional stations and the institutes received their funding from MINZDRAV but the former were still subordinate to the latter as far as scientific and methodological matters were concerned.⁵⁷⁷

The overall hierarchical organisation of life science research was further replicated in the context of individual institutions. Research institutes, for instance, were typically governed on the principle of *edinonachalie* (one-man management), with the director enjoying predominant influence and decision-making powers. Local party units played a major role in the selection of

laboratory. See Irina Karneeva, *Istoria Formirovaniya i Dinamika Struktury Rossiiskoi Akademii Meditsinskikh Nauk*, *op cit*, p.75-76.

⁵⁷⁵ Alexander Vucinich, *Empire of Knowledge: The Academy of Sciences of the USSR (1917-1970)*, (Berkeley: University of California Press, 1984), p.304-305.

⁵⁷⁶ Field stations typically referred to 'support points, test field and experimental stations'. See Alexander Korol, *Soviet Research and Development: Its Organization, Personnel, and Funds*, (Cambridge, MA: MIT Press, 1965), p.144.

⁵⁷⁷ See Sonia Ben Ouagrham-Gormley, 'Growth of the Anti-Plague System during the Soviet Period', *Critical Reviews in Microbiology*, vol.32 (2006), p.42-43.

candidates for the director's post and high-level sanction was required for any successful nominee before they could assume position. Once in power, institute directors could not be challenged and would often serve for an indefinite period of time.⁵⁷⁸ Beneath the director, there were a number of deputy directors each performing a distinct scope of functions. The deputy director for science (*zamestitel' direktora po nauke*) was the second most important person in the hierarchy, usually tasked with overseeing research activities and standing in for the director in their absence. By contrast, other deputy directors dealt with administrative matters for which a scientific background was often not required and, as such, served primarily as assistants to the director.⁵⁷⁹ The highest institutional collective body was the Academic Council (*uchenyi sovet*) which, whilst providing some space for inclusive discussion, had little decision-making power, insofar as its resolutions and recommendations needed the director's approval prior to implementation.⁵⁸⁰ The Council was further responsible for the monitoring and evaluation of projects and the overall progress of the institute, as well as for reviewing professional appointments and existing contract renewals. It was, by and large, made up of the senior management including administrative staff, the Communist Party local secretary, a trade union representative, senior researchers, and heads of departments (*otdely*) and laboratories.

Top-Down Regulation

In the USSR, the state was the chief and only patron of scientific R&D and the sole initiator and guardian of relevant rules and regulations. Virtually each and every aspect of science practice was subject to detailed and extensive regulatory oversight. Designated state agencies oversaw the implementation and verified compliance with the various respective laws, decrees, executive orders, and decisions.

⁵⁷⁸ Some commentators note, for example, that directors were appointed for a three-year term which was renewable indefinitely. See Norman Kaplan, 'Research Administration and the Administrator: U.S.S.R. and U.S.', *Administrative Science Quarterly*, vol.6:1 (1961), p.54.

⁵⁷⁹ See Stephen Fortescue, *Science Policy in the Soviet Union* (London: Routledge, 1990), p.100.

⁵⁸⁰ *Ibid*, p.102.

By dint of being closely linked to the economy, scientific research in the USSR was subject to meticulous high-level planning. Implicit in this trend was a recognition that science constituted a natural resource for the development of which the state was directly responsible. By the early 1930s, an array of principles of planned science were enunciated ranging from 'a stress on empirical data on the organisation and personnel of the science establishment, to enthusiastic calls for increased creativity by the promoters of NONT [*nauchnaya organizatsiia nauchnogo truda* – scientific management of scientific labour], to the efforts to establish priorities and identify the functions of science planning'.⁵⁸¹ In 1931 one of the key figures in the Bolshevik Party, Nikolai Bukharin, outlined a detailed proposal mapping five different areas of science that could be planned, including (1) the amount of labour force and budgetary resources to be devoted to science; (2) the logistical support of scientific research institutions; (3) the geographical placement of research facilities; (4) the number, distribution, qualifications and use of scientific personnel; and (5) the subjects of scientific research.⁵⁸² Following the administrative and structural reforms under Stalin, as part of which the State Planning Committee (*Gosudarstvennaya planovaya komissiya: GOSPLAN*) was brought under the auspices of SNK (and later, SOVMIN), planning became formally and permanently embedded in the overall science policy. By design, science planning covered not only budgetary, logistical, and personnel matters but also the range of research topics to be studied and the specific research targets to be met. For instance, the first *Five-Year Plan for the Development of AMN SSSR* presented in 1945 listed a number of basic research problems deemed of high priority, namely:⁵⁸³

1. Combating infectious diseases

⁵⁸¹ By the early 1920s Taylorism had become a buzzword for both the NOT movement – *nauchnaya organizatsiia truda* ['scientific management of labour'] – launched by Alexei Gastev with the goal of improving the productivity of factory workers and its companion, the NONT movement – *nauchnaya organizatsiia nauchnogo truda* ['scientific management of scientific labour'] – which focused specifically on increasing the productivity of researchers by examining the type of factors with impact on individual creativity. See Loren Graham, *The Soviet Academy of Sciences, 1927-1932*, *op cit*, particularly Chapter 2; Kendall Bailes, 'Alexei Gastev and the Soviet Controversy over Taylorism, 1918-24', *Soviet Studies*, vol.29:3 (1977), pp.373-394; Isaac Deutscher, 'Socialist Competition', *Foreign Affairs*, vol.30, April (1952), pp.376-390.

⁵⁸² See Loren Graham, 'The Development of Science Policy in the Soviet Union' in T. Dixon Long and Christopher Wright, *Science Policies of Industrial Nations*, *op cit*, p.24.

⁵⁸³ See Irina Karneeva, *Istoria Formirovaniya i Dinamika Struktury Rossiiskoi Akademii Meditsinskikh Nauk*, *op cit*, p.67.

2. Eradication of the health consequences of war
3. The issue of long-term effects of war trauma and disability
4. The issue of plastic surgery
5. The issue of child- and mother-care
6. The issue of cancer, tuberculosis, and ulcers.

Even so, some commentators, however, have remained deeply sceptical of the extent to which science planning developed in practice, noting that the Soviet Union's attempts to establish planned science remained contained 'in the rise and fall of various planning committees' and even Bukharin's report appeared more as a blueprint for the planning *for* science rather than for the planning *of* science.⁵⁸⁴

Research work was subject to strict state control with virtually each and every aspect being formally regulated. In the life sciences this is particularly vivid as far as laboratory biosafety practices and procedures were concerned. One aspect worth noting is that measures for ensuring research safety had a long-standing tradition in the biological sciences in the USSR dating back to the late nineteenth century. Indeed, accounts of the efforts to combat plague outbreaks in the Russian Empire in the pre-bacteriological age and early twentieth century offer some insight into the measures adopted by the medical personnel including personal protective equipment (PPE) and decontamination methods. Models of respirators and special clothing designed to ensure the safe treatment of patients emerged as early as 1878 and whilst no data are available whether those models achieved practical realisation at the time, evidence suggests that by 1910 crude prototypes were already in use.⁵⁸⁵ Moreover, a detailed description of the way in which Fort Alexander I was organised and operated has revealed that attempts to ensure the safe handling of dangerous pathogens under laboratory conditions seemed to have attracted scientists' attention long before the Bolshevik Revolution.⁵⁸⁶

⁵⁸⁴ See Loren Graham, *The Soviet Academy of Sciences and the Communist Party, 1927-1932*, *op cit*, p.67.

⁵⁸⁵ Mikhail Supotnitskii and Nadezhda Supotnitskaia, *Ocherki Istorii Chumy*, *op cit*, see Ocherk XXXI.

⁵⁸⁶ *Ibid*, see Ocherk XXX.

In the USSR MINZDRAV was the principal agency responsible for the development of relevant instructions, orders, and rules with regard to laboratory biosafety. By and large, those were binding documents which entered into force immediately after they had been officially issued. Key orders (*prikazy*) included 'On Measures for the Improvement of Occupational Safety in Institutions, Enterprises, and Organisations within the System of the USSR Ministry of Health' (1968), 'On Measures Undertaken for the Further Improvement Occupational Safety and Safety Equipment' (1982), and 'On Strengthening the Regime of Work with Pathogenic Microorganisms' (1977).⁵⁸⁷ Rules and state standards further covered such areas as the accounting, storage, handling, release and transfer of pathogenic and toxin cultures; safety equipment and occupation health regime during biotechnology production; occupational safety during disinfection and decontamination; and work with aerosols of highly pathogenic organisms.⁵⁸⁸ Non-compliance with any of the regulations was deemed a legal offence, with liability usually shared among the institution administration and laboratory/departmental heads. In 1989 MINZDRAV released a document titled *Health and Anti-Epidemic Rules on the Safety of Work with Recombinant DNA Molecules (Bezopasnost raboty s rekombinantnymi DNK. Sanitarno-protivoepidemicheskie pravila)* developed by the Interdepartmental Commission of the USSR Academy of Sciences and modelled on the Soviet *Temporary Rules of the Safety of Work with Recombinant DNA* (1978) and the US NIH *Guidelines for Research Involving Recombinant DNA Molecules* (1986). Unlike the NIH *Guidelines* which covered only federally-funded research, MINZDRAV *Rules* extended to any organisation or institution conducting research involving recombinant DNA, whether for scientific or industrial purposes.

⁵⁸⁷ See [in Russian] Prikaz Minzdrava SSSR, *O merakh po uluchsheniyu okhrany truda v uchrezhdeniyakh, predpriyatiyakh i organizatsiyakh sistemy Ministerstva zdravookhraneniya SSSR*, no.494, 20 June 1968; Prikaz Minzdrava SSSR, *O merakh po dal'neishemu uluchsheniyu okhrany truda i tekhniki bezopasnosti v organakh, uchrezhdeniyakh, organizatsiyakh i na predpriyatiyakh sistemy Ministerstva zdravookhraneniya SSSR*, No.862, 30 August 1982; Prikaz Minzdrava SSSR, *Ob usilenii rezhima raboty s patogennymi mikroorganizmami*, No.142, 22 February 1977.

⁵⁸⁸ See [in Russian] *Pravila ustroystva, tekhniki, bezopasnosti, proizvodstvennoi sanitarii, protivoepidemiologicheskogo rejima i lichnoi gigieny pri rabote v laboratoriyakh (otdeleniyakh, otdelakh) sanitarno-epidemiologicheskikh uchrezhdenii sistemy Ministrestva zdravookhraneniya SSSR*, Moscow: 1981; 'Occupational Safety Standard: Biological Safety' (GOST 12.1.008-76 *Mezhhgosudarstvennyi standart: Biologicheskaya bezopasnost'*), issued on 1/01/1977; 'Occupational Safety Standards System: Means of Protection' (GOST 12.4.011-89 *Gosudarstvennyi standart Soyuza SSR: Sistema standartov bezopasnosti truda: Sredstva zashtity rabotajushchikh*), issued on 1/07/1990.

Science secrecy, a trend characteristic of the Cold War period as noted in Chapter 3, was institutionalised in the USSR, effectively redefining the norm of scientific openness by equating it with a criminal ‘anti-patriotic’ activity. In 1947 the highest legislative body, the USSR Supreme Soviet (*Verkhovnyi Sovet SSSR*), enacted a new decree ‘On Responsibility for Disclosure of State Secrets’ which envisaged severe penalties, including confinement to a labour camp for a term of eight to twenty years for anyone who shared or otherwise revealed information classified as a ‘state secret’.⁵⁸⁹ For the purposes of the new law, ‘state secret’ was broadly defined and included ‘discoveries, inventions, technical improvements, research, and experimental work in all spheres of science, technology, and the national economy until they are fully completed and permission has been obtained for publication.’⁵⁹⁰ The law was in some respects the materialisation of a move toward enhanced secrecy that had been steadily underway at least from the 1930s. An administrative reform introduced by the revised 1936 USSR Constitution provides some evidence in this regard. The reform in question related to the restructuring of the Main Directorate for Literary and Publishing Affairs (*Glavnoe upravlenie po delam literaturnykh izdatel'stv: GLAVLIT*) originally created under NARKOMPROM to oversee the publication of written materials and ensure their ideological coherence and subsequently converted into a stand-alone unit under the direct control of SNK renamed to Main Directorate for the Protection of State Secrets in the Press (*Glavnoe upravlenie po okhrane gosudarstvennykh tain v pechati: GLAVLIT*). Thus reformed the agency was tasked with the supervision of the media and press, to prevent the broadcast, publication, or other forms of dissemination of classified and sensitive information.

Scientific publishing, too, was closely monitored and readily demonstrated compliance with the tightened secrecy measures. For example, when in 1947 the Orgburo of the Communist Party’s Central Committee (*Tsentral’nyi*

⁵⁸⁹ See Nikolai Kremntsov, ‘In the Shadow of the Bomb: US-Soviet Biomedical Relations in the Early Cold War, 1944-1948’, *Journal of Cold War Studies*, vol.9:4 (2007) p.59. See also, Nikolai Kremntsov, *The Cure: A Story of Cancer and Politics from the Annals of the Cold War* (Chicago, IL: University of Chicago Press, 2002). On the issue of scientific publication in the Soviet Union, see also Aleksey Levin, ‘Anatomy of a Public Campaign: “Academician Luzin’s Case” in Soviet Political History’, *Slavic Review*, vol.49:1 (1990), pp.90-108.

⁵⁹⁰ Nikolai Kremntsov, ‘In the Shadow of the Bomb’, *op cit*.

komitet: TsK) shut down several scientific journals which had been made available in foreign languages on the grounds of national security against potential espionage, the USSR Academy of Sciences was quick to release that same day its own instructions ‘On the Principle of Scientific Publications’ which prohibited the Academy’s journals from translating their abstracts and tables of contents into foreign languages.⁵⁹¹ The practice soon became ubiquitous thanks to the active intervention of the Communist Party and its regional and local committees. The culture of secrecy featured vividly in the life sciences, not least because of the blanket ‘information eclipse’ imposed over disseminating any information related to such socially sensitive issues as infant/children mortality, infectious diseases, abortion, drug abuse, sexually-transmitted diseases, and alcoholism.⁵⁹² Official statistics on those matters were often skewed in favour of the state in order to be suitable for propaganda purposes. Likewise, life science theses, whether at *kandidat* or *doctor* level that dealt with a topic deemed sensitive or secret were defended before much smaller committees comprising pre-selected individuals who had ‘the right to know’. Upon a successful defence, such theses were classified as ‘internal use only’ (*dlya sluzhebnogo pol’zovaniya: DSP*) and were never made publicly available.⁵⁹³

State/Party Control

According to Article 6 of the USSR Constitution adopted on 7 October 1977

The Communist Party of the USSR [CPSU] is the leading and directing force of the Soviet society, the nucleus of its political system and state and social organisations. CPSU exists for the people and serves the people.⁵⁹⁴

⁵⁹¹ Ibid, p.60.

⁵⁹² See Casey Mahoney, James Toppin, and Raymond Zilinskas, *Stories of the Soviet Anti-Plague System*, CNS Occasional Paper No.18, (Monterey CA: Monterey Institute of International Studies, 2013), particularly Part II, ‘The Anti-Plague System in Russian and Western Media’.

⁵⁹³ Interview, 25 March 2014, Tbilisi, Georgia. See also [in Russian] N. Makhotina, ‘Fond izdaniï ogranichenного rasprostraneniya v biblioteke: teoreticheskoe i instruktivno-metodicheskoe obespechenie’, *Bibliosfera*, No.1 (2007), pp.68-71.

⁵⁹⁴ See (in Russian) *Konstitutsia (Osnovnoi Zakon) Soyuza Sovetskikh Sotsialisticheskikh Respublik*, Verkhovnogo Soveta SSSR, 7 October 1977, available at <http://www.hist.msu.ru/ER/Etext/cnst1977.htm#i> (accessed 11/03/2015). Author’s translation.

What is curious about the text is not so much its contents as it is the fact that this was the first time it appeared in the Constitution, since neither of its earlier versions – of 1924 and 1936 – made an explicit reference to the leading role of the Party in the organisation and conduct of political and social affairs. Yet this is not to say that the 1977 addition introduced a substantive change but rather, it merely affirmed a long-established trend dating back to the early days of the Bolshevik regime. Indeed, enormous as it was, the state bureaucratic machine served as little more than a mechanism for putting into effect the vision, decisions, and proposals of the Communist Party's TsK and its Politburo.

Science governance, too, was subject to close supervision by the Party exercised through its dense network of institutional, local, regional, and national committees tasked with monitoring political behaviour and ensuring ideological obedience. Besides the formal measures codified in various legislative instruments, *prikazy* and policies, there existed other less conspicuous forms of political control. The *nomenklatura* system was a case in point. Whist not officially defined, it provided the basis for personnel recruitment, appointment and career development in virtually any walk of life, science included. By design, it constituted 'a list of posts that could not be occupied or vacated without permission from the appropriate party committee':

The *nomenklatura* system was strictly hierarchical – the higher the post, the higher the party committee controlling its personnel. The posts of president, vice-president, and scientific secretary of such central institutions as the USSR Academy of Sciences and VASKhNIL, were in the *nomenklatura* of the Politburo. The posts of institute director and editor-in-chief of a journal were in the *nomenklatura* of the Central Committee Secretariat. The position of laboratory head belonged to the *nomenklatura* of the regional party committee. Even the post of librarian in a scientific institute was in the *nomenklatura* of the local party committee.⁵⁹⁵

⁵⁹⁵ Nikolai Kremontsov, *Stalinist Science*, *op cit*, p.40.

The 'affirmative action' known in the Soviet Union as *vydvizhenie* was another set of measures designed to promote party loyalist to key positions within the scientific community. Featuring stipends, bursaries, relaxed entry requirements to higher education, university admission quotas, and accelerated courses, *vydvizhenie* granted trusted proletarian and peasant youth access to graduate training (*aspirantura*) and the prospect for a subsequent speedy ascent up the career ladder in their chosen field of study. As a result of the 'affirmative action', a considerable number of women, representatives of ethnic minorities, and students from underprivileged backgrounds and remote areas of the country found their way to comfortable positions in life science research.⁵⁹⁶

Taken together, the *nomenklatura* system and the *vydvizhenie* campaign allowed the Communist Party to tighten its grip and keep scientists in check. Their positive outcomes notwithstanding, the net effect of those policies manifested itself in the reconfiguration of power distribution across the scientific community both horizontally and vertically by dint of elevating political loyalty at the expense of talent as the primary criterion for promotion and awarding merit and recognition.

The negative impact of the State-Party monopoly on the development of science in qualitative terms is difficult to overstate. The prominent Soviet physicist and dissident, and a Nobel Peace Prize Laureate, Andrei Sakharov has described in a succinct manner the far-reaching pernicious implications of the institutionalisation and forced imposition of ideology upon society:

The complete unification of ideology at all times and places – from the school desk to the professorial chair – demands that people become hypocrites, timesavers, mediocre, and stupidly self-deceiving. The tragicomic, ritualistic farce of the loyalty oaths played over and over, relegating to the background all considerations of practicality, common sense, and human dignity. Writers, artists, actors, teachers, and scholars are under such monstrous ideological pressure that one wonders why art and humanities have not altogether

⁵⁹⁶ See Alexander Korol, *Soviet Research and Development, op cit*, p. 123; also see Olga Valkova, 'The Conquest of Science: Women and Science in Russia, 1860-1940', *Osiris*, vol.23:1 (2008), pp.136-165 (Special issue on 'Intelligentsia Science: The Russian Century, 1860-1960').

vanished in our country. The influence of those same anti-intellectual factors on the exact sciences and the applied sciences is more indirect but not less destructive.⁵⁹⁷

At times, the struggle to affirm the Party's dominant role in society and politics materialised in an overt expression of power, as evidenced in the activity of the secret police in the face of the People's Commissariat of Internal Affairs (*Narodnyi Komissariat Vnutrennikh Del: NKVD*) which reached its peak during the Stalinist era. Surveillance, repressions, purges, and arrests pervaded the scientific community spreading fear and creating an atmosphere of suspicion and permanent distrust, thus impinging scientific openness and eroding collegiality. The growing politicisation of the scientific community, structured along the lines of 'us' (true Communists) and 'them' ('bourgeois' researchers) paved the way for framing scientific disputes in political terms and thus, ridding science of traitors and unreliable cadres. International contacts were curtailed, foreign visits limited and trips abroad restricted. The organisation of scientific meetings and conferences was hampered, a vivid illustration of which were the administrative bottlenecks encountered during the preparation of the Seventh International Congress in Genetics initially scheduled to be held in Moscow in 1937 and subsequently relocated to Edinburgh in 1939.⁵⁹⁸

Aleksandr Solzhenitsyn's monumental work, *The Gulag Archipelago*, offers a glimpse of the harsh reality brought about by the Stalinist regime, whereby the state apparatus employed a vast array of cunning tactics to crush virtually any form of resistance or opposition.⁵⁹⁹ Arbitrary arrests, a prolonged detention under severe conditions, and an exile in gulag – the state operated network of concentration camps where human life was deemed expendable – was the most common scenario for those with 'dangerous minds', who were not immediately sentenced to death. More than 20 million people

⁵⁹⁷ Andrei Sakharov, *My Country and the World* (London: Collins and Harvill Press, 1975), p.30.

⁵⁹⁸ See Nikolai Kremontsov, *International Science between the World Wars: The Case of Genetics*, (London: Routledge, 2005).

⁵⁹⁹ Aleksandr Solzhenitsyn, *The Gulag Archipelago* (New York: Harper and Row, 1973). See also Oleg Khlevniuk, 'The Gulag and the Non-Gulag as One Interrelated Whole', *Kritika: Explorations in Russian and Eurasian History*, vol.16:3 (2015), pp.479-498; Harvey Fireside, 'Dissident Visions of the USSR: Medvedev, Sakharov and Solzhenitsyn', *Polity*, vol. 22:2 (1989), pp.213-229.

'disappeared' in Stalin's labyrinth of horror and hopelessness. The intelligentsia suffered immensely. Those scientists, who despite being arrested somehow managed to avoid a death sentence, or a placement in a labour camp (gulag), mostly continued their research in prison research institutes (*sharashki*) and prison scientific complexes under severe conditions.⁶⁰⁰ A case in point is the career of one of Nikolai Kol'tsov's students, Nikolay Timofeev-Ressovsky.⁶⁰¹ Upon Kol'tsov's recommendation, Timofeev-Ressovsky was sent to work at the Keiser Wilhelm Institute for Brain Research in Berlin, alongside with Oskar Vogt – the scientist who studied Lenin's brain after the Soviet leader's death. The 'German' period in the career of Timofeev-Ressovsky makes him a deeply controversial figure, not least because of the alleged links between his workplace and the Third Reich. There is some evidence that he wanted to return to the USSR in the mid-1930s, but was advised by Kol'tsov not to, due to the unravelling witch-hunt in the field of genetics, that was caused by the rise of Lynsekoism (the latter is discussed below). After the fall of Berlin in 1945, Timofeev-Ressovsky was arrested by the Soviet Army and subsequently sent to a 'sharashka' near Sungul' in the southern Urals, alongside with captured German scientists.⁶⁰² There, he headed the biology division of 'Laboratory B', taking the lead on the study of the impact of radiation on living organisms. Despite his post, he lived in similar conditions as the rest of the prisoners. Timofeev-Ressovsky's resilience during the years of imprisonment undoubtedly proved instrumental for reestablishing his scientific career on Soviet soil in the second half of the twentieth century. More importantly, it is indicative of what Joseph Brodsky's refers to as 'turning the other cheek' in a way that would make evil appear 'absurd through excess':⁶⁰³

[...] it suggests rendering evil absurd through dwarfing its demands with the volume of your compliance, which devalues the harm. [...] The victory that is possible here is not a moral but an existential one. The other cheek here sets in motion not the enemy's sense of guilt (which he is perfectly

⁶⁰⁰ On 'sharashki', see Aleksandr Solzhenitsyn, *The First Circle* (New York: Harper and Row, 1968); Asif Siddiqi, 'Scientists and Specialists in Gulag: Life and Death in Stalin's *Sharashka*', *Kritika: Explorations in Russian and Eurasian History*, vol.16:3 (2015), pp.557-588.

⁶⁰¹ See [in Russian] Daniil Granin, *Zubr* (Leningrad (St Petersburg): Sovetskii pisatel', 1987).

⁶⁰² See [in Russian] Aleksandr Moiseev, *Nemtsy na yuzhnom Urale* (Chelyabinsk: Moi dom, 2013).

⁶⁰³ Joseph Brodsky, *Less Than One: Selected Essays* (London: Penguin, 1986), p.389.

capable of quelling) but exposes his senses and faculties to the meaninglessness of the whole enterprise: the way every form of mass production does.⁶⁰⁴

By design, the 'sharashka' setting was anything but intellectually stimulating or welcoming to science. Work was organised in a routine manner, discipline was strict, and contacts with the outside world were close to non-existent. Still, the fact that the scientific mind and genius could not only survive, but, at times even thrive within this context highlights both the absurdity of the sharashka system and the limits of its dehumanising effects.

As the Cold War was moving into top gear in the late 1940s, the Party once more tightened its ideological grip, which the brief rapprochement with the West in the final stages of the Second World War seemed to have relaxed. This resolve, in turn, gave rise to a 'strident ideological campaign' named after its principal architect, the Politburo member Andrei Zhdanov – *zhdanovshchina*.⁶⁰⁵ Underpinned by vociferous criticism against 'the pernicious influence of bourgeois culture', the campaign vigorously attacked public figures for 'servility and slavishness before Western culture'.⁶⁰⁶ Science, just as other areas of social activity, was hardly insulated from the effects of the Party quest for ideological supremacy, whereby 'militant Soviet nationalism' supplanted scientific internationalism and ideologists assumed power over the management of science.⁶⁰⁷

The notorious KR Affair involving two prominent life scientists, Grigorii Roskin and Nina Klyueva, demonstrated that even in the late 1940s when the Soviet leadership was desperate to attain the nuclear weapon technology, physics was hardly the only area of science that attracted the attention of the Politburo. Indeed, symbolically referred to as a 'biological atomic bomb', Kluyeva and Roskin's anticancer drug research was deemed of such an immense value to the Kremlin that attempts to share the results with American colleagues and engage in active collaboration resulted in the

⁶⁰⁴ Ibid.

⁶⁰⁵ Nikolai Kremmentsov, *Stalinist Science, op cit*, p.129.

⁶⁰⁶ Ibid.

⁶⁰⁷ Ibid, p.131.

Soviet scientists being subject to official public reprimand for their anti-patriotic actions and forced to acknowledge their mistakes at an honour court trial.⁶⁰⁸ The case had far-reaching implications for the Soviet scientific community as a whole. For instance, following the TsK's Orgburo refusal to allow the USSR Academy of Sciences to elect prominent foreign scientists as corresponding members in the aftermath of the KR Affair, Soviet researchers were in turn required to give up their positions in scientific societies abroad. Moreover, any international scientific visits to and from the Soviet Union had to be explicitly approved by the Politburo, with Soviet delegations being accompanied by a representative of the secret police and specifically instructed on what they could and could not do.⁶⁰⁹ The Party further used the KR Affair to re-educate the scientific community about their patriotic duties and responsibilities and, more broadly, about the appropriate manner of professional behaviour in light of the constant threat of coming into contact with Western intelligence services.

By far the most often cited and well-documented example of an attempt to bring science under political control initiated by the Communist Party is the fate of genetics following the Lysenko Affair.⁶¹⁰ Contrary to the popular view, it is naïve to assess the events of 1948 and resultant 'death sentence' for modern genetics in the USSR solely through the lens of a clash between

⁶⁰⁸ See Nikolai Kremmentsov, 'In the Shadow of the Bomb, *op cit.*

⁶⁰⁹ *Ibid.*, p.60-61.

⁶¹⁰ The Lysenko Affair has been well documented. Examples include David Jarovsky, *The Lysenko Affair*, (Chicago IL: University of Chicago Press, 1986); Zhores Medvedev, *The Rise and Fall of T.D. Lysenko*, (New York, NY: University of Columbia Press, 1969); Dominique Lecourt, *Proletarian Science: The Case of Lysenko*, (London: NLB, 1977); Nils Roll-Hansen, *The Lysenko Effect: The Politics of Science*, (Amherst NY: Humanity Books, 2005); Richard Lewontin and Richard Levins, 'The Problem of Lysenkoism' in Hilary Rose and Steven Rose (ed.) *The Radicalisation of Science: Ideology of/in the Natural Sciences*, (Basingstoke: The Macmillan Press Ltd, 1976), pp. 32-64; Nils Roll-Hansen, 'The Persistence of T.D. Lysenko's Agrobiological in the Politics of Science', *Osiris*, vol.23:1 (2008), pp.166-188; William Dejong-Lambertand and Nikolai Kremmentsov, 'On Labels and Issues: The Lysenko Controversy and the Cold War', *Journal of the History of Biology*, vol.45 (2012), pp.373-388; Michael Gordin, 'How Lysenkoism Became Pseudoscience: Dobzhansky to Velikovsky', *Journal of the History of Biology*, vol.45 (2012), pp.443-468; George Bernard Shaw, 'Behind the Lysenko Controversy', *The Saturday Review of Literature*, 16 April 1949, p.10; H.J. Muller, 'It Still Isn't a Science: A Reply to George Bernard Shaw', *The Saturday Review of Literature*, 16 April 1949, p.11; Julian Huxley, 'Soviet Genetics: The Real Issue', *Nature*, vol.163:4155 (1949), pp.935-942; Nils Roll-Hansen, 'The Practice Criterion and the Rise of Lysenkoism', *Science and Technology Studies*, vol.2:1 (1989), pp.3-16; Maxim Mikulak, 'Darwinism, Soviet Genetics, and Marxism-Leninism', *Journal of the History of Ideas*, vol.31:3 (1970), pp.359-376; Nikolai Kremmentsov, 'A "Second Front" in Soviet Genetics: The International Dimension of the Lysenko Controversy, 1944-1947', *Journal of the History of Biology*, vol.29:2 (1996), pp.229-250; David Holloway, 'Scientific Truth and Political Authority in the Soviet Union', *Government and Opposition*, vol.5:3 (1970), pp.345-367; Kirill Rossianov, 'Editing Nature: Joseph Stalin and the "New" Soviet Biology', *Isis*, vol.84 (1993), pp.728-745; Olga Elina et al. 'Plant Breeding on the Front: Imperialism, War, and Exploitation', *Osiris*, vol.20 (2005), pp.161-179; [in Russian] E. Levina, *Vavilov, Lysenko, Timofeev-Resovskiy: Biologiya v SSSR: Istoriya i istoriografiya*, (Moscow: Airo, 1995). A far less documented example of pseudoscience is Olga Lepeshinskaya's theory of the critical role of cell membranes in the life of the cell. Despite her success in securing some political endorsement for her work, the case of Lepeshinskaya has received considerably less attention than the one of Lysenko's. See Valery Soyfer, 'Stalin and Fighters against Cellular Theory', *Studies in the History of Biology*, vol.3:2 (2011), pp.83-96.

science and ideology. Rather, in order to grasp and appreciate both the nature and implications of the Lysenko Affair, it is essential to uncover and analyse the complex dynamics that underpinned it, as well as to take into account the context provided by the rise of *zhdanovshchina*

The name of Trofim Lysenko gained in popularity during the 1930s and especially the 1940s in the USSR in connection with his ‘sensational’ discoveries in agrobiolgy, a discipline that he himself coined drawing upon concepts from plant physiology, genetics, cytology, and evolutionary theory.⁶¹¹ A notable representative of *vydvizhenie*, Lysenko managed to secure the Communist Party high command’s praise and protection on the grounds of his ‘scientific’ work on plant vernalisation which, in his own words, offered tremendous practical benefits for revitalising Soviet agriculture. To further boost his claims, he argued in favour of a proletarian-style (Lamarckian) genetics based on the theory of environmentally acquired characteristics. Lysenko’s quick ascent in the scientific hierarchy and eventual appointment as president of VASKhNIL in 1938 allowed him to solidify his position and set the scene for the fateful 1948 VASKhNIL meeting at which the triumph of Lysenkoism over ‘bourgeois’ genetics was officially proclaimed.⁶¹²

While high-level sanction and support from Politburo played an indispensable role in facilitating the rise of Lysenkoism as a dominant doctrine in science, several other factors provided a favourable atmosphere for it to flourish. By the mid-1930s, modern genetics and its scholars in the Soviet Union were already treated with suspicion by the Communist Party leadership, not least because of its linkage to eugenics and the racial discrimination and ‘fascist’ policies promulgated in Nazi Germany. At the same time, following the forced collectivisation of agriculture, finding ways to improve efficiency and increase crop yields became top state priorities. It was against this backdrop that the figure of Trofim Lysenko – a peasant with virtually no formal schooling but deeply committed to the goals and ideology of the party – came to the fore

⁶¹¹ See Nikolai Kremmentsov, *Stalinist Science*, p.59.

⁶¹² See, for example, [in Russian] Dmitrii Zykov, *Oshibochnye polozheniya v agronomicheskoy uchenii V.R. Vil'yamsa v svete nauchnogo analiza T.D. Lysenko*, (Alma-Ata: Kazakh State Publishing House, 1951).

proposing a relatively simple technique 'proven' to deliver rapid practical results and enhanced farming productivity. To complete the picture, his work enjoyed some initial recognition and praise from within the life science community and even one of his later, most vocal critics, Nikolai Vavilov, was on record proudly announcing Lysenko's 'remarkable discovery' at the Sixth International Congress in Genetics in the US in 1932.⁶¹³ A few years later, both Vavilov and Kol'tsov, among others, fell victims to the witch-hunt, directed against those who opposed Lysenko's ideas and as such, were seen as anti-Soviet.⁶¹⁴

One additional factor that had bearing on the way in which the Lysenko Affair unfolded pertained to the extension of party culture and rituals to the area of science. In the absence of political opposition, the Communist Party adopted a system of inter-party democracy featuring various deliberative mechanisms designed to resolve controversies and prevent power abuse within the hierarchies. Given the centrality of science as an institution of social and political significance and the need to stimulate its progress, the Party, through its Department of Propaganda and Agitation (*Upravlenie agitatsii i propagnady: AGITPROP*) sought to utilise the deliberative tools available at its disposal for tackling the scientific disputes of the day. Among the areas that attracted AGITPROP's attention were philosophy, genetics, linguistics, physiology, and political economy. The 1948 VASKhNIL meeting that affirmed the victory of Lysenkoism thus resembled a party congress (*s'ezd*) the overall goal of which was to produce a single unified and final true answer of the debate between geneticists and Lysenkoists. The defeated side was then expected to 'disarm' themselves through *samokritika* (self-criticism) and admit to their 'mistakes'. A similar pattern was adopted in the other four disputes of the period, yet none of them produced the tragic result

⁶¹³ See Nikolai Vavilov, *The Process of Evolution in Cultivated Plants*, Sixth International Congress of Genetics, 1932, Ithaca, USA. Available at <http://www.esp.org/books/6th-congress/facsimile/contents/6th-cong-p331-vavilov.pdf> (accessed 13/03/2015). On the point of initial scientific support for Lysenko's work, see also Nils Roll-Hansen, 'A New Perspective on Lysenko?', *Annals of Science*, vol.42 (1985), pp.261-278. On the tragic fate of Nikolai Vavilov in the years following Lysenko's rise to power, see Mark Popovsky, *The Vavilov Affair*, (Hamden, CT: Archon Books, 1984). More recently, some evidence has emerged suggesting that the fate of Nikolai Vavilov was decided even before his open confrontation with Lysenko. On the latter point, see Eduard Kolchinsky. 'Nikolai Vavilov in the Years of Stalin's "Revolution from Above"', *Centaurus*, vol.56:4 (2014), pp.330-358.

⁶¹⁴ Nikolai Vavilov was arrested and died in prison in 1942. See Mark Popovsky, *The Vavilov Affair* (Hamden, CT: Archon Books, 1984). Kol'tsov lost his directorship position at the Institute of Experimental Biology and died of stroke shortly thereafter in 1940. See Vadim Birstein, *The Perversion of Knowledge* (Cambridge MA: Westview Press, 2001).

yielded in the Lysenko Affair, a trend that has prompted Alexej Kojevnikov to describe the Stalinist system as ‘chaotic’, since it often ‘reacted on a random basis but with excessive power, producing outputs which were quite irrelevant to the level of the incoming “signal from below”.’⁶¹⁵ Nevertheless, any important political decision, even those resulting from an internal chaos were then presented as logical outcomes consistent with the Party’s ideology.⁶¹⁶

Nikolai Kremmentsov adds to the analysis of the 1948 meeting by contextualising it in the broader setting of socio-political polarisation, manifested in the *zhdanovshchina* campaign. Against this backdrop, science constituted ‘a mere extension of politics’ with ‘no broader loyalties to anything but the state; and no interests aside from those set by the state: it was a merely an instrument for pursuing state objectives.’⁶¹⁷ This model, in turn, required the complete subordination of science to the state – both institutionally and intellectually.

The net effect of the institutionalisation of Lysenkoism is hard to assess but it suffices to mention that following the 1948 August session of VASKhNIL modern genetics was treated as a scientific heresy and virtually ceased to exist in the Soviet Union before it was formally re-established in the 1960s. Textbooks were re-written, courses re-designed and research lines abandoned. Many prominent researchers suffered under the pressures of the Stalinist repressive apparatus as a result of their disinclination to ‘disarm’ and recognise the superiority of Lysenko’s pseudoscience (*I’zhenauka*). Equally devastating were the effects of the practical application of Lysenkoism in agriculture. Most of his ‘innovative methods’, including the planting of winter

⁶¹⁵ Alexei Kojevnikov, ‘Rituals of Stalinist Culture at Work: Science and the Games of Interparty Democracy circa 1948’, *The Russian Review*, vol.57 (1998), p.51. See also Ethan Pollock, ‘From Partiinost’ to Nauchnost’ and Not Quite Back Again: Revisiting the Lessons of the Lysenko Affair’, *Slavic Review*, vol.68:1 (2009), pp.95-115. On the significance of Party rituals in the Soviet Union, see Alexei Kojevnikov, ‘President of Stalin’s Academy: The Mask and Responsibility of Sergei Vavilov’, *Isis*, vol.87 (1996), pp.18-50.

⁶¹⁶ *Ibid.*

⁶¹⁷ Nikolai Kremmentsov, *Stalinist Science*, *op cit*, p.179.

wheat in Siberia, of sugar beet in Central Asia, or potatoes in summer met with little success and were eventually abandoned.⁶¹⁸

Military-Oriented Research

Efforts to develop biodefence capability in case of biological attacks dated back to 1930 when the Vaccine-Serum Laboratory under the auspices of the Military-Sanitary Directorate of the Red Army (*Vaksinno-sevyrotochnaya laboratoriya voenno-sanitarnogo upravleniya RKKA*) was established.⁶¹⁹ As it quickly became apparent, probably due to the Soviet intelligence reports that the Japanese army had commenced offensive biological activities in Manchuria, a single laboratory seemed hardly sufficient to ensure adequate preparedness in case of a biological attack. Hence, three years later the laboratory was converted into a specialised institute and its director, Professor Ivan Velikanov, was appointed as the institute chief. Between 1933 and 1937 the institute was tasked with the development of means of defence against biological and chemical weapons and some significant progress was made in this regard. Having changed its location on a number of occasions, in 1942 it was finally moved to Kirov where it became known as a Scientific Research Institute of Epidemiology and Hygiene (*Nauchno issledovatel'skii institute epidemiologii i gigieny: NIIEG*). During the War years a number of important medications, including vaccines against anthrax, tularaemia, and brucellosis, and methods for the mass production of penicillin and streptomycin were developed there.⁶²⁰ Other research centres under the direction of the military in the USSR were created in Sverdlovsk (today Yekaterinburg) and Zagorsk (today Sergiev Posad).

Some commentators have suggested that the origins of the Soviet bioweapons programme can be traced back to late 1920s, that is, offensive and defensive activities in the area of the biological sciences ran in parallel. According to Anthony Rimmington, the decision to pursue offensive biological

⁶¹⁸ Sarah White, 'Death of the Peasant Demagogue', *New Scientist*, vol.72:1029 (1976), p.528. For a detailed discussion on the negative impact of Lysenkoism on agriculture, see David Joravsky, *The Lysenko Affair* (Chicago IL: University of Chicago Press, 1970).

⁶¹⁹ Mikhail Supotnitskii and Nadezhda Supotnitskaia, *Ocherki Istorii Chumy*, *op cit*, see Ocherk XXXV.

⁶²⁰ A method for the mass production of streptomycin in the Soviet Union was first developed between 1946 and 1947. See *ibid*.

capability 'was made against a background of genuine alarm within the Soviet leadership concerning the deteriorating international position and the country's lack of military and economic preparation to defend itself.'⁶²¹ Another factor that possibly influenced that decision was the shared conviction among the Soviet echelons that the German and Japanese military command were pursuing biological weapons. From the scarce data available it appears that the effort to develop biological weapons initially met with some success, an example of which could be considered the establishment of an open-air testing site on Vozrozhdenie ('Resurrection') Island in the Aral Sea in 1935.⁶²² The programme received a fresh impetus after 1945, driven in part by the intensifying Cold War dynamics and resultant arm race, and in part by the revelations of the extensive offensive work conducted at Japan's Unit 731. By that time, however, the biological weapon endeavour had already suffered significant losses as a result of the Stalinist purges. It suffices to mention that the chief of the RKKA, Professor Velikanov, was executed in 1938 on suspicion of being a spy. In the subsequent years, the programme was significantly hampered by the triumph of Lysenkoism which set back the development of the biological sciences for almost two decades. Little is known about the activities carried out between 1945 and 1970, even though some evidence appears to suggest that open-air testing of biological weapons took place on Vozrozhdenie Island.

Perhaps the most controversial element of the history of the Soviet bioweapons programme is the period between the 1970s and the early 1990s. Over the past twenty years, a considerable body of literature has emerged shedding some light on the 'modern' period of the programme – the time when it is said to have been considerably expanded and equipped with the latest advances in biotechnology, including genetic engineering.⁶²³ Accounts of Soviet defectors such as Vladimir Pasechnik and Ken Alibek, and Igor Domaradskii, who did not defect but published his memoirs both in Russian and English, have played a significant role in piecing together the

⁶²¹ See Anthony Rimmington, 'Invisible Weapons of Mass Destruction: The Soviet Union's BW Programme and Its Implications for Contemporary Arms Control', *Journal of Slavic Military Studies*, vol.13:3 (2000), p.3.

⁶²² *Ibid.*, p.24.

⁶²³ See Milton Leitenberg and Raymond Zilinskas, *The Soviet Biological Weapons Program*, *op cit.*

history of how the military high command and the Party leadership assisted by senior science administrators set out to build an enormous web of institutes, laboratories and experimental stations in which research on deadly pathogens for the purposes of obtaining offensive capability was carried out.⁶²⁴ Shortly after the collapse of the Soviet Union, in 1992 the then President of the already independent Russian Federation, Boris Yeltsin formally admitted to the existence of the programme and announced its termination. Suspicions of possible bioweapons development in the USSR were already growing in the early 1980s as a result of an anthrax outbreak in Sverdlovsk in 1979 believed to have been caused by the accidental release of anthrax spores from a military research facility situated nearby, known as Compound 19, and reports that the Soviet Union supplied 'yellow rain' to Vietnam and later used it during the Afghan war.⁶²⁵ It is worth noting that by that time the development, production, stockpiling, transfer, and acquisition of biological weapons had been prohibited under the 1975 BTWC of which the USSR was a depositary State Party. Ironically, according to the prevailing narrative on the Soviet biological weapons programme, the decision to

⁶²⁴ On the Soviet bioweapons programme, see Ken Alibek with Stephen Handelman, *Biohazard: The Chilling True Story of the Largest Covert Biological Weapons Programme in the World – Told from the Inside by the Man Who Ran It*, (London: Arrow, 2000); Igor Domaradskij and Wendy Orent, *Biowarrior: Inside the Soviet/Russian Biological War Machine*, (Amherst NY: Prometheus Books, 2003); David Hoffman, *The Dead Hand: Reagan, Gorbachev and the Untold Story of the Cold War Arms Race*, (London: Icon Books Ltd, 2011); Jeanne Guillemin, *Biological Weapons: From the Invention of State-Sponsored Programmes to Contemporary Bioterrorism*, (New York, NY: Columbia University Press, 2005); Jeanne Guillemin, *Anthrax: The Investigation of a Deadly Outbreak*, (Berkeley CA: University of California Press, 2001); Kathleen Vogel, *Phantom Menace or Looming Danger?: A New Framework for Assessing Bioweapons Threats*, (Baltimore, MD: The Johns Hopkins University Press, 2013); Sonia Ben Ouagrham-Gormley, *Barriers to Bioweapons: The Challenges of Expertise and Organisation for weapons Development*, (Ithaca, NY: Cornell University Press, 2014); John Hart, 'The Soviet Biological weapons Programme' in Mark Wheelis et al (ed.), *Deadly Cultures: Biological Weapons Since 1945*, (Cambridge, MA: Harvard University Press, 2006), pp.132-156; Anthony Rimmington, 'The Soviet Union's Offensive Programme: Implications for Contemporary Arms Control' in Susan Wright (ed.), *Biological Warfare and Disarmament: New Problems / New Perspectives*, (New Delhi: Vision Books, 2003), pp.103-148; Igor Domaradskij and Wendy Orent, 'Achievements of the Soviet Biological Weapons Programme and Implications for the Future', *Revue Scientifique et Technique*, vol.25:1 (2006), pp.153-161; Valentina Markusova et al, 'From Bioweapon to Biodefense: The Collaborative Literature of Biodefence in the 1990s', *Scientometrics*, vol.53:1 (2002), pp.21-38; Anthony Rimmington, 'From Offence to Defence: Russia's Reform of Its Biological Weapons Complex and the Implications for Western Security', *The Journal of Slavic Military Studies*, vol.16:1 (2003), pp.1-43; Neil Metcalfe, 'A Short History of Biological Warfare', *Medicine, Conflict, and Survival*, vol.18:3 (2002), pp.271-282; Anthony Rimmington, 'Fragmentation and Proliferation: The Fate of the Soviet Union's Offensive Biological Weapons Programme', *Contemporary Security Policy*, vol.21:1 (1999), pp.86-110; Sonia Ben Ouagrham-Gormley and Kathleen Vogel, 'The Social Context Shaping Bioweapons (Non) Proliferation', *Biosecurity and Bioterrorism: Biodefence Strategy, Practice, and Science*, vol.8:1 (2010), pp.9-24; Raymond Zilinskas, 'Confronting Biological Threats to International Security: A Biological Hazards Early Warning Programme', *Annals of the New York Academy of Sciences*, vol.666 (1992), pp.146-176.

⁶²⁵ See Jeanne Guillemin, *Anthrax: The Investigation of a Deadly Outbreak*, (Berkeley CA: University of California Press, 2001); Philip Towle, 'The Soviet Union and the Biological Weapons Convention', *Arms Control*, vol.3:3 (1982), pp.31-40; Raymond Zilinskas, 'Anthrax in Sverdlovsk?', *Bulletin of Atomic Scientists*, vol.39:6 (1983), pp.24-27; Charles Gregg, 'Anthrax in Sverdlovsk: Commentary', *Bulletin of Atomic Scientists*, vol.39:8 (1983), p.63; Michael Gordin, 'The Anthrax Solution: The Sverdlovsk Incident and the Resolution of Biological Weapons Controversy', *Journal of the History of Biology*, vol.30 (1997), pp.441-480; Elisa Harris, 'Sverdlovsk and Yellow Rain: Two Cases of Soviet Noncompliance?', *International security*, vol.11:4 (1987), pp.41-95; Julian Perry Robinson, 'The Soviet Union and the Biological Weapons Convention and a Guide to Sources on the Sverdlovsk Incident', *Arms Control*, vol.3:3 (1982), pp.41-56; Jonathan Tucker, 'The "Yellow Rain" Controversy: Lessons for Arms Control Compliance', *The Nonproliferation Review*, Spring 2001, pp.25-42.

expand the offensive effort was made about the same when the BTWC negotiations were taking place. Nevertheless, any allegations of possible offensive biological activity still carried some political strength, something evident in verbal exchange between the US and Soviet delegation on the Sverdlovsk incident at the First Review Conference of the BTWC in 1980.⁶²⁶

From the 1970s onwards, the 'modern' Soviet BW programme reportedly commenced. Besides the military research facilities under the auspices of the Ministry of Defence (*Ministerstvo oborony: MO*), an enormous research complex, *Biopreparat*, was established as a branch of the Main Directorate of Biotechnology Industry (*Glavnoe upravlenie mikrobiologicheskii promyshlenosti: GLAVMIKROBIOPROM*). *Biopreparat* was supposedly conceived as a dual-use agency formally tasked with the development of vaccines and pharmaceuticals but in practice offering a comfortable disguise for military-related work to go unfettered. Given the involvement of the civilian sectors, it is believed that a significant number of institutes and laboratories of MINZDRAV, including the AP System, AMS, and the USSR Academy of Sciences contributed to weapons development. It is worth noting that as the programme ran under utmost conditions of secrecy with many of those on the frontlines of research being virtually unaware of the overall objectives of their work.⁶²⁷ Some commentators point out to a four-layer legend (*legenda*) used to ensure that only a handful of individuals at the highest level of authority were aware of the *real* purpose of *Biopreparat*. Alongside the offensive work, code-named *Ferment*, a defensive biological programme, Problem 5, was established. Besides the anti-personnel bioweapons programme, effort was made to acquire anti-crop and anti-livestock biowarfare capability. To this end, a special programme, code-names *Ekologiya* ('Ecology') was set up under the Main Directorate for Scientific-Research and Experimental-Production Establishments of the Ministry of Agriculture (*Glavnoe upravlenie*

⁶²⁶ Review Conference of the Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final Document*, BWC/CONF.I/10, 1980, Geneva, Switzerland. Available at http://www.unog.ch/bwcdocuments/1980-03-1RC/BWC_CONF.I_10.pdf (accessed 7/8/2015).

⁶²⁷ On the alleged involvement of the Anti-Plague System in the Soviet bioweapons programme, see Sonia Ben Ouagrham-Gormley, 'Growth of the Anti-Plague System during the Soviet Period', *Critical Reviews in Microbiology*, vol.32 (2006), pp.33-46; Raymond Zilinskas, 'The Anti-Plague System and the Soviet Biological Warfare Programme', *Critical Reviews in Microbiology*, vol.32 (2006), pp.47-64; Milton Leitenberg and Raymond Zilinskas, *The Soviet Biological Weapons Program*, *op cit*.

nauchno-issledovatel'skikh i eksperimental'no-proizvodstvennykh uchrezhdenii pri Ministerstve sel'skogo khozyaistva SSSR).⁶²⁸ At its peak, the Soviet biological weapons effort is considered to have encompassed tens of thousands of scientists spread across facilities nationwide.

Professional Life Science Culture

Neither the Communist Party nor the life science community constituted homogenous, static entities, which is why presenting them as such creates a partial and even distorted representation of their otherwise dynamic set of interactions. And it is precisely this multifaceted constantly-evolving relationship that gave rise to the Soviet life science professional culture with its whole gamut of distinct nuances, shared rituals and norms, and sanctioned jargon and behaviour. Contrary to the popular belief, in totalitarian systems pervaded with ubiquitous mechanisms for control and assertion of dominance of a single politico-ideological culture, the role of quasi-formal cultures is far from insignificant. Indeed, given the limitations of total forms of governance, such cultures occupy a central place filling in crevices and normative vacuums, moulding opaque hierarchical structures, and producing chaotic, often unexpected outcomes.

To be a scientist in the Soviet Union was synonymous with prestige and a corresponding social status. And even if the extent to which such privileges were shared among researchers depending on their rank and field of study varied, in the public mindset the scientific profession largely evoked respect and a sense of deep appreciation. The latter was particularly true as far as medical workers and life scientists were concerned, not least because their work was underpinned by a strong conviction of public service. This professional ethos had a long-standing tradition dating back to the time of the Russian Empire and was only enhanced rather than suppressed following the Bolshevik Revolution. For instance, in 1964 SOVMIN passed a resolution to raise the salaries of healthcare professionals as part of a broader strategy

⁶²⁸ Anthony Rimmington, 'Invisible Weapons of Mass Destruction', *op cit*, p.12; Ken Alibek with Stephen Handelman, *Biohazard*, *op cit*.

directed toward those working in 'branches of the state economy offering immediate public service'.⁶²⁹

Enhanced social standing was inevitably tied to increased duties and responsibilities before the state, a trend that manifested itself in the rapid Bolshevisation and politicisation of the scientific community from the 1930s onwards. With the rise of political loyalty as a vital precondition for acquiring a degree and making a career, demonstrating ideological compliance became an underlying normative feature of science professional culture. This is not to say that the majority of scientists joined the Communist Party overnight. On the contrary, by and large researchers found themselves playing political games, paying lip service to the Marxist-Leninist ideology. Thus, dressing up scientific writings in political jargon and referring to the 'founding fathers' of the respective fields, say Charles Darwin for biology and evolutionism and Ivan Pavlov for neurophysiology emerged as a commonly-used approach for enhancing the credibility of scientific findings.⁶³⁰ In a similar fashion, given the state's preoccupation with projects of practical utility, any research, be it of pure or applied character, was virtually presented as promising practical benefits in order to ensure that the work would be granted approval.

The rigid structures and impenetrable power hierarchies enforced by the dense bureaucracies of the Communist Party and state apparatus provided some space for informal interactions and 'behind the scenes' lobbying and policy-making. Personal contacts and ties and senior Party officials turned into indispensable tools which scientists vigorously employed in an attempt to push their agenda and secure a favourable answer to their requests. During the 1930s, for instance, when the Stalinist purges were unfolding, researchers often turned for help to the renowned writer Maxim Gorky, who, by dint of enjoying a preferential treatment by the Party echelon and Stalin himself, managed to successfully intervene and influence on several

⁶²⁹ [in Russian] Prikaz Minzdrava SSSR, *O povyshenii zarabotnoi platy rabotnikov zdravookhraneniya*, N 470, 15 August 1964, available at <http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=ESU;n=15806> (accessed 6/09/2015).

⁶³⁰ See Nikolai Kremmentsov, *Stalinist Science*, *op cit*.

occasions arrest decisions.⁶³¹ In a similar fashion, whilst Lysenko was striving to consolidate his position prior to the 1948 VASKhNIL meeting, leading Soviet geneticists joined forces utilising any possible channel of communication with the senior Party leadership, including writing directly to Stalin striving to expose the shortcomings of Lysenkoism and avert its spread. As discussed, their efforts did not meet with success in the end but the fact that such a campaign existed is vivid illustration that even at times of tightened political control, the scientific community was not completely left at the mercy of the state but actively sought ways of expressing resistance using the means it had at its disposal.⁶³²

For the most part, science in the USSR remained insulated from public scrutiny. With the state being the sole patron of research, scientists were not required to compete for funding, nor were they held regularly accountable about how the money was spent. Research priorities were typically determined by GOSPLAN in the Five-Year Plans and subsequently announced to the Academies and the administration of the respective institutions. The presidium of each Academy was then expected to rubber-stamp the proposed plan and move on to its implementation. In research institutes the Academic Council fulfilled a similar function. The general public usually learnt about the Soviet latest scientific and technological breakthroughs from the media and press but overall had very little if any bearing on the decision-making process regarding the role and place of science in society. It was only toward the late 1980s within the context of *perestroika* (restructuring) and *glasnost'* (openness) that this trend began to change, something evident in the emergence of 'green' and 'eco' movements as the scale and degree of environmental degradation caused by industrial production, including the biotechnology industry, became apparent.⁶³³

⁶³¹ See Alexei Kojevnikov, *Stalin's Great Science: The Times and Adventures of Soviet Physicists*, (London: Imperial College Press, 2006).

⁶³² See Nikolai Kremontsov, *Stalinist Science*, *op cit*.

⁶³³ See Anthony Rimmington, 'Biotechnology Falls Foul of the Environment in the USSR', *Nature Biotechnology*, vol.7 (1989), pp. 785-788; Marjorie Sun, 'Soviet Biotechnology Meets Glasnost', *Science*, vol.241:4867 (1988), p.781.

Chapter 7: Post-Cold War Institutional and Infrastructural Legacies

*Walking down the street
Distant memories
Are buried in the past
Forever
'Scorpions', 1990*

The Collapse of the USSR and Its Impact on the Life Sciences

On 25 December 1991 Mikhail Gorbachev, the last Secretary General of the Communist Party of the USSR, resigned from his post, effectively announcing the dissolution of what had been one of the world's two superpowers. The processes unleashed by the radical reforms as part of *perestroika* and *glasnost*' introduced over the previous six years, coupled with a crippled economy and social stagnation, swept the country fuelling waves of nationalism and inspiring calls for independence. As a result, by the early 1990s the socialist system had collapsed with the former 'evil empire',⁶³⁴ giving rise to fifteen sovereign states. The world's political map thus redrafted has prompted some commentators to proclaim the 'end of history',⁶³⁵ manifested in the overall triumph of liberal democracy and market-based economy. In the former Soviet space the time was ripe for a fundamental Change.⁶³⁶

The chief successor of the USSR was the Russian Federation which took over not only the lion's share of its former territory and population but also assumed its positions in international organisations, including the permanent seat in the United Nations Security Council. The first president of the newly-independent state was Boris Yeltsin who won Russia's first presidential

⁶³⁴ Ronald Reagan, *Remarks at the Annual Convention of the National Association of Evangelicals*, 8 March 1983, Orlando, Florida, USA. Available at <http://www.reagan.utexas.edu/archives/speeches/1983/30883b.htm> (accessed 3/09/2015).

⁶³⁵ See Francis Fukuyama, *The End of History and the Last Man*, (London: Penguin, 1992).

⁶³⁶ In the popular culture of the countries of the Former Soviet Union, the concept of 'change' is a temporal signifier commonly used in everyday speech. Time is divided into two epochs: before the 'changes' and after the 'changes'. On the final years of the Soviet Union, see Alexander Dallin and Gail Lapidus (ed.), *The Soviet System in Crisis: A Reader of Western and Soviet Views*, (Boulder CO: Westview Press, 1991); Archie Brown, *The Gorbachev Factor*, (Oxford: Oxford University Press, 1996); Stephen White, *Gorbachev and After*, (Cambridge: Cambridge University Press, 1991). For an overview of Russian politics after 1991, see Richard Sakwa, *Russian Politics and Society*, 4th ed. (London: Routledge, 2008); Stephen White et al. (ed.), *Developments in Russian Politics*, 8th ed. (Basingstoke: Palgrave, 2014); Michael Waller, *Russian Politics Today*, (Manchester: Manchester University Press, 2005); Cameron Ross, *Russian Politics Under Putin*, (Manchester: Manchester University Press, 2004); Rick Fawn (ed.), *Realignments in Russian Foreign Policy*, (London: Frank Cass, 2003).

elections held in June 1991, defeating the Gorbachev-backed Communist Party's candidate, Nikolai Ryzhkov.⁶³⁷ Starting in 1992, Russia's new leadership embarked on a large-scale campaign for socio-economic transformation, a course which had been hinted at by President Yeltsin a few months prior to the country's official declaration of independence. In essence, the package of measures that the government introduced, such as price liberalisation, strict fiscal discipline, and privatisation sought to achieve a rapid conversion of the state-controlled command economy into a market-based one. The resultant 'shock therapy' exacerbated the already skyrocketing hyperinflation, cut social welfare spending and state subsidies to critical levels, and a severe credit crunch unfolded. Amidst growing impoverishment, mass bankruptcy of industries, shortage of basic goods, and flourishing black markets the cabinet of Yegor Gaidar was forced to resign. For the most part, the 1990s constituted a volatile and unpredictable period, marked by socio-economic instability and political uncertainty. Oligarchs, organised crime, and a military intervention in Chechnya were among the highlights of the turbulent transition from a totalitarian past to a relatively freer, quasi-democratic society. With yet another economic crisis well underway in 1998 and NATO (North Atlantic Treaty Organisation) bombers flying over Kosovo in the following year, the prospects for Russian domestic and foreign policy as widely perceived in the Kremlin on the brink of the new millennium were hardly bright.

The dissolution of the USSR had a tremendous impact on the organisation and governance of science. Calls for reforms to democratise science institutions and make the funding system more competitive intensified in the late 1980s culminating in Gorbachev's decree of 1990, which made the Soviet Academy of Sciences independent from the government.⁶³⁸ Struggles for power predominantly driven by those on the margins of the scientific community manifested themselves in vociferous attacks on the Academy and

⁶³⁷ Boris Yeltsin played a key role in the attempted coup of 19-22 August 1991 (*Avgustovskii putch*) when a group of hardliners of the Communist Party tried to overthrow the Gorbachev regime. For a timeline of the events of August 1991, see [in Russian] 'Avgustovskii putch GChKP. Khronika sobytii 19-22 avgusta 1991goda', *RiaNovosti*, 19 August 2011, available at <http://ria.ru/spravka/20110819/415632412.html> (accessed 3/09/2015).

⁶³⁸ See *Ukaz Prezidenta SSSR O Statuse Akademii Nauk SSSR*, No.627, 23 August 1990, Moscow. The decree was later reversed by President Boris Yeltsin.

deliberate campaigns for the establishment of rival intuitions, developments which subsequently resulted in the creation of a separate Russian Academy of Sciences (*Rossiiskaya akademiya nauk: RAN*) even before the USSR disintegration was formally announced. Yet the socio-economic environment in the new, independent Russia proved far less favourable to science, especially in the early days of the transition to democracy. State support for science, virtually taken for granted during the Soviet time, ceased once the government commenced the implementation of its 'shock therapy' policies. With the flow of money practically frozen, many research institutes were compelled to close and those that still managed to reorganise faced the brutal reality of equipment and materials shortages and irregular, meagre salaries. Confronted with the dire consequences of the financial crisis, a significant number of talented individuals opted out of science to seek employment in other walks of life. Ironically, the job of a shop assistant or a taxi driver appeared much more attractive in terms of pay compared to what even a senior researcher could earn labouring on the bench.⁶³⁹ Emigration constituted another tempting alternative option which scientists, especially those enjoying some prominence in their respective fields, readily embraced. Brain drain thus soon emerged as a disturbing trend hardly limited to a particular generation of researchers or field of scholarship but being particularly acute in the natural sciences. By the mid-1990s job hunting abroad among fresh Russian graduates peaked, as many of them, lured by the prospects of a comfortable career in their desired area of study aimed to secure a position in a foreign institution even before their diploma was issued.⁶⁴⁰

⁶³⁹ See Paul Josephson, 'Russian Scientific Institutions: Internationalisation, Democracy and Dispersion', *Minerva*, vol.32:1 (1994), pp.1-24; Peter Aldhous, 'A Scientific Community on the Edge', *Science*, vol.264 (1994), pp.1262-1264; Colin Norman and Daniel Koshland Jr, 'Editorial: Science in Russia', *Science*, vol.264 (1994), p. 1235; Elena Mirskaya, 'Russian Academic Science Today: Its Societal Standing and the Situation within the Scientific Community', *Social Studies of Science*, vol.25 (1995), pp.705-725; Toni Feder, 'New Minister Is Unlikely to Resuscitate Russian Science', *Physics Today*, vol.51:8 (1998), pp.54-55; James Watson and Gerson Sher, 'Does Research in the Former Soviet Union Have a Future', *Science*, vol.264 (1994), pp.1280-1281.

⁶⁴⁰ See 'The Soviet Brain Drain is the U.S. Brain Gain', *Bloomberg Businessweek*, 3 November 1991, available at <http://www.bloomberg.com/bw/stories/1991-11-03/the-soviet-brain-drain-is-the-u-dot-s-dot-brain-gain> (accessed 5/09/2015); R.Adam Moody, 'Reexamining Brain Drain from the Former Soviet Union', *The Nonproliferation Review*, Spring-Summer 1996; Irina Ivankhnyuk, *Brain Drain from Russia: In Search for a Solution*, (Warsaw, Poland: Centre for International Relations, 2006); Loren Graham and Irina Dezhina, *Science in the New Russia: Crisis, Aid, Reform*, (Bloomington, IN: Indiana University Press, 2008).

Against the backdrop of economic hardship and mass exodus of scientists from Russia to the West, efforts to salvage science and ensure its long-term survival were two-sided – internal and external – entailing domestic institutional and infrastructural reforms in the system of knowledge production, as well as, international aid and cooperation. Far from being a novelty, the links between Russian scientists and foreign-based philanthropies went back a long time, as evidenced in the fellowship programme of the Rockefeller Foundation which allowed gifted Soviet scholars in the 1920s to undertake research abroad.⁶⁴¹ Whilst the Foundation never managed to provide substantial material assistance in terms of new facilities and equipment, mainly due to political constraints, it still replied positively to requests for books and scientific literature. In a similar fashion, around the same period the Harriman Foundation demonstrated a favourable inclination to supply RES with relevant publications in the field of genetics and eugenics.⁶⁴² East-West scientific collaboration received fresh impetus during the *détente* years when it was incorporated in a range of formal agreements.⁶⁴³ Exchange programmes jointly administered by the Soviet Academy of Sciences and the US NAS allowed researchers across both sides of the iron curtain to catch a glimpse of one another's professional settings at a time when the USSR borders remained largely sealed for average citizens. Given those long-standing scientific ties, it is barely surprising that when the political conditions in Russia radically changed in the early 1990s private philanthropies and charities were among the first to offer assistance in an attempt to bring science back to its feet. The list of donors featured prominent organisations including the George Soros's International Science Foundation (ISF), Fulbright, and IREX (International Research and Exchanges Board). Following the example of their American counterparts, European charities such as the Wellcome Trust, British Council, and International Association for the Promotion of Cooperation with Scientists

⁶⁴¹ See Susan Gross Solomon and Nikolai Kremontsov, 'Giving and Taking across Borders: The Rockefeller Foundation and Russia, 1919-1928', *Minerva*, vol.39 (2001), pp.265-298; Susan Gross Solomon, 'Being There: Fact-Finding and Policymaking: The Rockefeller Foundation's Division on Medical Education and the "Russian Matter", 1925-1927', *Journal of Policy History*, vol. 14:4 (2002), pp.384-416; [in Russian] Alexei Kojevnikov, 'Filantropia Rokfelleri i sovetskaya nauka', *Voprosy istorii estestvoznaniya i tekhniki (VIET)*, No.2 (1993), pp.80-111.

⁶⁴² Nikolai Kremontsov, 'From "Beastly Philosophy" to Medical Genetics', *op cit*.

⁶⁴³ See David Finley, 'Soviet-U.S. Cooperation in Space and Medicine: An Analysis of the *Détente* Experience' in Nish Jamgotch Jr. (ed.), *Sectors of Mutual Benefit in U.S.-Soviet Relations*, (Durham, NC: Duke University Press, 1985), pp.137-151.

from the Independent States of the former Soviet Union (INTAS) announced funding calls aimed at supporting local research projects and encouraging scientific partnerships. In the absence of a regular flow of state funding for science, foreign aid proved indispensable in sustaining research activities in Russia. Moreover, through the assistance channels thus created Russian scientists for the first time became exposed to an alternative system for money procurement, one based on peer-review and competition, whereby individual talent and ingenuity could be recognised, acknowledged, and rewarded accordingly.⁶⁴⁴

For their part, the Russian government introduced a range of measures and policies directed at ameliorating the budgetary deficit in science financing and promoting innovation and growth. Throughout the 1990s the Ministry of Science and Technology (at present the Ministry of Education and Science, *Ministerstvo obrazovaniia i nauki: MINOBRANAUKI*) strived to implement its grand strategy for reforming the way in which science was managed. In pursuing the goal of a radical transformation of the science system, privatisation was deemed a top priority. To this end, new legislation regarding the establishment of foundations and non-governmental organisations and intellectual property rights was adopted with the view of fostering private ownership and market-oriented R&D.⁶⁴⁵ As far as foreign aid is concerned, provisions were made for tax exemption and co-financing. The science

⁶⁴⁴ See Loren Graham and Irina Dezhina, *Science in the New Russia: Crisis, Aid, Reform*, (Bloomington, IN: Indiana University Press, 2008). For an overview of the biotechnology sector in the Soviet Union in the years of Perestroika, see Rod Greenshields et al. 'Perestroika and Soviet Biotechnology', *Technology Analysis and Strategic Management*, vol.2:1 (1990), pp.63-70. On the financial support provided by foreign donors, see Valery Soyfer, 'Soros Support for Science Education in the Former Soviet Union', *Science*, vol.264, (1994), pp.1281-1282; Peter Aldhous and Alexander Dorozynski, 'Saving Russia's Threatened Biological Heritage', *Science*, vol.264 (1994), p.1266; Richard Stone, 'U.S., Russia to Provide Crucial Aid to Scientists', *Science*, vol. 268 (1995), p.979; Peter Aldhous, 'Elite Groups Struggle on with a Little Help from the West', *Science*, vol.264 (1994), pp.1264-1267; Richard Stone, 'Post-Cold War Science Thrives in the Heart of Siberia', *Science*, vol.270:5243 (1995), pp.1753-1755. On the reforms in the Russian science policy and system of science funding, see Nadezhda Gaponenko, 'Transformation of the Research System in a Transitional Society: The Case of Russia', *Social Studies of Science*, vol.25 (1995), pp.685-703; Irina Dezhina, 'Financing Russian Science: New Reforms and Mechanisms', *Problems of Economic Transition*, vol. 39:11 (1997), pp.78-92; Valentina Markusova et al. 'Information Behaviour of Russian Scientists in the "Perestroika" Period: Results of the Questionnaire Survey', *Scientometrics*, vol.37:2 (1996), pp.361-380; Theodore Gerber and Deborah Yarsike Ball, 'Scientists in a Changed Institutional Environment: Subjective Adaptation and Social Responsibility Norms in Russia', *Social Studies of Science*, vol.39:4 (2009), pp. 529-567; Natalia Gorodnikova, 'Transformation of R&D in Russia: The Role of Government Priorities' in David Dyker and Slavo Radosevic (ed.), *Innovation and Structural Change in Post-Socialist Countries: A Quantitative Approach*, NATO ASI Series: Science and Technology Policy – Vol.20, (Dordrecht: Kluwer Academic Publishers, 1999), pp.261-290; Natalia Kovaleva, 'Higher Education and the Labour Market in Russia: Trends in the Transition Period' in David Dyker and Slavo Radosevic (ed.), *Innovation and Structural Change in Post-Socialist Countries: A Quantitative Approach*, NATO ASI Series: Science and Technology Policy – Vol.20, (Dordrecht: Kluwer Academic Publishers, 1999), pp.429-446.

⁶⁴⁵ See Loren Graham and Irina Dezhina, *Science in the New Russia*, *op cit*.

funding system was fundamentally restructured. Block funding for research institutes whereby the amount of money allocated to a particular facility was determined by its size and previous budgets was replaced with a grant competition awarded on the principle of peer-review. The drastic departure from the Soviet status quo manifested itself in the creation of the Russian Foundation for Basic Research (*Rossiiskii fond fundamental'nykh issledovaniï: RFFI*) in 1992 and, to an extent, constituted an expedient measure designed to make up for the significant reductions in the state expenditure on science.⁶⁴⁶ Funds (*fondy*) were another source of material support set up specifically for the purpose of promoting innovation and commercially-viable research. For instance, the Russian Fund for Technological Development (*Rossiiskii fond tekhnologicheskogo razvitiia: RFTR*) established in 1992 depended solely on voluntary allocations from industry to finance technology-oriented projects in various fields of study.⁶⁴⁷ By contrast, the Fund for Assistance to Small Innovative Enterprises (*Fond sodeistvia razvitiu malykh form predpriatii v nauchno-tekhnicheskoi sfere*), which came into existence two years later had its own state budget line independent from other agencies to provide support to science entrepreneurs and start-ups.⁶⁴⁸

Significant effort was dedicated to the development of laws on intellectual property rights. The USSR acceded to the Paris Convention for the Protection of Industrial Property in 1965, which brought the Soviet domestic patent legislation in line with the international legal requirements.⁶⁴⁹ Yet it is worth noting that the Soviet system for protection of intellectual property recognised two types of instruments: certificates and patents. Certification was by far a more commonly used form of ascertaining inventor's rights but,

⁶⁴⁶ Ibid. For an English summary of the mission, objectives, goals and activities of the Russian Foundation for Basic Research, see the organisation's Erawatch page, available at http://erawatch.jrc.ec.europa.eu/erawatch/opencms/information/country_pages/ru/organisation/organisation_mig_00_04 (accessed 6/09/2015). The official page of the Foundation in Russian is available at <http://www.rfbr.ru/rffi/ru/> (accessed 6/09/2015).

⁶⁴⁷ In 2014 the Russian Fund for Technological Development was restructured and renamed Fund for Industrial Development. Information about the Fund and its history is available at the Fund's official webpage, <http://www.rftr.ru/fund/> (accessed 6/09/2015).

⁶⁴⁸ The Fund is still in existence at the time of writing and in 2014 celebrated its twentieth anniversary. Further information is available at the Fund's official webpage, <http://www.fasie.ru/> (accessed 6/09/2015).

⁶⁴⁹ On the Soviet patent system, see M.Hoseh, 'The U.S.S.R. Patent System', *4 Patent, Trademark and Copyright Journal of Research and Education*, 220 (1960), pp.220-232; Lisa Cook, *A Green Light for Red Patents?: Evidence from Soviet Domestic and Foreign Inventive Activity, 1962 to 1991*, April 2011, Michigan State University, USA.

in contrast to patents, it assigned exclusive rights of use, exploitation, and development to the state. The inventor was nonetheless entitled to certain remuneration in the form of cash, especially in those cases when the new research product was deemed commercially viable.⁶⁵⁰ Soviet citizens were largely expected to apply for certificates, whereas foreign applicants were typically granted patents in their name with the ultimate ownership remaining with the Soviet state.⁶⁵¹ Major changes were introduced during the final years of Gorbachev's rule when revolutionary legislation was adopted patterned on the European and American patent regulations. This trend persisted after 1992 when Russia's patent agency, ROSPATENT (*Federal'naya sluzhba po intellektual'noi sobstvennosti*) took over the responsibilities of the USSR GOSPATENT (*Gosudarstvennoe patentnoe agentsvo SSSR*), with the new Russian laws on intellectual property mirroring the provisions of the European Patent Convention (EPC).⁶⁵² Based on the 1992 Patent Act, research institutes, industrial enterprises, and innovation firms received rights to intellectual property on knowledge and technology that were previously the property of the government.⁶⁵³

A major area of concern that attracted considerable international attention in the newly independent Russian Federation was the need both for securing the enormous arms arsenal inherited from the USSR and demilitarising science. The risk of possible proliferation of WMD was high. Besides Russia, several sovereign republics, including Belarus, Ukraine, and Kazakhstan, found themselves in possession of Soviet nuclear stockpiles. At the same time, the revelation that the USSR maintained and operated a clandestine biological weapons programme alarmed the international community, which demanded that immediate steps should be taken to assess the potential threat and dismantle any equipment used for the conduct of offensive activities in the life sciences. With the bulk of scientific R&D and industrial

⁶⁵⁰ See Raymond Zilinskas, 'Biotechnology in the U.S.S.R, Part 2', *Nature Biotechnology*, vol.2 (1984), p.687; Bernie Burrus, 'The Soviet Law of Inventions and Copyright', *Fordham Law Review*, vol.30:4 (1962), p.709.

⁶⁵¹ Raymond Zilinskas, 'Biotechnology in the USSR, Part 2', *op cit*.

⁶⁵² For further information on ROSPATENT, see the organisation's official webpage, <http://www.rupto.ru/> (accessed 6/09/2015). On the restructuring of the patent system in Russia, see also Laura Pitta, 'Intellectual Property Laws in the Former Soviet Republics: A Time of Transition', *Santa Clara High Technology Law Journal*, vol.8:2 (1992), pp.499-505, especially p. 503.

⁶⁵³ Loren Graham and Irina Dezhina, *Science in the New Russia*, *op cit*.

production dedicated to military ends and the prospect of a 'brain drain' of weapons scientists to 'rogue' states or terrorist groups looming large against the backdrop of the dire financial circumstances of post-Soviet science, the question of the Russian defence conversion became a pressing matter of paramount importance.⁶⁵⁴

Under the Nunn-Lugar Soviet Threat Reduction Act passed in November 1991, the US DoD initiated a Cooperative Threat Reduction (CTR) Programme, which pursued the following objectives:

- Dismantling FSU's WMD and associated infrastructure;
- Consolidating and securing FSU WMD and related technology and materials;
- Increasing transparency and encouraging higher standards of conduct in adherence to nuclear agreements and non-proliferation activity;
- Supporting defence and military cooperation with the objective of preventing proliferation.⁶⁵⁵

Initially conceived to address nuclear proliferation concerns, the Programme was subsequently expanded to support biological and chemical disarmament

⁶⁵⁴ See, for example, Kathleen Vogel, 'Pathogen Proliferation: Threats from the Former Soviet Bioweapons Complex', *Politics and the Life Sciences*, vol.19:1 (2000), pp.3-16; Colin Macliwain, 'Russian Weapons Labs Become the Top Priority for Western Funding', *Nature*, vol.384 (1996), pp.295-296; Anthony Rimmington, 'Fragmentation and Proliferation? The Fate of the Soviet Union's Offensive Biological Weapons Programme', *Contemporary Security Policy*, vol.20:1 (1999), pp.86-110; Amy Smithson, *Toxic Archipelago: Preventing Proliferation from the Former Soviet Chemical and Biological Complexes*, Report No.32, December 1999, The Henry Stimson Centre, Washington DC; Stephen Black, 'Threats to and from the Former Soviet Union', *The Journal of Slavic Military Studies*, vol.21:3 (2008), pp.491-526; Richard Wenzel, 'Recognizing the Real Threat of Biological Terror', *Transactions of the American Clinical and Climatological Association*, vol.113 (2002), pp.42-55. On the efforts to convert former weapon facilities to peaceful use and work, see Vlad Genin (ed.), *The Anatomy of Russian Defense Conversion*, (Walnut Creek, CA: Vega Press, 2001); Erhard Geissler et al. (ed.), *Conversion of Former BTW Facilities*, NATO Science Series: Disarmament Technologies – Vol.21, (Dordrecht: Kluwer Academic Publishers, 1998); Lev Sandakhchiev and Sergey Netesov, 'Strengthening the BTWC through R&D Restructuring: The Case of the State Research Centre of Virology and Biotechnology "VECTOR"' in Alexander Kelle et al. (ed.), *The Role of Biotechnology in Countering BTW Agents*, NATO Science Series: Disarmament Technologies – Vol.34, (Dordrecht: Kluwer Academic Publishers, 2001), pp.53-60; John Compton, 'Dissolution of the Soviet Union, Introduction of a Market Economy and the Future BTWC Compliance Protocol: Impact on the Russian Biotechnology Industry' in Alexander Kelle et al. (ed.), *The Role of Biotechnology in Countering BTW Agents*, NATO Science Series: Disarmament Technologies – Vol.34, (Dordrecht: Kluwer Academic Publishers, 2001), pp. 61-68; Sonia Ben Ouaghran and Kathleen Vogel, *Conversion at Stepnogorsk: What the Future Holds for Former Bioweapons Facilities*, Occasional Paper No.28, February 2003, Cornell University Peace Studies Programme, Ithaca, NY; Gulbarshyn Bozheyeva et al, *Former Soviet Biological Weapons Facilities in Kazakhstan: Past, Present, and Future*, Occasional Paper No.1, June 1999, Monterey Institute of International Studies, Monterey CA.

⁶⁵⁵ See David Steensman, Testimony Statement to the House Committee on Armed Services on US-Russian Cooperative Threat Reduction and Non-Proliferation Programs, Department of Defence, Office of Inspector General, 4 March 2003; see also Justin Bresolin, *Fact Sheet: The Nunn-Lugar Cooperative Threat Reduction Program*, June 2014, available at [http://armscontrolcenter.org/publications/factsheets/fact_sheet_the_cooperative_threat_reduction_program/\(accessed 27/03/2015\)](http://armscontrolcenter.org/publications/factsheets/fact_sheet_the_cooperative_threat_reduction_program/(accessed%2027/03/2015)). See also United States Government Accountability Office, *Biological Weapons: Effort to Reduce Former Soviet Threat Offers Benefits, Poses Risks*, April 2000, Washington DC. Available at <http://www.gao.gov/products/GAO/NSIAD-00-138> (accessed 6/09/2015).

efforts. Assistance with regard to biological-related concerns and their effective management has included the

- Consolidation of dangerous pathogen collections into central reference labs or repositories;
- Improvement in the safety and security of biological facilities;
- Enhancement of states' capabilities to detect, diagnose, and report bio-terror attacks and potential pandemics;
- Engagement of scientists with biological weapon-related expertise in research that supports force protection, medical countermeasures, diagnostics, and modelling.⁶⁵⁶

Attention was given to the need both for keeping weapon-scientists in employment and for their re-direction to civilian and peace-oriented work. A prominent actor in this domain has been the International Science and Technology Centre (ISTC), an intergovernmental body, set up in 1992 on the basis of an agreement between Russia, Japan, the EU, and the United States and still active at the time of writing. Since 1994, the ISTC has been providing material assistance and research grants across the former Soviet space to prevent diversion and help ensure that activities in the area of science are consistent with international law.⁶⁵⁷ A sister organisation – the Science and Technology Centre in Ukraine (STCU) – was established in 1995 to 'support research and development activities for peaceful

⁶⁵⁶ See Paul Bernstein and Jason Wood, *The Origins of Nunn-Lugar and Cooperative Threat Reduction: Case Study 3*, (Washington DC: National Defence University Press, 2010); Sharon Weiner, 'Reconsidering Cooperative Threat Reduction: Russian Nuclear Weapons Scientists and Non-Proliferation', *Contemporary Security Policy*, vol.29:3 (2008), pp.477-501; John Shields and William Potter (ed.), *Dismantling the Cold War: U.S. and NIS Perspectives on the Nunn-Lugar Cooperative Threat Reduction Program*, (Cambridge MA: Harvard University Press, 1997); Mary Nikitin and Amy Woolf, *The Evolution of Cooperative Threat Reduction: Issues for Congress*, CRS Report for Congress, June 2014, Washington DC; Office of Cooperative Threat Reduction Programme, official webpage available at <http://www.state.gov/t/isn/offices/c55411.htm> (accessed 6/09/2015); National Research Council, *The Biological Threat Reduction Program of the Department of Defense: From Foreign Assistance to Sustainable Partnerships*, (Washington DC: National Academies Press, 2007); National Research Council, *Countering Biological Threats: Challenges for the Department of Defense's Nonproliferation Program Beyond the Former Soviet Union*, (Washington DC: National Academies Press, 2009), 'Celebrating 20 Years of the Nunn-Lugar Program', *Nuclear Threat Initiative Newsroom*, 3 December 2012, available at <http://www.nti.org/newsroom/news/celebrating-20-years-nunn-lugar-program/> (accessed 6/09/2015). In 2012 Russian President Vladimir Putin reportedly announced that his country will not renew the agreement for a further extension of the Nunn-Lugar Programme. See David Herszenhorn, 'Russia Won't Renew Pact on Weapons with U.S.', *The New York Times*, 10 October 2012, available at <http://www.nytimes.com/2012/10/11/world/europe/russia-wont-renew-pact-with-us-on-weapons.html> (accessed 7/09/2015); Bryan Bender, 'Russia Ends US Nuclear security alliance', *The Boston Globe*, 19 January 2015, available at <https://www.bostonglobe.com/news/nation/2015/01/19/after-two-decades-russia-nuclear-security-cooperation-becomes-casualty-deteriorating-relations/5nh8NbtjitUE8UqVWFlooL/story.html> (accessed 7/09/2015).

⁶⁵⁷ For further information about the goals and activities of the ISTC, see its official webpage at http://www.istc.ru/istc/istc.nsf/fa_MainPageMultiLang?OpenForm&lang=Eng (accessed 6/09/2015). As of July 2015, the Russian Federation has officially withdrawn from the organisation and the ISTC Headquarters has been moved from Moscow to Astana, Kazakhstan.

applications by Ukrainian, Georgian, Uzbekistani, Azerbaijani and Moldovan scientists and engineers, formerly involved with development of WMD and their means of delivery, as part of the general process of conversion to a civilian, market-oriented environment.⁶⁵⁸ The USA unilaterally has also contributed to the efforts to demilitarise Soviet science and facilitate its conversion to civilian work through fostering partnerships and exchange visits. Several arms of the American government, including the Department of Agriculture, Department of Health and Human Services, Department of Energy, and the Environmental Protection Agency have pursued collaborative projects and active engagement with Russian scientists in such areas as plant and animal diseases, vaccine development, detection and prevention of infectious diseases, and environmental effects of biowarfare.⁶⁵⁹ Non-governmental organisations, too, have further sought to promote dialogue and scientific cooperation. Notable examples in this regard are the Civilian Research and Development Foundation (CDRF), a public-private partnership non-profit entity founded in 1995 to ‘facilitate mutually-beneficial scientific and technical collaboration’ between the USA and the FSU countries, and the US National Academies of Science which have provided expert advice on non-proliferation policy issues.⁶⁶⁰

Persistence of Soviet Inertia

The Scorpions’ emblematic song ‘Wind of Change’ released shortly after the fall of the Berlin Wall to celebrate the positive effects of *perestroika* and subsequent end of the Cold War conjures up a vivid picture of the ‘restructured’ USSR: ‘the world is closing in’ and the old regime is ‘buried in the past forever’. Such was the atmosphere of the time that, for once, a fundamental change toward a freer and more open society seemed both possible and attainable. It is precisely this idealist vision of a quick and smooth transition from a socialist past to a democratic future that gave the early reforms in the new Russia a fresh impetus. Over the following years, it

⁶⁵⁸ For further information about the goals and activities of the STCU, see its official webpage at <http://www.stcu.int/> (accessed 6/09/2015).

⁶⁵⁹ See Michelle Cook and Amy Woolf, *Preventing Proliferation of Biological Weapons: U.S. Assistance to the Former Soviet States*, CRS Report for Congress, April 2002, Washington DC, especially p.7-13.

⁶⁶⁰ *Ibid.*

has gradually become evident that there is more to democracy than elections and party pluralism; more to market economy than privatisation; and more to a civil society than a freedom of speech. In a similar fashion, the reforms in the governance of the life sciences have demonstrated that ‘borrowing’ foreign practices and ‘modelling’ foreign institutions do not automatically meet with success but instead, require the development of a relevant mentality and professional ethos in order to produce a long-lasting sustainable change. To this end, old habits need to be abandoned; past patterns need to be altered; and previously-established power relations need to be reconfigured. Since those processes are products of historical, cultural, and political contingencies, they are likely to prove resistant to a rapid, let alone, smooth change. Hence, it is hardly surprising that despite the effort invested in reforming the legislative, institutional, and administrative context of Russia’s biotechnology over the past two decades, trends related to the Soviet heritage persist and manifest themselves in the policy and everyday practice of life science research.

Biotechnology as a Vital State Asset

If throughout the 1990s the Russian government strived to ensure that science did not perish under the pressures of economic uncertainty, Yeltsin’s successors have set themselves a far more ambitious goal, namely to restore Russia’s scientific and technological prowess, and thus solidify the nation’s position on the international stage. Implicit in the strategic vision of the need to invest in R&D has been the assumption that scientific and technological advancement is an essential prerequisite for ensuring sustainable national security through economic growth and prosperity, flourishing industry, military superiority, and political prestige. Indeed, in the National Security Strategy of the Russian Federation until 2020, science, technology, and education are listed as ‘strategic national priorities’ in their own right:

24. In order to ensure national security and achieve the basic priorities of national security, the Russian Federation concentrates its efforts and resources on the following priorities of sustainable development:

- increasing the quality of life of Russian citizens by guaranteeing individual security and high standards of living;
- economic growth which is achieved first and foremost by developing a national system of innovation and by investing in human capital;
- science, technology, education, health care and culture, which are developed by reinforcing the role of the state and improving public-private partnership [...]⁶⁶¹

Within this context, biotechnology is deemed a sector of a particular significance, which despite being ripe for development as demonstrated in the experience of Western industrialised states, is still lagging behind in Russia. According to the State Coordination Programme for the Development of Biotechnology in the Russian Federation until 2020 (BIO 2020), a lengthy government document published in 2012 with the approval of the then Prime Minister, Vladimir Putin:

Three areas of technological advancement are key for the development of modern innovation economy: information technology, nanotechnology, and biotechnology. Advanced information technology has been implemented in Russia over the last twenty years. [...] For the past five years nanoindustry has been in a state of an active development. Whilst promising and with an enormous potential for sizable new markets, biotechnology, with the exception of biopharmacy has not yet received sufficient impetus for development in Russia.⁶⁶²

The overall objective of BIO 2020 is ‘the emergence of Russia as a global leader in the area of biotechnology and its various sub-disciplines, including biomedicine, agrobiotechnology, industrial biotechnology and bioenergy, as well as, the creation of a globally competitive bioeconomy.’⁶⁶³ To this end,

⁶⁶¹ [in Russian] ‘Strategia natsional’noi bezopasnosti Rossiiskoi Federatsii do 2020 goda’, approved by a Presidential Decree No.537, 12 May 2009, Moscow. Full text in Russian is available at <http://www.scrf.gov.ru/documents/99.html> (accessed 7/09/2015). Author’s translation. On the link between basic life science research and national security, see [in Russian] A. Spirin, ‘Fundamental’naya nauka i problemy biologicheskoi bezopasnosti’, *Vestnik RAN*, vol.74: 11 (2004), pp.963-972.

⁶⁶² See [in Russian] ‘Kompleksnaya programma razvitiya biotekhnologii v Rossiiskoi Federatsii na period do 2020’, 24 April 2012, Moscow. Full text in Russian is available at http://economy.gov.ru/minec/activity/sections/innovations/development/doc20120427_06 (accessed 7/09/2015). English summary is available at [http://bio-economy.ru/upload/BIO2020%20\(eng\)%20-%20short.pdf](http://bio-economy.ru/upload/BIO2020%20(eng)%20-%20short.pdf) (accessed 7/09/2015).

⁶⁶³ *Ibid.*

the Programme seeks to foster infrastructure that will support biotechnology development; promote bioindustry nationwide; attract and execute high-priority innovation and investment biotechnology projects; support research in the life sciences and physic-chemical biology; and implement novel education programmes to build capacity in biotechnology. The federal budgetary spending on the implementation of the programme between 2011 and 2015 is estimated to be 5659.8 million roubles and the approximate extra-budgetary expenditure for the same period is 6208.5 million roubles.

Analysing the current trends of biotechnology expansion in Russia, there are at least two issues that merit specific attention. The first one pertains to the context—that is, the global state of biotechnology development and the nation's ranking vis-à-vis the rest of the world. Part of the rationale for BIO 2020 is the argument that Russia has been lagging behind in terms of biotechnology when compared both with the Western economies, including the USA and EU, and some of its BRICS counterparts, most notably China and India. Whereas the Soviet bioindustry used to be a symbol of national pride and international prominence, its sudden drop from lead standing to seventieth place has invited a good deal of criticism from politicians and industry representatives alike. An article that appeared in *Rossiiskaya Gazeta* in 2008 summarised Russia's unsatisfactory performance in a warning tone:

The coming decade in Russia will be decisive for laying the foundations of innovation economy. We will either very soon become closely familiar with novel technologies which determine the face of the twentieth-first century, or will be left behind forever. In the conditions of vigorous international competition this is not just a question regarding the rate and quality of our economic growth but a question regarding the survival of Russia as a great power.⁶⁶⁴

⁶⁶⁴ Oleg Morozov and Raif Vasilov, 'I nakormit, i vylechit: K 2010 godu mirovoi rynek bioekonomiki sostavit bolee 2 trillionov evro', *Rossiiskaya Gazeta*, No. 4572, 25 January 2008, available at <http://www.rg.ru/2008/01/25/biotehnologii.html> (accessed 7/09/2015). Author's translation.

Critics have pointed out the government's neglect of the life sciences and the lack of a clear systemised policy of how best to revitalise and further enhance domestic R&D in areas as diverse as pharmaceutical and food production, environment-friendly technology, and industrial manufacturing in order to both boost economic growth and avoid dependency on foreign imports. In an attempt to ameliorate the existing deficiency in strategic planning and adequate state approach to biotechnology, the ruling party – United Russia – has actively joined forces with the Russian Society of Biotechnologists aiming to promote modernisation and foster cross-sectorial innovation. The scope of its policies will be discussed in detail in the next chapter but at this stage it suffices to highlight that the ongoing trajectory of biotechnology expansion is unlikely to be abandoned. Given the strong linkage between scientific progress and state power and security, and Russia's quest for asserting its status of a global leader once associated with the Soviet Union, establishing sustainable systems for biotechnology advancement remains a task of paramount importance. Moreover, this trend has been further reinforced over the past year with the international sanctions imposed as a result of the situation in Ukraine, forcing the Kremlin to concentrate resources on domestic production.

The second important aspect of the ongoing biotechnology is the way in which it is being framed. During the Soviet era, science used to be regarded as an essential prerequisite for social welfare and national prosperity and, as a result, enjoyed generous support and a privileged position within society. The resurgence of government interest in promoting R&D and innovation in Russia can be seen as a continuation of this trend, not least because of the prevalent unquestioned belief that the progress of the life sciences is inherently positive and desirable. Official policy texts more often than not tend to present a one-sided account of scientific advancement underscoring the wide range of potential benefits which can be accrued through sustained state investment. Thanks to the image thus constructed, biotechnology is granted the status of a public good which needs to be supported in its own right which in turn paves the way for the unfettered expansion of the life sciences on terms dictated by the government.

State Control over Life Science Institutions

In 2013 the Russian Duma passed highly controversial legislation with far-reaching implications for the overall organisation of science. The bill, entitled 'On Russian Academy of Science, Reorganisation of the State Science Academies, and Amendments to Certain Legislative Acts of the Russian Federation' was signed into law on 27 September and effectively dissolved the two principal science bodies responsible for the coordination and distribution of funds in the area of life sciences – the Russian Academy of Medical Sciences (*Rossiiskaya akademiya meditsinskiikh nauk: RAMN*) and the Russian Academy of Agricultural Sciences (*Rossiiskaya akademiya sel'skokhozyaistvennykh nauk: RASKhN*).⁶⁶⁵ Both entities used to be direct heirs of their Soviet counterparts and following the end of the Cold War assumed most of their responsibilities. But before examining in detail the fate of RAMN and RASKhN, it is worth tracing back some of the key episodes of the evolution of the science institutional infrastructure in independent Russia. During the last years of the Soviet Union one of the chief bones of contention in the realm of science policy pertained to the status and organisation of the Academy of Sciences. Increased political openness and growing decentralisation gave rise to calls for reforms, a phenomenon which was particularly notable among junior scientists who saw the strictly hierarchical system of the Academy as an obstacle to their career advancement. Those in favour of radical changes maintained that the Academy should be transformed into an honorary institution pointing to the example of the British Royal Society or the US NAS. By contrast, those on the opposite end of the spectrum held a much more conservative view, expressing a strong preference for the preservation of the status quo. It suffices to mention that during the 1991 coup, a few months before the disintegration of the Soviet Union, a significant number of senior Soviet Academy's scientists sided with the supporters of the old regime. Yet contrary to the expectation that RAN would bear virtually no resemblance in substance to its Soviet counterpart and would rather 'become a mere learned society, prestigious but not

⁶⁶⁵ [in Russian] Federal'nyi zakon RF, *O Rossiiskoi akademii nauk, reorganizatsii gosudarstvennykh akademii nauk i vnesenii izmenenii v otdel'nye zakonodatel'nye akty Rossiiskoi Federatsii*, No.253-FZ, 27 September 2013, full text of the Act published in *Rossiiskaya Gazeta*, No.6194, 30 September 2013, available at <http://www.rg.ru/2013/09/27/ran-site-dok.html> (accessed 7/09/2015).

administratively important',⁶⁶⁶ the transformation did not occur. In other words, it seems to be the case that when a choice had to be made between more democracy but little say in policy matters, and a rigid hierarchy but material and decision-making powers, the temptation of retaining the Academy's established position within society turned out to be too hard to resist. As a result, RAN managed to preserve an enormous network of institutes and laboratories, maintain its insulation from public accountability, and retain its primacy in the area of fundamental research.

Over the years, the Academy has been seriously criticised on at least two grounds. The first source of criticism stems from the poor performance of Russia's basic science when compared to the progress being made in the USA and EU. Whilst some commentators have pointed out that neither the number of publications, nor the citation index provide a precise representation of the quality of Russian research, such claims do not seem to be entirely ill-founded. For instance, an extensive evaluation study on the state of RAN published in 2005 showed that the Academy was performing at about 40% of its overall research potential, that is, less than half of all the scientists employed in the institutes under its auspices were actively engaged in research.⁶⁶⁷ Analysing the causes of this worrying trend, the study highlighted the poor management or the lack thereof observed within many research institutes and the Academy as a whole; the poor links between fundamental science and its practical application; the disconnect between universities (which are still perceived mainly as teaching institutions) and the Academy; and the lack of a clear regulatory framework regarding trade secrets and intellectual property.⁶⁶⁸

⁶⁶⁶ On the issue of the future of the Russian Academy of Sciences after 1991, Loren Graham and Irina Dezhina, *Science in the New Russia*, *op cit.*

⁶⁶⁷ See [in Russian] Sergei Belanovskii, *Otsenka sostoyaniya Rossiiskoi Akademii Nauk: Kratkii otchet*, 2005, Centre for Strategic Research, Moscow, available at <http://polit.ru/article/2005/12/15/ran/> (accessed 7/09/2015). On the need for an institutional reform, see also [in Russian] Irina Dezhina, *Reforma RAN: Prichiny i posledstviya dlya nauki v Rossii*, No.77, May 2014, IFRI, Paris, France, available at http://www.ifri.org/sites/default/files/atoms/files/ifri_rnv_77_ran_reforma_rus_dezhina_may_2014.pdf (accessed 7/09/2015). On the debate on the need for a reform, see [in Russian] Alexandr Ogurtsov, 'Kto zakazal klasterizatsiju?', *Nezavisimaya gazeta*, 26 October 2005, available at http://www.ng.ru/science/2005-10-26/13_claster.html (accessed 7/09/2015); Sergei Belanovskii, 'Nauka: ot finansovogo audita k vlasti effektivnykh menedzherov', *Polit.ru*, 15 December 2005, available at <http://www.polit.ru/article/2005/12/15/science/> (accessed 7/09/2015).

⁶⁶⁸ Sergei Belanovskii, *Otsenka sostoyaniya Rossiiskoi Akademii Nauk: Kratkii otchet*, *op cit.* By contrast, Dezhina points out that among the chief criticisms levelled at the Academy has been the poor management of property. She further rejects the allegation of the lack of links between the Academy and universities elaborating on their close

The second criticism levelled at RAN relates to the lack of transparency regarding the distribution of financial support among its subordinate institutes.⁶⁶⁹ Critics have pointed out that there appears to be an apparent conflict of interests, built into the structure of the Academy, since the same people who sat on its Presidium holding decision-making powers on a range of matters, including budget spending, were also more often than not institute directors.

Some of the initial attempts to reform RAN date back to the early 2000s when the Ministry of Industry, Science and Technology developed a plan for restructuring the network of research institutions by dividing them into three separate categories. Thus, (1) academic entities involved in first-class R&D were to remain budgetary institutions; (2) less successful academic entities were to be re-oriented toward scientific servicing; and (3) some academic entities were to be transformed into commercial organisations but were nonetheless to remain within the Academy's system.⁶⁷⁰ Another round of reforms was proposed in 2004 as part of the Government's *Conception of Participation of the Russian Federation in the Management of Government R&D Organisations* which envisioned a substantial reduction both in the number of existing research institutes under the auspices of the Academy and its staff.⁶⁷¹ Yet the *Conception* offered only general criteria for determining which research institutes were to be preserved and did not assign clear responsibility as to which agency was to be tasked with overseeing the reform process. The situation was further complicated, as the *Conception* in its final version not only re-affirmed the Academy's leading role

collaboration. See Irina Dezhina, *Reforma RAN: Prichiny i posledstviya dlya nauki v Rossii*, No.77, May 2014, IFRI, Paris, France,

http://www.ifri.org/sites/default/files/atoms/files/ifri_rnv_77_ran_reforma_rus_dezhina_may_2014.pdf (accessed 7/09/2015). For a comparative analysis of the performance of the Russian Academy of Science vis-a-vis its foreign counterparts, see Quirin Schiermeier, 'Russia to Boost University Science', *Nature*, vol.464 (2010), p.1257.

⁶⁶⁹ Irina Dezhina, *Reforma RAN: Prichiny i posledstviya dlya nauki v Rossii*, No.77, May 2014, IFRI, Paris, France, http://www.ifri.org/sites/default/files/atoms/files/ifri_rnv_77_ran_reforma_rus_dezhina_may_2014.pdf (accessed 7/09/2015), p.14.

⁶⁷⁰ See [in Russian] Irina Dezhina 'Reforma RAN: Popytki i Itogi', *Polit.ru*, 3 August 2014, available at <http://polit.ru/article/2014/08/03/science/> (accessed 22 April 2015).

⁶⁷¹ Loren Graham and Irina Dezhina, *Science in the New Russia*, *op cit*. On the same point, see also [in Russian] Roy Medvedev, *Vladimir Putin: Tret'ogo sroka ne budet?*, (Moscow: Vremya, 2006), p.40. For a draft of the *Conception*, see [in Russian] *Kontseptsiya uchastiya Rossiiskoi Federatsii v upravlenii imushchestvennymi kompleksami gosudarstvennykh organizatsii, osushchestvlyayushchikh deyatelnost' v sfere nauki*, available at <http://www.intelros.org/lib/doklady/nauka/nauka3.htm> (accessed 10/09/2015).

in the governance of fundamental research but also granted it additional functions as a coordinator for state-funded applied research.⁶⁷² The resultant process of 'self-reformation' initiated by RAN itself at that time was largely cosmetic.⁶⁷³

A notable development in the government-led campaign toward the reformation of RAN took place in 2006 when the then President Vladimir Putin approved amendments to the Act 'On Science and State Science and Technology Policy'.⁶⁷⁴ By dint of the newly-introduced provisions, the Academy and two sector-specific academies, including RAMN and RASKhN, were defined as 'state academies of science', that is, they were given the status of government entities. Thus, their respective Charters were to be approved by the Government and their presidents were to be approved by the President of the Russian Federation. The Act further clarified the question of ownership as far as the infrastructure and land within the remit of the academies was concerned. As a result, all relevant property was to be treated as state property. The latter point is crucial, not least because the issue of the academies' property and estate has attracted a significant attention from the government to the extent that some commentators have referred to the battle over RAN's substantial land assets as the primary rationale for the amendments.⁶⁷⁵ At the same time, others saw the move as an attempt by the government to take over science and an infringement on academic freedom. Still others have described the law as nothing more than a continuation of an established trend highlighting the long-standing relationship based on dependency between the Academy and the state ever since the former's initial conception back in the late eighteenth century.⁶⁷⁶ The debate over the motives underpinning the 2006 amendments notwithstanding, in retrospect there seem to be some grounds to treat them

⁶⁷² See [in Russian] Irina Dezhina, 'Osnovnye napravleniya reform v rossiiskoi nauke: tseli i rezul'taty', *Informatsionnoe obshchestvo*, No.1 (2006), pp.50-56. For a detailed overview of the early RAN reforms, see [in Russian] N.A. Gordeeva and M.M. Fil', *Pravo i reformirovanie nauki: problem i resheniya*, (Moscow: Novaya Pravovaya Kul'tura, 2005); Irina Dezhina, *Gosudarstvennoe regulirovanie nauki v Rossii*, (Moscow: Magistr, 2008).

⁶⁷³ [in Russian] Irina Dezhina, 'Osnovnye napravleniya v rossiiskoi nauke', *op cit*.

⁶⁷⁴ See [in Russian] Federal'nyi zakon RF, *O vnesenii izmenenii v Federal'nyi zakon "O nauke i gosudarstvennoi nauchno-tekhnicheskoi politike"*, No.202-FZ, 4 December 2006, published in *Rossiiskaya Gazeta*, No.4243, 8 December 2006, available at <http://www.rg.ru/2006/12/08/nauka-dok.html> (accessed 28/09/2015).

⁶⁷⁵ Andrey Allakhverdov and Vladimir Pokrovsky, 'Kremlin Brings Russian Academy of Sciences to Heel', *Science*, vol.314 (2006), p.917.

⁶⁷⁶ Loren Graham and Irina Dezhina, *Science in the New Russia*, *op cit*.

as part of a well-planned strategy, the pinnacle of which arguably was the 2013 legislation and resultant power shift from RAN to the government.

The Bill on the reform of RAN came as a surprise to the majority of the scientific community in Russia. Drafted in secrecy, the Bill was largely perceived as a deliberate assault against the Academy and upon disclosure, provoked an outcry and spurred a wave of protests, rallies, and petitions in an attempt to reverse the process of implementation of the reforms.⁶⁷⁷ Amidst lengthy negotiations with the government, the scientific community strived to introduce a number of crucial amendments to the original text which, as some commentators have pointed out, has only highlighted how radical the tone of the initial version of the document had been.⁶⁷⁸ Among the most notable changes were: (1) the Academy should not be dissolved but reorganised by merging it with RAMN and RASKhN; (2) the main objective of RAN should be the conduct of fundamental and applied research; (3) the functions of the coordinating government agency proposed by the bill should be limited only to dealing with the Academy's estate, land, and property; (4) the three regional branches of the Academy – the Uralsk, Siberian, and the Far-Eastern – should retain their status of legal entities; (5) the two-tier system of Academy membership and the corresponding titles 'corresponding member' and academician should be preserved and the Academy should retain its right to decide when and how new members should be elected.⁶⁷⁹

The Act approved at third reading contained some of the proposed changes leaving out the one that was arguably of paramount importance to scientists, namely the division of functions and responsibilities between the Academy and the federal agency to be created. As a result, all entities, over a thousand in total, previously associated with RAN, including research institutes, hospitals, and museums, were to be placed under the auspices of

⁶⁷⁷ On the controversy surrounding the RAN reform, see [in Russian] Anton Didikin, *Pravovoe regulirovanie innovatsionnoi deyatel'nosti v Rossii*, (Novosibirsk: IFPR SO RAN, 2014); Vladimir Gubarev, *Ubiistvo RAN: Noveishaya istoriya nauki v Rossii*, (Moscow: Algoritm, 2014). A detailed database and timeline with relevant materials, documents, and meeting proceedings is available [in Russian] at <http://www.ccas.ru/reforma/reforma.htm> (accessed 10/09/2015). The database is hosted on the web page of the Dorodnicyn Computing Centre of RAS (Vychislitel'nyi tsentr im. A.A. Dorodnicyna, Rossiskaya akademii nauk), <http://www.ccas.ru/index-e.htm> (accessed 10/09/2015).

⁶⁷⁸ See Irina Dezhina, *Reforma RAN: Prichiny i posledstviya dlya nauki v Rossii*, *op cit*.

⁶⁷⁹ Ibid. See also [in Russian] Tamara Shkel', 'Zakon o reforme RAN uchel popravki akademikov', *Rossiiskaya Gazeta*, 29 September 2013, available at <http://www.rg.ru/2013/09/27/ran2-site.html> (accessed 11/09/2015).

the government. The Presidential decree announcing the creation of the Federal Agency of Scientific Organisations (*Federal'noe agentstvo nauchnykh organizatsii: FANO*) was issued just a day after the Duma had passed the legislation. FANO assumed full responsibility not only for dealing with the Academy's estate and property but also for developing and implementing science policy.⁶⁸⁰ Thus, the 2013 Act effectively achieved what back in the early 1990s appeared a virtually impossible task, namely to convert the Academy into an honoured society with few decision-making powers.

Two years after its entry into force the Act on the reform of RAN continues to be a vigorously debated issue. The lack of clear, reliable information on either the reasons for its enactment, or the objectives which it has sought to achieve has left a significant space for speculation over the driving forces behind the reform process. That said, the scarce facts available still lend themselves to preliminary analysis. There seems to be a certain degree of consensus that a reform of the Academy was deemed both necessary and desirable. Yet given the high level of resistance demonstrated by RAN previously, there have been serious doubts regarding the extent to which a reform could be prompted internally. Indeed, over the past two decades the Academy has proved to be a conservative structure keen on maintaining its privileged position in society at all costs. Against this backdrop, a government-led reform appeared a logical step forward. However, the way in which the reform was planned and implemented has raised a lot of questions regarding the actual motivations and goals of its architects. The secrecy surrounding the draft Act, including the anonymity of its authors, the haste with which the Act was passed, and the reluctance of the government to actively engage and listen to the concerns voiced by scientists make it hard to imagine that the reform was genuinely aimed at serving the interests of Russian science. A further sign that the provisions of the new Act were poorly defined and myopic was the resolve of President Putin to impose a year-long

⁶⁸⁰ See [in Russian] Ukaz Prezidenta RF, *O Federal'nom agentstve nauchnykh organizatsii*, No.735, 27 September 2013, published in *Rossiiskaya Gazeta*, No.6194, 30 September 2013, available at <http://www.rg.ru/2013/09/27/fano-site-dok.html> (accessed 11/09/2015).

moratorium on any deals by FANO involving the Academy's estate and property.⁶⁸¹

In effect, the clash over the 2013 reform was not a matter solely between RAN and the government but rather between *science* and the state. True, the Academy has been at the forefront of the debate but that debate, perhaps for the first time over the past two decades, has managed to unite the scientific community against what has been perceived as a government-led attack on fundamental research. Within this context, the chief bone of contention lies in the transfer of responsibility for research policy from RAN to FANO, a move which many fear would lead to mass reductions in the number of personnel and institutions, and could eventually result in dismantling of the system of research institutes.⁶⁸² Since the onus is on state bureaucrats with little understanding of science to decide which lines of research are worth pursuing and by whom, there is an uneasy feeling among scientists about the future of Russian scientific research.⁶⁸³ It suffices to note that a recent study suggests that a significant proportion of junior scientists appear dissatisfied with the new Act and even contemplate searching for career prospects abroad, a trend which, if it materialises, could further deepen the 'brain drain' problem.⁶⁸⁴ But the battle seems far from over just yet. Increased

⁶⁸¹ See [in Russian] 'Putin predlozhit ustanovit' godovoi moratoria na reformy RAN', *Forbes*, 31 October 2013, available at <http://www.forbes.ru/news/246824-putin-predlozhit-ustanovit-godovoi-moratorii-na-reformu-ran> (accessed 11/09/2015). On the same point, see also [in Russian] Kira Latukhina, 'Za grantom: Vladimir Putin obsudil s uchenymi reformirovanie nauki', *Rossiiskaya Gazeta*, No.6265, 23 December 2013, available at <http://www.rg.ru/2013/12/23/putin-ran.html> (accessed 11/09/2015).

⁶⁸² See [in Russian] Vladimir Kuz'min, 'Komu FANO nado: Kabinet ministrov utverdil polozhenie o FANO', *Rossiiskaya Gazeta*, No.6218, 28 October 2013, available at <http://www.rg.ru/2013/10/25/kotukov-site.html> (accessed 11/09/2015); Yuri Medvedev, 'Akademicheskii treugol'nik', *Rossiiskaya Gazeta*, No.6644, 8 April 2015, available at <http://www.rg.ru/2015/04/08/kotikov.html> (accessed 11/09/2015); Nataliya Demina, 'Reforma v bol'shikh kavychkakh', *Troitskii variant*, No.143, 3 December 2013, p.6-7, available at <http://trv-science.ru/2013/12/03/reforma-v-bolshikh-kavychkakh-2/> (accessed 11/09/2015); Marina Sklyarenko i Roman Romanyuk, 'V trevozhnom ozhidanii akademicheskogo effekta', *Ekspert Severo-Zapad*, 12 February 2015, available at <http://www.expertnw.ru/news/2015-02-12/v-trevozhnom-ozhidanii-akademicheskogo-effekta> (accessed 11/09/2015).

⁶⁸³ See I. Libin et al, 'The Reform of the Russian Academy of Science: Possible Causes and Consequences of the Reform: For Whom the Bell Tolls', [in Russian], *Mezhdunarodnyi zhurnal eksperimental'nogo obrazovaniya*, No.8 (2014), pp.115-117, available at <http://www.rae.ru/meo/pdf/2014/8-2/5915.pdf> (accessed 7/09/2015); [in Russian] Askol'd Ivanchik, 'Reforma buksuet, ili Apofeoz bjurokratii', *Troitskii variant*, No.176, 7 April 2015, p.2, available at <http://trv-science.ru/reforma-buksuet/> (accessed 7/09/2015); Vladimir Gubarev, "'Reforma RAN" na chinovnichii maner', *Pravda.Ru*, 15 March 2014, available at <http://www.pravda.ru/science/academy/15-03-2014/1198830-ran-0/> (accessed 11/09/2015); Aleksandr Yemel'yanenkov, 'Trio "Akademiya" v poiskakh sebya', *Rossiiskaya Gazeta*, No.6334, 19 March 2014, available at <http://www.rg.ru/2014/03/19/fortov.html> (accessed 11/09/2015); Kira Latukhina, 'Putin: Gosudarstvo ne budet komandovat' uchenymi', *Rossiiskaya Gazeta*, 20 December 2013, available at <http://www.rg.ru/2013/12/20/soviet-site.html> (accessed 11/09/2015).

⁶⁸⁴ See [in Russian] Ol'ga Kolesova, 'Chemodan, vokzal...reforma RAN vyzvala u molodykh zhelanie uekhat'', *Poisk*, No.4-5, 31 January 2014, available at <http://www.poisknews.ru/theme/ran/8940/> (accessed 11/09/2015). On the issue of a possible 'brain drain' among perspective scientists, see also [in Russian] Nikolai Podorvanyuk, 'Zhalko, esli vpered' vybor – professiya ili strana', *Gazeta.Ru*, 17 December 2013, available at http://www.gazeta.ru/science/2013/12/17_a_5806413.shtml (accessed 11/09/2015); Richard Stone, 'Embattled

bureaucracy and discontent with FANO's handling of science affairs following the introduction of the reform has apparently motivated scientists to try once more to reclaim the Academy and restore at least some of its lost powers, particularly in the area of coordinating fundamental research.⁶⁸⁵ Moreover, there seems to be increasing 'critical mass' within the scientific community in favour of modernisation both of the system of higher education and research entities.⁶⁸⁶ At this stage it is still uncertain how the process of science reformation will proceed but unless the Academy manages to come up with constructive proposals on how best to move forward, there is little doubt that further government-initiated reforms would be introduced.

Science funding institutions also remain largely under state control. Despite the emergence of private foundations offering support for science and education in Russia over the past fifteen years, the state continues to be the main source of research funding.⁶⁸⁷ Given the drastic decrease in science expenditure in comparison with the Soviet period, several new schemes have been developed to replace 'block funding' for research organisations. One features subsidies, whereby various arms of the government, including the Ministry of Education, FANO, Ministry of Healthcare, and Ministry of Agriculture, allocate a fixed amount of money in exchange for a specific project. In other words, the government tasks a particular institute to fulfil a

President Seeks New Path for Russian Academy', *ScienceInsider*, 11 February 2014, available at <http://news.sciencemag.org/people-events/2014/02/embattled-president-seeks-new-path-russian-academy> (accessed 11/09/2015); Quirin Schiermeier, 'Putin's Russia Divides and Enrages Scientists', *Nature*, vol.516 (2014), pp.298-299.

⁶⁸⁵ Dariya Mendeleeva, 'Reforma Rossiiskoi akademii nauk: chto budet dal'she?', *Pravoslavie i Mir*, 27 May 2015, available at <http://www.pravmir.ru/reforma-ran-poryadok-dostizheniya-haosa/> (accessed 11/09/2015); Alexey Yablokov, 'Academy "Reform" is Stifling Russian Science', *Nature*, vol.511 (2014), p.7; Nataliya Demina, 'God posle reform: byurokratizatsiya usillilas', *Troitskii variant*, No.158, 15 July 2014, p.2, available at <http://trv-science.ru/2014/07/15/god-posle-reformy-byurokratizatsiya-usillilas/> (accessed 11/09/2015).

⁶⁸⁶ On the civil society initiatives that developed as a result of the RAN reform, see [in Russian] Boris Shtern, 'Klub "1 iyulya"', *Troitskii variant*, No.133, 16 July 2013, p.5, available at <http://trv-science.ru/2013/07/16/klub-1-iyulya/> (accessed 28/09/2015). Beside the dissident Club '1 July', other initiatives include [in Russian] Komissiya obshchestvennogo kontrolya v sfere nauki (Committee for Public Control over Science), available at <http://rascommission.ru/statements/125-club-1-july-20-04-2015> (accessed 28/09/2015); and [in Russian] 'Sokhranim nauku vmeste' ('Save Science' Movement), available at http://iph.ras.ru/save_ran.htm (accessed 28/09/2015). The latter social movement also maintains a web platform, available at <http://www.saveras.ru/> (accessed 28/09/2015).

⁶⁸⁷ A notable exception in this regard constitutes the 'Dynasty' Fund set up by Dmitrii Zimin, Honourable President of the Open Joint Stock Company 'VypelKom' which own the Beeline trademark – one of the main mobile network providers. The Fund operates four principal sponsorship programmes, namely 'Support for Science and Education', 'Popularisation of Science', 'Social Science Enlightenment' and 'Special Projects' related to culture or aimed at solving a social problem. Further information is available at <http://www.dynastyfdn.com/> (accessed 7/09/2015). On 5 July 2015, the Fund's Council took a decision to terminate its activity, see [in Russian] <http://www.dynastyfdn.com/news/1296> (accessed 11/09/2015). For news reports on the topic see Paevl Kotlyar and Nikolai Podorvanyuk, 'Konets "Dinastii"', *Gazeta.Ru*, 8 July 2015, available at http://www.gazeta.ru/science/2015/07/08_a_7629877.shtml (accessed 11/09/2015); Pavel Kotlyar, 'Esli "Dinastiyu" zakroyut, eto budet moshtnyi signal', *Gazeta.Ru*, 12 May 2015, http://www.gazeta.ru/science/2015/05/12_a_6683177.shtml (accessed 11/09/2015).

certain project and provides it with the required funds. In theory, the scheme is supposed to offer both researchers and institute administrators a degree of flexibility, as it does not lay down strict requirements regarding the number of staff expected to participate on the project, nor the amount of salary to be paid. In practice, however, it has been described as a 'bureaucratic nightmare', not least because the way in which the size of funding is calculated does not take into account the criteria used at research institutes for determining staff payment.⁶⁸⁸ As a result, the bulk of subsidies are largely spent on staff salaries rather than on research.⁶⁸⁹ Critics have argued that the existing arrangements are self-serving for the government, providing state bureaucracies with a comfortable excuse for making scientists at former Academy institutes redundant.⁶⁹⁰

As already mentioned, state research foundations emerged in the early 1990s as an alternative funding mechanism to compensate for the reduced science budget in the immediate post-Soviet period. Based on the 2011 amendments to the 1996 Act 'On Science and State Scientific and Technological Policy' and Article 251 of the Tax Code, 'state foundations can be budgetary or autonomous entities'.⁶⁹¹ In the former case, an entity's budget is part of the overall state budget and therefore guaranteed; in the latter, the entity is solely responsible for raising funds to support its activity.⁶⁹² The amendments further stipulated that the Government of the Russian Federation acts as the founder of state foundations and all corresponding functions and powers lay with it. According to its revised 2012 Charter, the RFFI is a 'non-profit organisation in the form of a federal state budgetary entity'.⁶⁹³ By dint of being tasked with the duties and responsibilities of its

⁶⁸⁸ See [in Russian] Evgenii Onishchenko, 'Byurokraticheskaya revolyutsiya', *Troitskii variant*, No.177, 21 April 2015, pp.1-2, available at <http://trv-science.ru/2015/04/21/byurokraticheskaya-revolyuciya/> (accessed 11/09/2015). See also [in Russian] Erofei Esperazus, 'Byudzhet vsekh institutov RAN sokrashen', *Moskovskii komsomolets*, 27 March 2015, available at <http://www.mk.ru/science/2015/03/27/nachalsya-vtoroy-etap-reformy-ran-finansirovanie-institutov-sokratyat.html> (accessed 11/09/2015).

⁶⁸⁹ Evgenii Onishchenko, 'Byurokraticheskaya revolyutsiya', *op cit*.

⁶⁹⁰ Interview, 29 May 2015, Moscow, Russia.

⁶⁹¹ See [in Russian] Federal'nyi zakon RF, *O vnesenii izmenenii v Federal'nyi zakon "O nauke i gosudarstvennoi nauchnoi-tekhnikeskoi politike" i statiju 251 chasti vtoroi Nalogovogo kodeksa Rossiiskoi Federatsii v chasti utocneniya pravovogo statusa fondov podderzhki nauchnoi, nauchno-tekhnikeskoi i innovatsionnoi deyatel'nosti*, 13 July 2011, Moscow. Full text of the Act is available at <http://www.rfb.ru/rffi/ru/documents> (accessed 7/09/2015).

⁶⁹² See [in Russian] Federal'nyi zakon RF, *Ob avtonomnykh uchrezhdeniyakh*, No.174-FZ, 3 November 2006, Moscow. Full text of the Act is available at <http://www.rg.ru/2006/11/08/zakon-doc.html> (accessed 7/09/2015).

⁶⁹³ See [in Russian] Postanovlenie Pravitel'stva RF, *Ob ustave federal'nogo gosudarstvennogo bjudzhetnogo uchrezhdeniya "Rossiiskii fond fundamental'nykh issledovaniy"*, No.133, 15 February 2012, Moscow. <http://www.rfb.ru/rffi/ru/documents> (accessed 7/09/2015).

founder, the Russian Government holds decision-making powers with regard to any re-organisation of the RFFI, altering its type and dismantling; it approves the RFFI's Charter and any amendments made to it; appoints and dismisses the Chair of the RFFI Board and the RFFI Director; and approves the RFFI Board's composition.

Besides the RFFI, the Russian Science Foundation (*Rossiiskii nauchny fond: RNF*) created in 2013 offers grants for pure and applied research in various fields of science, including biology, medicine, and agriculture.⁶⁹⁴ The RNF is a legal entity governed by a Board of Trustees appointed by the President of the Russian Federation for a maximum term of five years.⁶⁹⁵ The Board's Chair is also appointed by the Russian President and each Board member, including the Chair, can be dismissed pre-term on the basis of a Presidential decision. The Director General of the RNF is a Board member and his appointment is subject to approval by the President of the Russian Federation. All Board members apart from the RNF Director can hold public sector and civil service positions alongside their Board membership.

Two additional schemes launched under the auspices of MINOBRANAUKI – the Federal Targeted Programme (*Federal'naya tselevaya programma: FTsP*) on 'R&D in Priority Directions for the Development of the Russian Scientific and Technological Complex 2014-2020' and Mega-grants (*Megagranty*) – have further sought to boost applied science and enhance the research capacity within Russian universities.⁶⁹⁶ Initiated in 2010, *Megagranty* has attracted substantial international attention, not least because of its size (90 billion-roubles which at that time amounted to about 2.8 billion US dollars) and the ambitious goals it was set to achieve.⁶⁹⁷ Whilst

⁶⁹⁴ See [in Russian] Federal'nyi zakon RF, *O Rossiiskom nauchnom fonde i vnesenii izmenenii v otchel'nye zakonodatel'nye akty Rossiiskoi Federatsii*, No.291-FZ, 2 November 2013. Full text of the Act is available at <http://www.rscf.ru/?q=node/17> (accessed 7/09/2015).

⁶⁹⁵ Ibid.

⁶⁹⁶ See [in Russian] Postanovlenie, *O federal'noi tselevoi programme "Issledovaniya i razrabotki po prioritetyam napravleniyam razvitiya nauchno-tekhnologicheskogo kompleksa Rossiina 2014-2020 gody"*, No.426, 21 May 2013. Full text is available at <http://fcpir.ru/upload/medialibrary/332/tekst-programmy.pdf> (accessed 7/09/2015). The programme can be seen as a continuation of Russia's earlier efforts to enhance the standing of its universities. On this point, see Quirin Schiermeier, 'Russia to Boost University Science', *Nature*, vol.464 (2010), p.1257. On 'Megagrants', see Irina Dezhina, 'State of Science and Innovation in 2011' in S.Sinelnikov-Murylev et al. (ed.), *Russian Economy in 2011: Trends and Outlooks*, Issue 33 (Moscow: Gaidar Institute, 2012), pp.344-375.

⁶⁹⁷ See Quirin Schiermeier and Konstantin Severinov, 'Russia Woos Lost Scientists', *Nature*, vol. 465 (2010), p.858; Editorial, 'Seizing the Moment', *Nature*, vol.467:7313 (2010), p.251; Quirin Schiermeier, 'Russia Revitalises

aimed at home universities, the scheme is intended to lure Russian scientists working and residing abroad to return and undertake projects in the motherland. Thus, the competition for grants of a maximum value of 150 million roubles is open to both local and foreign-based researchers and the involvement of junior scientists is explicitly required as part of the application process.

All grant schemes operate on a competitive basis through a peer-review process, which in itself is a significant departure from the Soviet funding system, whereby researchers were not required to compete for financial resources. Although the development has been largely welcomed by the scientific community, its overall success has been overshadowed by a number of limitations. Bureaucratic obstacles, lack of transparency, and bias and preferential treatment are only some of the concerns voiced by scientists familiar with the system.⁶⁹⁸ Lack of anonymity at the application and evaluation process has further raised concerns of the money being allocated on the basis of affiliation rather than individual merit.⁶⁹⁹ Limited rotation of peer reviewers and senior foundation staff has stimulated heavy lobbying by prominent scientists and science administrators which means that more often than not vested interests and not individual merit dictate how funding decisions are made.⁷⁰⁰ In some cases, e.g. the Mega-grants scheme, foreign experts have been recruited as part of the peer-review process as a way of improving quality control and helping ensure that grants are distributed in a fair manner and in accordance with the established criteria. Additional hurdles in the competition for funding include poor relations between the foundations and the public, especially with regard to the communication of

Science', *Nature*, vol.473 (2011), pp.428-429; [in Russian] Nikolai Podorvanyuk i Aleksandra Borisova, 'Poshli navstrechu nauchnomu soobshesvu', *Gazeta.Ru*, 30 October 2010, available at http://www.gazeta.ru/science/2010/10/29_a_3433172.shtml (accessed 11/09/2015).

⁶⁹⁸ On the problems and limitations of the existing science funding mechanisms in Russia, see Loren Graham and Irina Dezhina, *Science in the New Russia*, *op cit.* While some of the complaints about the quality of the peer-review system voiced by the Russian scientific community are not uncommon among scientists in the West (see, for example, Daniel Greenberg, *Science, Money and Politics*, *op cit.*), there have been reports about quite serious problems. See [in Russian] 'Eto takie khoroshie lyudi, kak im mozhno ne dat' deneg: Kak uchenye raspredelyayut den'gi na fundamental'nyu nauku v Rossii', *Gazeta.Ru*, 16 July 2014, available at http://www.gazeta.ru/science/2014/07/16_a_6116337.shtml (accessed 11/09/2015); Nikolai Podorvanyuk, 'Voprosy lukavstva v nauke stali reshat'sya', *Gazeta.Ru*, 30 January 2015, available at http://www.gazeta.ru/science/2015/01/30_a_6392429.shtml (accessed 11/09/2015); Aleksandr Fradkov, 'Ideal'naya ekspertiza', *Troitskii variant*, No.159, 29 July 2014, pp.1-2, available at <http://trv-science.ru/2014/07/29/idealnaya-ehkspertiza/> (accessed 11/09/2015).

⁶⁹⁹ Loren Graham and Irina Dezhina, *Science in the New Russia*, *op cit.*

⁷⁰⁰ *Ibid.*

relevant information; the existence of programmes for which only applicants of certain age are eligible (e.g. 'young'); required minimum number of publications; complicated application procedures and grant bookkeeping; and delays and incompleteness in financing projects.⁷⁰¹ Whilst the criticisms levelled at the science funding system are by no means unique to the Russian context, here the problem is particularly acute, not least because grants constitute a vital source not only of material support for research but in many cases also of a salary and employment. The absence of adequate block funding, coupled with a fierce competition for foundations' money thus creates favourable conditions for reducing the size of the scientific community by making anyone who fails to meet the funding requirements set by the state institutions redundant.

The Legacy of the Soviet Bioweapons Programme

Arguably one of the most controversial aspects of the history of the biological sciences in the Soviet Union is the development of an offensive biological weapons programme, a topic which more than twenty years after the dissolution of the USSR is still deemed sensitive and enveloped in the legacies of secrecy, including partial information and competing narratives.⁷⁰² Kalinina, for instance, argues that whereas there seems to be little doubt that the Soviet Union was involved in biological weapons development, the bulk of relevant data regarding the programme remains classified and the official statements issued by the Soviet and later Russian government suggest that

⁷⁰¹ Ibid. On the various criteria for science funding, see [in Russian] Aleksandr Khlunov, 'RNF: teoriya vs. praktika', *Troitskii variant*, No.151, 8 April 2014, p.4, available at <http://trv-science.ru/2014/04/08/rnf-teoriya-vs-praktika/> (accessed 11/09/2015). What is more, once awarded the grant apparently could be terminated at any point if the researcher fails to meet any of the bureaucratic requirements. For instance, in 2013 the RFFI annulled more than 20 per cent of the nearly 300 initially approved awards to junior scientists justifying its decision by a late receipt of the contract from the awardees. The case is staggering, for according to the RFFI rules, 'the fund preserves the right to re-consider its decision whether to terminate a grant if the Contract has been received after the deadline.' On the latter issue, see [in Russian] Mariya Logacheva, 'Molodym vezde u nas – chto? Ili edinyi bilet – kuda?', *Troitskii variant*, No.144, 24 December 2013, p.2, available at <http://trv-science.ru/2013/12/24/molodym-vezde-u-nas-chto-ili-edinyi-bilet-kuda/> (accessed 11/09/2015).

⁷⁰² There is very limited Russian literature on the bioweapons programme and the few existing works are based on information already made available through Western academic scholarship. See, for example, [in Russian] Lev Fedorov, *Sovetskoe biologicheskoe oruzhie: istoriya, ekologiya, politika*, (Moscow: International Social-Ecological Union, 2005); N. Kalinina, *Mezhdunarodnye i natsional'nye problemy biologicheskoi bezopasnosti i perspektivy ikh resheniya*, (Moscow: IMEMO RAN, 2012); Aleksei Arbatov (ed.), *Protivodeistvie bioterrorizmu: politicheskie, tekhnicheskoe i pravovye aspekty*, (Moscow: Russian Political Encyclopedia, 2008). Igor Domaradskii, an esteemed academician and microbiologist, published his memoirs in Russian in 1995 under the title *Perevertysk* (lit. Changeling). There he discussed his involvement in the Soviet biological weapons programme during his time at the Institute for Applied Microbiology at Obolensk near Moscow. Subsequently, the book was translated into English, see Igor Domaradskij and Wendy Orent, *Biowarrior: Inside the Soviet/Russian Biological War Machine*, (Amherst, NY: Prometheus Books, 2003).

only biodefence-related activities were carried out.⁷⁰³ She nevertheless acknowledges that the primary purpose of President Yeltsin's decree issued on 11 April that same year was to terminate the offensive biological weapons programme but highlights that the information provided by the government to the United Nations (UN) as part of the BTWC CBMs process has not been publicly disclosed in Russia.⁷⁰⁴ The submission in question pertains to Form F of the politically-binding CBMs in which States Parties to the BTWC are expected to declare any past offensive biowarfare activities. Based on the information contained therein, the Soviet biowarfare programme reportedly commenced in the late 1940s under the auspices of the Ministry of Defence.⁷⁰⁵ Experimental work was conducted in the biological research centres in Kirov, Sverdlovsk (Yekaterinburg), and Zagorsk (Sergiev Posad) and later, in the 1960s, production facilities were established in Sverdlovsk and Zagorsk. Aerosol test chambers and an open-air test site were situated on the Island of Vozrozhdenie (Resurrection Island) in the Aral Sea. In the early 1970s, a biological defensive programme began encompassing a number of research centres, including Kol'tsovo, Obolensk, and Leningrad (St Petersburg). The biodefence effort focused on assessing protection against biological agents, including those in aerosolised form. In the military facilities, offensive biological research continued. Bioweapons production lines were dismantled during the 1980s in preparation of the Second Review Conference of the BTWC in 1986. Research activities formally ceased in

⁷⁰³ See [in Russian] N. Kalinina, *Mezhdunarodnye i natsional'nye problemy biologicheskoi bezopasnosti i perspektivy ikh resheniya*, (Moscow: IMEMO RAN, 2012); p.46. Also see [in Russian] Verkhovnyi soviet Rossiiskoi Federatsii, Postanovlenie, *Ob obespechenii vypolneniya mezhdunarodnykh obyazatel'stv Rossiiskoi Federatsii v oblasti khimicheskogo, bakteriologicheskogo (biologicheskogo) i toksinnogo oruzhiya*, No.3244-1, 8 July 1992. The Resolution confirmed that Russia accepted the obligations of the USSR under the BTWC. In an interview given shortly after the publication of Ken Alibek's book *Biohazard* the then Head of the Biodefence Control Department (Upravleniya po biologicheskoi zashchite) of the Ministry of Defence, Valentin Evtigneev, re-asserted the narrative presented in the 1992 CBM underscoring that the principal goal of the Soviet military programme was the development of adequate biodefence. When asked about the Soviet biological offensive capability, he explained 'that the development of biodefence measures required the development of a model of offensive measures. It was this cycle of work that constituted the so called offensive element of the Ministry of Defence's programme [...] and which in 1992 was banned and terminated.' According to Evtigneev, all equipment which could potentially be deemed questionable for peaceful purposes was dismantled in 1989 and ever since Russia could be suspected only of intentions, for in his words, there were no clear internationally-agreed criteria regarding the definition of a 'biological weapon', the relevant equipment necessary for its production, and the equipment and technical production means which should be prohibited. See [in Russian] Interview with Valentin Yevstigneev, 'Shtamm Eboly v Rossiju privezli razvedchki', *Yadernyi kontrol'*, vol.46:4 (1999), pp.16-26. Author's translation. On the issue of denial, see Jan Knoph and Kristina Westerdahl, 'Re-Evaluating Russia's Biological Weapons Policy, as Reflected in the Criminal Code and Official Admissions: Insubordination Leading to a President's Subordination', *Critical Reviews in Microbiology*, vol.32 (2006), pp.1-13.

⁷⁰⁴ See [in Russian] Ukaz Prezidenta RF, *Ob obespechenii vypolneniya mezhdunarodnykh obyazatel'stv v oblasti biologicheskogo oruzhiya*, No 390, 11 April 1992.

⁷⁰⁵ See Tatyana Elleman, 'Russian Federation' in Kathryn McLaughlin et al. (ed.), *Bioweapons Monitor 2014*, (Bradford: University of Bradford, 2014), p.207, available at <http://www.bwpp.org/documents/BWM%202014%20WEB.pdf> (accessed 8/09/2015).

1992 and a Trilateral Agreement between Russia, the US, and the UK designed to help foster reassurance and ensure compliance with international law was signed.

One aspect on which the CBM offers little clarification is the 1979 anthrax outbreak in Sverdlovsk, which caused 68 fatalities. According to the records of the First Review Conference of the BTWC held in March 1981, the head of the USSR delegation, Victor Israelyan when responding to the allegations that the outbreak was a result of illicit activities carried out in a military facility located nearby, '[t]he Soviet Union had always scrupulously observed the Convention's provisions, pursuant to a decree by the Presidium of the Supreme Soviet on 11 February 1975. The incident in 1979 referred to by the United States delegation had in fact resulted from an epidemic caused by consumption of infected meat which had not been subjected to normal inspection before sale; it in no way reflected on the Soviet Union's compliance with the Convention.'⁷⁰⁶ The 'infected meat' thesis thus emerged as the prevailing explanation of the outbreak during the Soviet era and has been subsequently adopted by the Russian leadership. Yet throughout the 1980s and the 1990s teams of foreign experts led by Matthew Meselson, a renowned microbiologist and former science policy advisor to the US President Richard Nixon, conducted independent detailed enquiries yielding results which ran counter to the narrative put forward by Soviet and later Russian officials. In particular, their findings suggested that the outbreak 'resulted from the windborne spread of an aerosol anthrax pathogen; [and] that the source was at the military microbiology facility.'⁷⁰⁷ Drawing upon a range of sources, including scientific and victims' accounts, administrative data, the geographical distribution of anthrax cases, and surface observations showing the wind directions and speed, Meselson and his colleagues presented evidence that:

⁷⁰⁶ Review Conference of the Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Summary Record of the Twelfth Meeting*, BWC/CONF.I/SR.12, 21 March 1981, Palais des Nations, Geneva, Switzerland, available at http://www.unog.ch/bwcdocuments/1980-03-1RC/BWC_CONF.I_SR.12.pdf (accessed 8/09/2015).

⁷⁰⁷ Matthew Meselson et al. 'The Sverdlovsk Anthrax Outbreak of 1979', *Science*, vol. 266:5188 (1994), p.1206.

- (i) most people who contracted anthrax worked, lived, or attended daytime military reserve classes during the first week of April 1979 in a narrow zone, with its northern end in a military microbiology facility in the city and its other end near the city limit 4 km to the south;
- (ii) livestock died of anthrax in villages located along the extended axis of the same zone, out to a distance of 50 km;
- (iii) a northerly wind parallel to the high-risk zone prevailed during most of the day on Monday, 2 April, the first day that the military reservists who contracted anthrax were within the zone; and
- (iv) the first cases of human and animal anthrax appeared 2 to 3 days thereafter.⁷⁰⁸

The team further asserted that:

The narrowness of the zone of human and animal anthrax and the infrequency of northerly winds parallel to the zone after 2 April suggest that most or all infections resulted from the escape of anthrax on that day. Owing to the inefficacy of aerosol deposition and resuspension, few if any inhalatory infections are likely to have resulted from secondary aerosols on subsequent days. A single date of inhalatory infection is also consistent with the steady decline of onsets of fatal cases in successive weeks of the epidemic.⁷⁰⁹

Jeanne Guillemin's compelling account based on scientific evidence and extensive interviews with victim families, medical personnel involved in the treatment of 1979 patients, and senior state officials has further cast serious doubts on the plausibility of the 'infected meat' thesis revealing how a concerted action by the military and the government carried out in utmost conditions of secrecy has made it possible to keep the incident away from the

⁷⁰⁸ Ibid.
⁷⁰⁹ Ibid.

public domain.⁷¹⁰ To date, the Russian government has never openly acknowledged whether there was any military involvement in the Sverdlovsk outbreak, as a result of which no responsibility for the 68 fatalities has been ascribed, nor has anyone ever been held to account in relation to the event. According to Guillemin, the persistent silence regarding the role of Compound 19 in causing the largest epidemic of inhalation anthrax yet on record has reinforced the army's right to remain aloof, allowing the military to disregard their responsibility to the local citizens they were bound to serve and protect in the first place.⁷¹¹

As noted in Chapter 3, secrecy pertains not only to the restriction of information but also to the context that allows sustaining and perpetuating secrets. Both of those dynamics seem to be at play as far as the Sverdlovsk case is concerned. The rapid intervention of the KGB (Committee of State Security: *Komitet gosudarstvennoi bezopasnosti*) has reportedly helped ensure that any relevant information related to the outbreak remains only with those who need to know. Given the lack of publicly accessible evidence, the tragedy could relatively easily be depicted as a natural disease outbreak, an explanation, which despite being challenged scientifically, still appears to be upheld politically.

Secrecy breeds uncertainty and uncertainty in turn breeds suspicion. When in 1992 Russia made its CBM submission admitting to the development of an offensive biological weapons programme, concerns were raised over what appeared to be a discrepancy between the content of the submitted text and the accounts provided by several high-ranking Soviet defectors regarding its size and scope. Some analysts have argued that the CBM submission is

⁷¹⁰ See Jeanne Guillemin, *Anthrax: The Investigation of a Deadly Outbreak*, (Berkeley, CA: University of California Press, 1999). See also Jeanne Guillemin, 'Detecting Anthrax: What We Learned from the 1979 Sverdlovsk Outbreak' in Malcolm Dando et al. (ed.), *Scientific and Technological Means of Distinguishing Between Natural and Other Outbreaks of Disease*, NATO Science Series: Disarmament Technologies – Vol.35, (Dordrecht: Kluwer Academic Publishers, 2001), pp.75-86.

⁷¹¹ Jeanne Guillemin, *Anthrax: The Investigation of a Deadly Outbreak*, (Berkeley, CA: University of California Press, 1999), p.232. In April 1992, President Yeltsin approved a law designed to grant financial support to those families who suffered losses during the 1979 Sverdlovsk anthrax outbreak. The law, however, avoided any mention of the causes of the outbreak. See [in Russian] Zakon, *Ob uluchshenii pensionnogo obespecheniya semei grazhdan, umershikh vsledstvie zabollevaniya sibirskoi yazvoi v gorode Sverdlovskoe v 1979 godu*, No.2667-1, 4 April 1992.

incomplete and suffers from 'significant omissions',⁷¹² a point that the US highlighted at the time when the Russian government disclosed the initial draft history of the offensive programme.⁷¹³ Nevertheless, no subsequent revised versions of Form F have been submitted. As part of the efforts to guarantee Russia's biological disarmament under the 1992 Trilateral Agreement a series of inspection visits on an exchange basis were held.⁷¹⁴ British and American teams were thus granted access to several non-military biodefence facilities. However, the Russian government has demonstrated reluctance to open up for international inspection any of the three biological research institutions under the auspices of the military.⁷¹⁵

Over the past two decades Russia's intention to comply with international law has been questioned on a several occasions. For instance, in 1997 *Vaccine* published a paper describing a study in which a team of Russian scientists of the State Research Centre for Applied Microbiology at Obolensk created a vaccine-resistant genetically engineered strain of *Bacillus anthracis*, the agent responsible for anthrax.⁷¹⁶ Against the backdrop of the information provided by Ken Alibek, the experiment has been widely cited as an example of offensive biological research.⁷¹⁷ Moreover, when assessing Russia's compliance with the BTWC, the 2005 *Adherence to and Compliance with Arms Control, Non-Proliferation, and Disarmament Agreements and Commitments* report prepared by the US Department of State concluded that 'based on all available evidence [...] Russia continues to maintain an

⁷¹² Nicolas Isla, *Transparency in Past Offensive Biological Weapon Programmes: An Analysis of Confidence Building Measure Form F, 1992-2003*, Occasional Paper No.1, June 2006, Hamburg Centre for Biological Arms Control, Hamburg, Germany. Available at http://www.biological-arms-control.org/publications/FormF_1992-2003.pdf (accessed 26/04/2015).

⁷¹³ See Nicolas Sims, *The Evolution of Biological Disarmament*, SIPRI Chemical and Biological Warfare Studies, no.19, (Oxford: Oxford University Press, 2001), p.13.

⁷¹⁴ See David Kelly, 'The Trilateral Agreement: Lessons for Biological Weapons Verification' in Trevor Findlay and Oliver Meier (ed.), *Verification Yearbook 2002*, (London: VERTIC, 2002), pp.93-109.

⁷¹⁵ Milton Leitenberg and Raymond Zilinskas, *The Soviet Biological Weapons Program*, *ip.cit*, p.711. In 1997 an ISTC-sponsored international scientific conference took place at one of the civilian institutes situated in Kirov, namely the Volga-Vyatka State Scientific Centre for Applied Microbiology. For more information on this event, see National Research Council, *The Unique U.S. – Russian Relationship in Biological Science and Biotechnology*, (Washington DC: National Academies Press, 2013), p.40.

⁷¹⁶ See A.P. Pomerantsev, 'Expression of Cereolysine AB Genes in *Bacillus Anthracis* Vaccine Strain Ensures Protection against Experimental Hemolytic Anthrax Infection', *Vaccine*, vol.15:17/18 (1997), pp.1846-1850.

⁷¹⁷ See Jonathan Tucker, 'In the Shadow of Anthrax: Strengthening the Biological Disarmament Regime', *The Non-Proliferation Review*, Spring 2002, pp.112-121; Jan van Aken and Edward Hammond, 'Genetic Engineering and Biological Weapons', *EMBO Reports*, vol. 4 (2003), pp.S57-60; William Broad, 'Gene-Engineered Anthrax: Is It a Weapon?', *New York Times*, 14 February 1998, available at <http://www.nytimes.com/1998/02/14/world/gene-engineered-anthrax-is-it-a-weapon.html> (accessed 5/05/2015).

offensive BW programme in violation of the Convention.⁷¹⁸ Despite being considerably softened, the tone of the 2014 report shows that ambiguity regarding Russia's activities of relevance to the BTWC persists:

Available information during the reporting period indicated Russian entities have remained engaged in dual-use, biological activities. It is unclear that these activities were conducted for purposes inconsistent with the BWC. It also remains unclear whether Russia has fulfilled its BWC obligations in regard to the items specified in Article I of the Convention that it inherited.⁷¹⁹

Also in 2014, a US Congressional Hearing titled 'Assessing the Biological Weapons Threat: Russia and Beyond' was held during which Russia's potential offensive biological capability was given considerable attention.⁷²⁰ At that Hearing, a reference was made to a passage in a 2012 essay published by the then-Prime Minister Putin, 'Staying Strong: Guarantees for Russia's National Security', listing the scope of novel weapons likely to be developed in the distant future including beam, geophysical, genetic, and psychophysical.⁷²¹ In particular, it was claimed that the passage was 'extremely problematic and troubling', for it indicated Russia's intention to develop genetic weapons, which would be in contravention with the BTWC.⁷²² In a statement released shortly after the Hearing, the Russian Ministry of Foreign Affairs refuted the allegations as 'absolutely groundless', pointing out to Russia's consistent support for strengthening the Convention through a legally-binding Protocol.⁷²³ As far as the 2012 essay was

⁷¹⁸ See U.S. Department of State, *Adherence to and Compliance with Arms Control, Nonproliferation, and Disarmament Agreements and Commitments*, August 2005, available at <http://www.state.gov/t/avc/rls/rpt/51977.htm> (accessed 8/09/2015).

⁷¹⁹ See U.S. Department of State, *Adherence to and Compliance with Arms Control, Nonproliferation, and Disarmament Agreements and Commitments*, July 2014, available at <http://www.state.gov/documents/organization/230108.pdf> (accessed 8/09/2015).

⁷²⁰ House Committee on Foreign Affairs, Subcommittee on Europe, Eurasia, and Emerging Threats, *Subcommittee Hearing: Assessing the Biological Weapons Threat: Russia and Beyond*, 7 May 2014, Washington DC, available at <http://foreignaffairs.house.gov/hearing/subcommittee-hearing-assessing-biological-weapons-threat-russia-and-beyond> (accessed 8/09/2015).

⁷²¹ See [in Russian] Vladimir Putin, 'Byt' sil'nymi: garantii natsional'noi bezopasnosti dlya Rossii', *Rossiiskaya Gazeta*, 20 February 2012, available at <http://www.rg.ru/2012/02/20/putin-armiya.html> (accessed 8/09/2015). Author's translation.

⁷²² See Milton Leitenberg, Testimony Statement, *The Biological Weapons Program of the Soviet Union*, House Committee on Foreign Affairs, Subcommittee on Europe, Eurasia, and Emerging Threats, *Subcommittee Hearing: Assessing the Biological Weapons Threat: Russia and Beyond*, 7 May 2014, Washington DC, p.44, available at <http://docs.house.gov/meetings/FA/FA14/20140507/102195/HRG-113-FA14-Transcript-20140507.pdf> (accessed 8/09/2015).

⁷²³ See [in Russian] Ministerstvo inostrannykh del Rossiiskoi Federatsii, *Komentarii Departamenta informatsii i pechati MID Rossii po povodu iskazheniya v Kongresse SShA pozitsii Rossii po voprosam KBTO*, 12 May 2015,

concerned, the passage in question was designed to underscore the potential military implications of scientific and technological advances for the future of warfare. Instead, 'the thought was turned upside down and misinterpreted as Russia's aspirations for creating new types of weapons.'

In the absence of an internationally-agreed verification mechanism to monitor States Parties' compliance with the provisions of the BTWC, biological weapons are likely to continue to be treated as a sensitive matter hardly immune to interpretation and speculation. According to Kalinina's rather pessimistic verdict:

If [...] a mechanism for international inspections is not implemented, and clear criteria for reporting are not defined, mutual accusations among states of unscrupulous intentions will continue, and their intensity will be determined by the prevalent political circumstances at any given point in time.⁷²⁴

Hurdles to International Scientific Collaboration

During the Cold War, tight state controls over the Soviet scientific community severely impeded foreign professional contacts and collaborative effort. Travel restrictions, secrecy, background checks, and systematic surveillance guarded scientists from 'degrading, imperialist influence' and sought to ensure that only trusted, politically loyal individuals were allowed to represent the Soviet science abroad. In short, just as in other areas of professional activity involving foreign interaction, scientific cooperation was subject to state sanction. The US-Soviet cooperation in the field of medicine is a case in point.⁷²⁵ The Lacy-Zarubin agreement signed in 1958 laid the foundations of an exchange programme which facilitated not only information sharing in the form of films, scientific journals, and publications but also reciprocal visits of medical delegations and individual specialists between the two countries. The professional and diplomatic ties thus fostered set the scene for two key

available at http://www.mid.ru/brp_4.nsf/newsline/EFB4514EC9DD87C744257CD60051B081 (accessed 8/09/2015).

⁷²⁴ See N. Kalinina, *Mezhdunarodnye i natsional'nye problemy biologicheskoi bezopasnosti i perspektivy ikh resheniya*, *op cit*, p.51.

⁷²⁵ David Finley, 'Soviet-U.S. Cooperation in Space and Medicine: An Analysis of the Detente Experience', *op cit*, p.139.

developments that occurred in the early 1970s, namely the establishment of a US-USSR Joint Committee for Health Cooperation in 1972 and the Nixon-Brezhnev accords in the Field of Medical Science and Public Health finalised in May that same year. The latter in particular gave joint work a fresh impetus and visibility. Besides collaborative research activities, medical cooperation further entailed exchange programmes, sharing of equipment and biological samples, organisation of conferences and symposia, and exchange of data on investigation trends. Moreover, the 1972 agreement made provisions for collaboration with international organisations, most notably the WHO, from which the Soviet Union had previously withdrawn. Although the joint medical effort was hailed largely as a success, the activities waned rapidly following the Soviet invasion of Afghanistan in 1979.

The dissolution of the Soviet Union effectively terminated the isolation of Russian science and offered an opportunity for a revived international cooperation. What initially began as assistance programmes in the early 1990s has gradually evolved over the years into professional partnerships of mutual benefit. Nevertheless, carrying out international collaborative life science activities in Russia remains an area pervaded by obstacles ranging from administrative and bureaucratic barriers through legal conundrums to diplomatic hurdles.⁷²⁶ For a joint foreign project to commence, all appropriate paperwork needs to be in place.⁷²⁷ To this end, a formal high-level approval needs to be obtained from the senior management of the respective institution or relevant government authorities, or sometimes both. Failure to present the required documentation with the correct stamps and signatures may result in unnecessary delays, disruption, and suspension of the endeavour in question, its objectives and anticipated outcomes notwithstanding. Once in progress, the project is susceptible to impediments of various kinds to the extent that even otherwise mundane work-related aspects may turn into insurmountable challenges. Consider, for instance, foreign travel and exchange visits. Visa applications take time to be processed and delays cannot always be accommodated. Moreover, under

⁷²⁶ National Research Council, *The Unique U.S. – Russian Relationship in Biological Science and Biotechnology*, (Washington DC: National Academies Press, 2013), Chapter 7.

⁷²⁷ *Ibid.*, p.92.

the existing rules, foreigners are allowed to conduct research in Russia for no more than 90 days on a single or double entry visa, which automatically imposes constraints on the duration of their stay and the contribution they could make.⁷²⁸

Whilst in-person contact may not be deemed critical given the availability of low-cost, reliable means for long-distance communication, a number of practical issues still need to be addressed. One pertains to the exchange of experimental samples. Shipping biological agents across the Russian border is subject to strict customs regulations and as such, prone to significant delays. As one life scientist jokingly summarised the conundrum: 'It is possible to send biological material internationally but no one in Russia has done it yet.'⁷²⁹ Receiving cultures from abroad is also pervaded with obstacles. In some cases, by the time the samples are cleared by the customs office, they have become unusable.⁷³⁰ The international transfer of biological phials appears just as challenging. In 2006 customs officials at Moscow's Sheremetyevo Airport confiscated twenty phials with non-pathogenic strains of typhus vaccine.⁷³¹ Oleg Mediannikov, a researcher of the capital-based Gamelaya Institute of Epidemiology and Microbiology who carried the phials was on his way to Marseilles as part of a collaborative effort with colleagues at the University of the Mediterranean. The two institutions shared a long-standing partnership in the study of typhus and were recognised WHO Collaborating Centres for Rickettsial Reference and Research. In early 2007 Mediannikov was accused of having attempted to smuggle the samples for the purpose of bioterrorism even though the export was formally sanctioned by the Russian Ministry of Healthcare. In May the same year the shipment of a human specimen abroad was temporarily prohibited as a result of an intelligence report suggesting that such material could be utilised for the development of genetic weapons.⁷³² The ban was lifted two weeks later amidst an outcry in the media and the scientific

⁷²⁸ Ibid, p.93-94.

⁷²⁹ Interview, 7 April 2014, Novosibirsk, Russia.

⁷³⁰ Interview, 15 April 2014, Moscow, Russia.

⁷³¹ Quirin Schiermeier, 'Russian Scientists See Red over Clampdown', *Nature*, vol.449 (2007), pp.122-123.

⁷³² See [in Russian] Dmitrii Butrin et al. 'Rossiya blyudet chelovecheskii obrazets', *Kommersant*, 30 May 2007, available at <http://www.kommersant.ru/doc/769777> (accessed 11/09/2015).

community. The shipment of pathogens, however, has remained under tight control.

Mediannikov's case unravelled against the backdrop of a series of high-profile investigations in which Russian scientists came under fire and faced serious charges for allegedly disclosing state secrets. Secrecy is yet another factor that has bearing on scientific cooperation.⁷³³ Apart from classified projects, research on sensitive topics, including in the area of the life sciences, is subject to restrictions regarding data sharing and findings dissemination. Scientists involved in such activities are supposedly required to report any interactions with foreigners they may have, whether by phone, email, or in person, and any manuscripts to be submitted to foreign journals need to be cleared for publication beforehand.⁷³⁴ Given the lack of a clear definition of what topics should be treated as 'sensitive', the policy has been largely left open to interpretation with few in-built mechanisms to prevent abuse.

Possible legal complications can further arise. The concept of intellectual property is not yet sufficiently well understood in Russia, which could severely inhibit data sharing as part of joint international projects (see Chapter 8). Given the Soviet predicament, patents and research commercialisation are still considered novel practices with which Russian life scientists, unlike their Western counterparts, hardly have any in-depth experience. Similarly, despite the existence of an extensive body of laws designed to ensure intellectual property protection, the Russian court system has barely dealt with cases of this kind and as such may appear unreliable in

⁷³³ See, for example, Amy Ninetto, "Civilisation" and Its Insecurities: Traveling Scientists, Global Science, and National Progress in the Novosibirsk Akademgorodok', *Kroeber Anthropological Society Papers*, Vol.86 (2001), pp.181-201; Bryon McWilliams, 'Russia Says Scientist Revealed State Secrets', *Chronicle of Higher Education*, vol. 51:26 (2005), p.A38; [in Russian] Dariya Sukhikh, 'Zachem FSB i Gostaina b'yut po sud'bam uchenykh v Rossii', *Troitskii variant*, No.194, 22 December 2015, pp.1-2, available at <http://trv-science.ru/2015/12/22/zachem-fsb-i-gostajina-bjyut-po-sudbam-uchenykh-v-rossii/> (accessed 7/02/16). On the legal framework pertaining to state secrets, see [in Russian] Federal'nyi zakon RF, *O gosudarstvennoi taine*, No. 5485-1, 21 June 1993 (last amended on 8 March 2015), available at https://www.consultant.ru/document/cons_doc_LAW_2481/ (accessed 7/02/16); Ukaz Prezidenta RF, *Ob utverzhdenii perechnya svedenii, otnesennykh k gosudarstvennoi taine (s izmeneniyami i dopolneniyami)*, No.1203, 30 November 1995 (last amended on 28 May 2015), available at http://base.garant.ru/10105548/#block_1000 (accessed 7/02/16).

⁷³⁴ Amy Ninetto, "Civilisation" and Its Insecurities', *op cit*.

the eyes of foreign partners.⁷³⁵ Russia's tax policy is also perceived as a hindrance, particularly as far as funding from foreign-based organisations and agencies is concerned. In 2008 the Russian Government issued Decree 485 titled 'On the List of International Organisations whose Grants (free-of-charge assistance) Awarded to Russian Tax-Payers Shall Be Exempt from the Taxation Levied against the Revenues of Russian Grantees'.⁷³⁶ The Decree was highly consequential as it significantly reduced the total number of international donors allowed to provide tax-exempt financial support to non-for-profit entities in Russia, including universities and research institutes, from 101 to 12. Thus, the revised list featured the following international bodies:

United Nations Educational, Scientific and Cultural Organisation (UNESCO)

United Nations Industrial Development Organisation (UNIDO)

EU Commission

The Council of the Baltic Sea States

The Nordic Council of Ministers

International Atomic Energy Agency (IAEA)

Organisation of the Black Sea Economic Cooperation

United Nations Environment Programme (UNEP)

United Nations Development Programme (UNDP)

United Nations Children's Fund (UNICEF)

European Cinema Support Fund of the Council of Europe Joint Institute for Nuclear Research (EURIMAGES)

In 2010, the Intergovernmental Foundation for Educational, Scientific and Cultural Cooperation (IFESCO) was added to the list.⁷³⁷ The Decree, however, laid down no clear criteria for the selection of specific

⁷³⁵ National Research Council, *The Unique U.S. – Russian Relationship in Biological Science and Biotechnology*, *op cit.*

⁷³⁶ See [in Russian] Postanovlenie Pravitel'stva RF, *O perechne mezhdunarodnykh organizatsii, poluchaemy nalogoplatel'shchikami granty (bezvozmezhnaya pomosh') kotorykh ne podlezhat nalogooblozheniju i ne uchityvajutsya v tselyakh nalogooblozheniya v dokhodakh rossiiskikh organizatsii – poluchitelei grantov*, No.485, 28 June 2008, Moscow, available at <http://www.rg.ru/2008/07/03/granti-nalogi-dok.html> (accessed 9/09/2015).

⁷³⁷ See [in Russian] Postanovlenie Pravitel'stva RF, *O vnesenii izmeneniya v perechen' mezhdunarodnykh i inostrannykh organizatsii, poluchaemy nalogoplatel'shchikami granty (bezvozmezhnaya pomosh') kotorykh ne podlezhat nalogooblozheniju i ne uchityvajutsya v tselyakh nalogooblozheniya v dokhodakh rossiiskikh organizatsii – poluchitelei grantov*, No.585, 2 August 2010, available at http://www.consultant.ru/document/cons_doc_LAW_103411/ (accessed 9/09/2015).

organisations.⁷³⁸ Many of the institutions previously involved in offering grants to Russian life scientists, most notably the CRDF and the various arms of the US Government have been left out, as a result of which they are now liable to pay taxes to the state budget. In 2011 the Russian government further announced that it would cease its cooperation with the ISTC which has been a major vehicle for channelling foreign financial and material support to life scientists. As of 2015, ISTC no longer operates on the territory of Russia.

Russia's annexation of the Crimea and subsequent crisis in Eastern Ukraine in 2014 have led to a growing tension between Moscow and the West which has manifested itself in the sanctions that both sides have imposed against one another. Whilst it is difficult to assess the overall impact of the geopolitical diplomatic confrontation on scientific cooperation, not least because of the relative progress being made toward ending the hostilities in Donetsk region, it is noteworthy that by the summer of 2014 the US had already put on hold a number of collaborative scientific projects with Russia and each joint project was to be evaluated on a case-by-case basis.⁷³⁹

Limited Engagement among Life Scientists with the Broader Implications of Their Work

Situated in Bolotnaya Square in downtown Moscow, Shemyakin's famous sculpture complex, 'Children – Victims of Adults' Vices' (*Deti – zherty porokov vzroslykh*) constitutes an original allegory of what the artist deems to be the most critical challenges confronting society in the twentieth-first century. Among the thirteen statues depicting various representations of evil, there is one titled *L'zhe-uchenost'* (literally, pseudoscience). It is a statue of a blind-folded woman dressed in robes holding a scroll and marionette. The scroll symbolises pseudoscientific knowledge, which, if misapplied, could

⁷³⁸ Aleksey Bogoriditskii, 'Russia', *The International Journal of Not-for-Profit Law*, vol.12:3 (2010), pp.28-34.

⁷³⁹ Eli Kintisch, 'Geopolitics Disrupt Scientific Exchange with Russia', *ScienceInsider*, 1 August 2014, available at <http://news.sciencemag.org/scientific-community/2014/08/geopolitics-disrupt-scientific-exchange-russia> (accessed 9/09/2015). For analysis of the broader impact of the sanction on Russian science, see [in Russian] Irina Dezhina, 'Sostoyanie nauki i innovatsii' in B. Mau et al. (ed.), *Rossiiskaya ekonomika v 2014 godu: Tendentsii i perspektivy*, (Moscow: Gaidar Institute, 2015).

result in a mass catastrophe, the development of dangerous weapons, or unnatural interference with the environment. The potential negative consequences of pseudoscience are demonstrated by the marionette presented here as a two-headed mutant dog. The idea for the marionette has allegedly arisen when the author came across information about the deleterious effects of thalidomide in the 1960s (see Chapter 3).⁷⁴⁰ Another curious detail about the statue is that its English caption does not read 'pseudoscience' but 'irresponsible science', which if literally translated into Russia would read *bezotvestvennaya nauka*. The discrepancy matters insofar as the former seeks to uphold the value of science as the pursuit of true objective knowledge emphasising honesty and rigour whereas the latter draws attention to the link between science and its broader social context. A recent report by the IAP Responsible Conduct in the Global Research Enterprise (formerly the Inter-Academy Panel), of which the RAN is a member, defines the role of scientists with regard to society as follows:

Because of the increasing importance of research in the broader society, scientists and other scholars bear a responsibility for how research is conducted and how the results of research are used. They cannot assume that they work in a domain isolated from the needs and concerns of the broader world.⁷⁴¹

According to Academician Boris Judin, far from being incidental, the inaccuracy in translation could, at least in part, be ascribed to the fact that in Russia the concept of responsible science (*otvestvennaya nauka*) as related to the relationship between scientists and society remains underdeveloped.⁷⁴² To an extent, it even sounds like an oxymoron. This is hardly surprising given the dominant lens through which science was perceived during the Soviet period. From its inception, the Soviet state laid a

⁷⁴⁰ Guided tour of the sculpture complex, 30 May 2015. For a brief overview of the sculpture complex, see [in Russian] *Neobychnye pamyatniki Moskvy: No 20 Porokam* (Moscow's Unconventional Monuments: No 20 Vices), available at <http://www.unmonument.ru/mon020.html> (accessed 9/09/2015).

⁷⁴¹ See InterAcademy Council / IAP, *Responsible Conduct in the Global Research Enterprise: A Policy Report*, September 2012, p.x, available at <http://www.interacademies.net/file.aspx?id=19789> (accessed 9/09/2015).

⁷⁴² See [in Russian] Lyubov Borusyak, 'Mozhet li etika ogranichit' nauku: Beseda s filosofom Borisom Yudinym', *Polit.Ru*, 19 August 2009, available at http://polit.ru/article/2009/08/19/b_judin/ (accessed 9/09/2015). On the issue of pseudoscience (*izhenauka*) in Russia today, see [in Russian] David Raskin, 'Uchenye o bolevykh tochkakh rossiiskoi nauki', *Troitskii variant*, No.177, 21 April 2015, pp.4-5, available at <http://trv-science.ru/2015/04/21/uchenye-o-bolevykh-tochkakh-rossijskoj-nauki/> (accessed 11/09/2015).

tremendous emphasis on scientific progress, turning it into a driving force of prosperity and public welfare. Science was thus construed as an inherently moral activity and a source of significant socio-economic and political benefits. Similarly, scientists were considered moral in their own right, not least because they worked in the service of the Soviet society, which, as propagated by the official Communist Party line, was organised on the principles of justice, fairness, and equality. In other words, if the society was moral and if science was deemed the primary engine of progress in that society, then science could only be praised as beneficently-intended activity:

It was a particular society that gave science and its implications a moral value and passed a value judgement on concrete scientific endeavours: in immoral society, science would be immoral, while in a moral society, science would 'automatically' become moral.⁷⁴³

Implicit in this assumption is an uncritical belief that science was value-free and when applied in the context of the Marxist-Leninist ideology, it would yield solely positive outcomes. For instance, in the immediate aftermath of the Bolshevik revolution, one area of science that enjoyed generous endorsement from the state was experimental biology.⁷⁴⁴ Promulgated as possessing transformative potential for enhancing human resilience against disease, experimental biology attracted substantial attention from the government. Whilst some of the studies conducted as part of the newly-established research agenda were considered at best questionable, the ethical issues arising therefrom were barely addressed. Commenting in private correspondence on a report entitled 'Experiments with a revived dog's head' (*Opyty s ozhivlennoi golovoi sobaki*) published in 1926, the eminent Russian writer and anthroposophist, Ivanov-Razumnik complained about the 'ethical deafness' of scientists who refused to think about the ethical implications of their work.⁷⁴⁵ Even he, however, proved reluctant to offer a definitive answer whether such studies would have been justified if the goal was the improvement of human health.

⁷⁴³ Nikolai Kremontsov, *Revolutionary Experiments*, op cit, p.62.

⁷⁴⁴ Ibid, p.26.

⁷⁴⁵ See [in Russian] A. Lavrov and D. Mal'mstad, *Andrei Belyi i Ivanov-Razumnik: Perepiska*, (St Petersburg: Atheneum, 1998), p. 408.

By contrast, the development of medical ethics has followed a significantly different trajectory. Humanist ethics constituted an indispensable element of the medical practice in Russia long before the Revolution. Evidence suggests that by 1917 at least several of what are considered to be fundamental principles of biomedical research in the twenty-first century were formally codified, including confidentiality, autonomy, voluntary participation, and informed consent.⁷⁴⁶ In 1936 the Academic Council of the Russian Soviet Federative Socialist Republic (RSFSR), the supreme body governing the healthcare services, issued a set of regulations 'On the Order of Testing New Medical Remedies and Methods, which Could Be Harmful to the Health and Life of the Patient' (*O poryadke ispytaniya novykh meditsinskikh sredstv i metodov, mogushtikh predstavit' opasnost' dlya zdorov'ya i zhizni bol'nykh*) which defined the required legal criteria for conducting clinical trials. In particular, emphasis was laid on the need for an adequate preclinical examination; the need for voluntary informed consent; the need for medical staff to be properly qualified; and the need for disclosure of the research results irrespective of the findings.⁷⁴⁷ Nevertheless, for its most part, biomedical ethics, just as other areas of life in the Soviet Union, was framed in a way which unconditionally prioritised the state's interests over the interests of the individual.⁷⁴⁸ Dubious practices indicative of this trend included breaches of confidentiality and forced medical treatment for certain medical conditions in such areas as psychiatry and venereology.⁷⁴⁹ Life science research that did not involve human subjects was regulated primarily from the standpoint of safety with little appreciation being dedicated to the potential ethical concerns pertaining to scientific advances, including those prompted by the advent of genetic engineering.

⁷⁴⁶ See [in Russian] G.L. Mikirtichan et al, 'Rossisskaya Federatsiya', in O.I. Kubar', *Eticheskaya ekspertiza biomeditsinskikh issledovaniy v gosudarstvakh-uchasnikakh SNG (sotsial'nye i kul'turnye aspekty)*, (St Petersburg: Phoenix: 2007), pp.248-316.

⁷⁴⁷ Alexei Sozinov et al. 'The Development of Ethical Review Practices in Eastern Europe and Central Asia: Past, Present, and Future', *Pharmaceutical Medicine*, vol.22:5 (2008), p.278.

⁷⁴⁸ See [in Russian] Yurii Lopukhin, 'O bioetike: Bioetika v Rossii', *Vestnik RAN*, vol.71:9 (2001), pp.771-774.

⁷⁴⁹ See, for example, Robert van Voren, 'Political Abuse of Psychiatry: An Historical Overview', *Schizophrenia Bulletin*, vol.36:1 (2010), pp.33-35; Richard Bonnie, 'Political Abuse of Psychiatry in the Soviet Union and China: Complexities and Controversies', *Journal of the American Academy of Psychiatry Law*, vol.30 (2002), pp.136-144.

Following the collapse of the Soviet Union bioethics was institutionalised as a university discipline and by 1994 it was already being taught across medical universities in Russia. The content of the courses, however, remains narrow covering mainly issues of relevance to medical practice rather than to laboratory life science research. In the context of the latter, bioethics is still largely limited to the requirement of humane treatment of animals. The remit of work of the institutional bioethics committees in place is thus narrowly focused on a single facet of scientific conduct. Likewise, the rules pertaining to laboratory safety deal exclusively with the technical aspects of scientific work. Broader issues related to the potential legal and social implications of biotechnology are marginalised and there are virtually no adequate mechanisms which would allow such concerns to be raised and tackled. The prevalent conviction within the life science community seems to be that a clear demarcation line needs to be drawn between biotechnology research, on the one hand, and the use thereof, on the other. ‘The problem is not science *per se* but how it is applied, and this depends on the individual’ is a common leitmotif among Russian life scientists.⁷⁵⁰ The debate on the dual use and biosecurity aspects of the biological sciences so prominent in the West is practically non-existent and little local effort has been made to engage practising life scientists with the broader context of their work (see Chapter 8). Part of the reason for this trend is the fact that most health officials in Russia consider issues such as the prevention of deliberate misuse of biological assets to be a less urgent task than servicing the day-to-day public health needs of the general population.⁷⁵¹ At the same time, there seems to be persistent resistance among life scientists to broadening scientific debates and opening them up to the public. Against the backdrop of the legacy of Lysenkoism, the involvement of ‘lay people’ is largely perceived as potentially dangerous to science and research integrity.

⁷⁵⁰ See, for example, [in Russian] Vladimir Gubarev, ‘Chaepitiya v Akademii: v zerkale jizni’, *Pravda*, 15 May 2012, available at http://www.pravda.ru/science/academy/15-05-2012/1114971-rem_petrov-0/ (accessed 9/09/2015).

⁷⁵¹ National Research Council, *The Unique U.S. – Russian Relationship in Biological Science and Biotechnology*, *op cit*, p.88. Also see National Research Council, *Biological Sciences and Biotechnology in Russia: Controlling Diseases and Enhancing Security*, (Washington DC: National Academies Press, 2006).

Chapter 8: Life Science Policy and Practice in Present-Day Russia

Current State of Biotechnology in Russia

The development of biotechnology in Russia following the collapse of the Soviet Union can generally be divided into three phases, with the first phase spanning the two Yeltsin administrations up until the late 1990s; the second encompassing the first decade of the 2000s; and the third spanning the aftermath of the global economic crunch. Each of those phases has been extremely dynamic and subject to internal and external socio-political contingencies and market fluctuations. Prior to its dissolution in 1992, the Soviet Union maintained a vast biotechnology complex coordinated by *GLAVMIKROBIOPROM*, later the Ministry of the Medical Industry (*Ministerstvo Meditsinskoi Promyshlenosti: MINMEDPROM*).⁷⁵² With its more than 130 microbiological factories, 192, 000 employees, and 634 million roubles worth of investment, the Soviet biotechnology industry made a tremendous contribution to the country's agriculture and medicine, and constituted, in bulk terms, the world's largest such enterprise.⁷⁵³ Key areas of specialisation included large-scale production of single-cell protein, microbial pesticides, enzymes, amino acids, antibiotics, vitamins, and influenza vaccine.⁷⁵⁴ Whilst significant, this output was largely limited to developments that were relatively easy in terms of concept and scale-up, which in turn created a technological gap between the Soviets and their Western counterparts, as the latter embarked on introducing more sophisticated biotechnologies in food, agriculture, pharmaceuticals, and waste management. Far from stemming from a scientific lag, the gap was mainly a consequence of the organisational and structural limitations which pervaded the Soviet biotechnology industry such as the poor links between research and production facilities, the lack of incentives for innovation and keeping up with contemporary technology trends, and top-down administrative

⁷⁵² Established in 1966 under SOVMIN, GLAVMIKROBIOPROM existed until 1985 before it was restructured and renamed MINMEDPROM.

⁷⁵³ Rod Greenshields et al. 'Perestroika and Soviet Biotechnology', *Technology Analysis & Strategic Management*, vol.2:1 (1990), p.63.

⁷⁵⁴ *Ibid*, p.64.

hierarchies.⁷⁵⁵ Toward the late 1980s, the sector further acquired notoriety for being associated with pollution and environmental degradation.

The first phase of biotechnology development in independent Russia was associated with a turbulent decline and severe industrial downturn. Production decreased, enterprises shut and research subsidies shrunk. Macroeconomic instability and political uncertainty put investors off and limited career prospects forced gifted prospective Russian scientists to search for employment elsewhere. By the late 1990s many biotechnology products available on the Russian market were replaced by imported ones with domestic manufacturing accounting for about 30 per cent of consumption.⁷⁵⁶

During President Putin's first term in office in the early 2000s, the tide gradually began to turn. Oil prices surged and it was not long before Russia was on track for an economic recovery. The second phase of biotechnology development thus started on a positive note, as the government strived to fulfil its ambitions for modernisation through scientific and technological advancement and innovation. The state bonded with the private sector over the need for support for cutting-edge technologies for the purposes of promoting drug development, diagnostics, food security, and an environment-friendly economy. By 2007 then, Russia was a leading producer of a range of items, including immunological medications, veterinary products, and environmental protection technology.⁷⁵⁷ The total annual investment for 2007 increased more than two-fold in comparison with the 2006 levels and the projected rate of market growth for the period of 2008-2010 was 10 per cent.⁷⁵⁸ The list of forward-looking products to be developed entailed bio-targets, computer-based methods for drug discovery, peptides and biopharmaceuticals, antivirals and antimicrobials, biochips and biosensors, biopesticides and biofertilizers, and probiotics. Over a thousand institutions

⁷⁵⁵ Ibid; see also See Raymond Zilinskas, 'Biotechnology in the U.S.S.R, Part 2', *op cit*.

⁷⁵⁶ See Roger Roffey, *Biotechnology in Russia: Why Is not a Success Story?*, April 2010, FOI, Swedish Defence Research Agency, Stockholm, p.66. Full text is available at <http://www.foi.se/report?rNo=FOI-R--2986--SE> (accessed 9/09/2015).

⁷⁵⁷ Mikhail Rabinovich, 'Biotech in the Russian Federation', *Biotechnology Journal*, vol.2 (2007a), p.778.

⁷⁵⁸ Ibid. See also Roger Roffey, *Biotechnology in Russia*, *op cit*, p.65.

were involved in research in physicochemical biology. Other areas of interest ripe for investment featured cell technologies, bioinformatics, post-genome technologies, such as proteomics and metabolomics. Nanobiotechnology and nanomedicine were singled out as fields of high priority and a detailed research agenda was set out. Among the specific lines of study to be pursued were:

- Biological nanochips for diagnostics of somatic and infectious diseases;
- Nanoparticles as new-generation pharmaceuticals;
- Medical nanorobots;
- Nanopores for molecular devices for genome sequencing;
- Biocompatible nanomaterials with a wide spectrum of applications.⁷⁵⁹

The 2008 global financial crisis has had a significant impact on Russia's economy. In 2009 the GDP fell by almost 8 per cent and the bulk of foreign investment alone declined by 41 per cent.⁷⁶⁰ Commenting on the inability of the state to face up to the challenges posed by the economic downturn Russia, the then President Dmitry Medvedev stated:

We need to recognise that we have not done enough over these last years to resolve the problems we inherited from the past. We have not freed ourselves from a primitive economic structure and humiliating dependence on raw materials. We have not refocused our industry on consumers' real needs. The habit of living off export earnings is still holding back innovative development. Russian business still prefers to sell goods produced abroad, and our own goods' competitiveness is disgracefully low.⁷⁶¹

⁷⁵⁹ Mikhail Rabinovich, 'Prospects of Nanobiotechnology and Nanomedicine in Russia', *Biotechnology Journal*, vol.2 (2007b), p.788.

⁷⁶⁰ 'Russia's GDP Falls 7.9%, Hit by Falling Oil Prices', *MarketWatch*, 1 Feb 2010, available at <http://www.marketwatch.com/story/russias-economy-contracts-79-in-2009-2010-02-01> (accessed 13/05/2015); see also Roger Roffey, *Biotechnology in Russia*, *op cit*, p.61.

⁷⁶¹ Dmitry Medvedev, *Presidential Address to the Federal Assembly of the Russian Federation*, 12 November 2009, available at <http://en.kremlin.ru/events/president/transcripts/messages/5979> (accessed 13/05/2015). See also Evgeny Klochikhin, 'Russia's Innovation Policy: Stubborn Path-Dependencies and New approaches', *Research Policy*, vol.41 (2012), pp.1620-1630.

He then went on to highlight Russia's chief priorities as part of the modernisation effort:

The modernisation area of top importance for our people is developing medical technology, medical equipment, and the pharmaceuticals industry. We will provide people with quality and affordable medicines and also the latest technology for preventing and treating diseases, especially the diseases that are the biggest causes of sickness and death in our country.⁷⁶²

Drug development, especially for treating cardiovascular disease and cancer was deemed a strategically important area which had to be vigorously promoted domestically so that by 2020 Russian-made medicines would account for more than half of the market.⁷⁶³ A similar message echoed in the President's address delivered the following year when he added that the share of domestic innovative pharmaceutical products should rise by 60 per cent.⁷⁶⁴ Overcoming Russia's high dependence (about 80 per cent)⁷⁶⁵ on imported biotechnology products and raw materials, particularly in critical fields such as pharmaceuticals and food production has thus become a crucial state imperative and even more so in light of the still ongoing crisis in Eastern Ukraine and resultant economic sanctions.

As of 2015, Russia's share of the international biotechnology market remains about 0.1 per cent, although this figure is distributed unevenly as far as different sectors are concerned. For instance, whereas its share on the world market of veterinary biopreparations amounts to 5 per cent, in the areas of biofuels and biodegradable substances Russia's contribution is virtually non-existent.⁷⁶⁶ Agricultural biotechnology is considered a vital asset, not least because agriculture accounts for 3 per cent of the state's GDP, employing 7 per cent of its population. Other sectors are also slowly undergoing

⁷⁶² Ibid.

⁷⁶³ Ibid.

⁷⁶⁴ Dmitry Medvedev, *Presidential Address to the Federal Assembly of the Russian Federation*, 30 November 2010, available at <http://en.kremlin.ru/events/president/transcripts/messages/9637> (accessed 13/05/2015).

⁷⁶⁵ Nicole Burghardt et al. 'Industrial Biotechnology in Russia: Waking up from Its Deep Sleep', *Industrial Biotechnology*, vol.6 (2015), p.60.

⁷⁶⁶ See [in Russian] Tekhnologicheskaya platforma BioTekh2030, *Strategicheskaya programma issledovaniy*, 22 April 2015, Moscow, p.6, available at <http://biotech2030.ru/deyatelnost/> (accessed 9/09/2015). Author's translation.

expansion. Two plants for amino acid manufacturing are to open in 2015, in Belgorod and Volgodonsk Rostov regions, respectively; as of 2011 one of the world's largest plants for the production of wood pellets – Vyborgskaya Timber Corporation – has been in operation in Leningrad region; and in late 2014 the first plant for the production of protein concentrates was established in the Altai region.⁷⁶⁷ Whilst poorly developed at the time of writing, bioenergy constitutes an area with prospects for economic viability. Indeed, estimates demonstrate that in the coming decades the production of biofuel from biomass in Russia could be commensurate with the annual output of oil, coal, or natural gas.⁷⁶⁸ Similarly, forestry biotechnology holds a tremendous promise given Russia's significant wood resources. Along with it, industrial biotechnology and bioenergy, agricultural and food biotechnology, environmental biotechnology, and marine biotechnology have been defined as key priorities for the next fifteen years.⁷⁶⁹

Mapping Russia's Life Science Policy

Together with information and communication technologies and nanotechnology, biotechnology is seen as one of the three fundamental pillars upon which the modernisation of the Russian economy is expected to rest upon. Over the past several years, considerable attention, effort, and financial resources have been dedicated to the goal of building sustainable bio-industry underpinned by domestic production, internationally competitive export goods, and favourable market conditions. The purpose of this section therefore is to examine the chief trends in Russia's biotechnology policy and map the wide range of initiatives and actors involved in the endeavour. Key elements of the regulatory framework within which life science R&D takes place in Russia as well as its main sources of funding will also be discussed.

The biotechnology policy landscape in Russia is rich, comprising an array of instruments and initiatives that aim to foster innovation and facilitate scientific and technological development. State Programmes (*Gosudarstvennyye*

⁷⁶⁷ See Arnold Dale, *Wood Pellets in Russia*, presentation at the Wood Pellet Association of Canada, 18-20 November 2013, Vancouver, Canada. Available at http://www.pellet.org/images/21_-_Arnold_Dale_-_From_Russia_with_Love_2013.pdf (accessed 18/07/15).

⁷⁶⁸ Tekhnologicheskaya platforma BioTekh2030, *Strategicheskaya programma issledovaniy, op cit*, p.14.

⁷⁶⁹ *Ibid*, p.77.

programmy), for example, are deemed important instruments for promoting sector-specific action. Federal Targeted Programmes (*Federal'nye tselevye programmy: FTsP*) and Sub-Programmes (*Podprogrammy*) constitute auxiliary mechanisms featuring activities, regulations, and procedures which aim to facilitate the execution of the goals, proposals, and recommendations defined by the State Programmes. By design, Federal Targeted Programmes are used by the state as instruments both for fulfilling priority tasks and channelling budgetary support for science.⁷⁷⁰ Each State Programme is usually underpinned by a set of Targeted Programmes outlining concrete steps and measures. Appendix 1 contains detailed information on the main policy documents with relevant to biotechnology, including State and Federal Targeted Programmes.

In terms of policy priorities, a significant emphasis has been laid on promoting applied research and product development.⁷⁷¹ A case in point is the constant increase of public funding envisaged for supporting the Federal Targeted Programme, 'Research and Development in Priority Areas of Development of the Russian Scientific and Technological Complex for 2014-2020', which in 2014 was entirely re-directed toward applied research for the purposes of industry. The underlying rationale behind this trend has been the Russian Government's resolve to address the country's dependency on foreign imports, an issue that has become particularly acute in light of the international sanctions that were introduced against Russia after the annexation of Crimea.

Another aspect that merits attention is that biotechnology and medical research are among the areas of prime interest for state investment. Whilst the funds available for space and aviation programmes are being reduced, those for medicine and pharmacy are increasing.⁷⁷² If this trend is preserved, by 2017 medicine and pharmacy will be second in the top five spheres of national economy, as far as budgetary contributions to applied research are concerned.

⁷⁷⁰ See [in Russian] Irina Dezhina, *Mekhanizmy gosudarstvennogo finansirovaniya nauki v Rossii*, (Moscow: IEPP, 2006), p.71. Author's translation.

⁷⁷¹ [in Russian] Irina Dezhina, 'Sostoyanie nauki i innovatsii', in V. Mau et al., *Rossiskaya ekonomika v 2014: Tendentsii i perspektivy* (Moscow: Gaidar Institute, 2015), p.345.

⁷⁷² *Ibid.*

Although the focus on biotechnology as an area of state investment is certainly to be welcomed, it needs to be highlighted that the various policy instruments leave little scope for public deliberation on the potential risks and implications of novel life science advances. This trend, in turn, raises questions regarding the extent to which the governance of new technologies can be properly ensured.

Regulations

The aim of this sub-section is to outline some of the key regulations pertinent to life science research and practice in Russia.

a. Laboratory Biosafety

In 2005 the WHO published a revised version of the International Health Regulations (IHR) which require states to develop a set of core capacities for the purpose of disease prevention, surveillance, detection, reporting, and response.⁷⁷³ Thus, the overall aim of the IHR is to help enhance states' preparedness to address public health threats regardless of whether those are naturally-occurring diseases or caused by the accidental or deliberate release of pathogens.⁷⁷⁴ The IHR core capacity titled 'Laboratory' deals with laboratory biosafety and biosecurity practices directed at ensuring the safe handling of pathogens under appropriate containment conditions, as well as the security of research facilities against possible theft, displacement, or misuse of hazardous biological materials. The IHR are legally binding and all states are required to report on the steps taken at national level to demonstrate compliance. Back in 2004, the WHO issued a third edition of its 'Laboratory Biosafety Manual' which first appeared in 1983.⁷⁷⁵ The Manual is an authoritative guiding document but is not mandatory. In 2008 the European Committee for Standardisation (CEN) released CWA 15973:2008

⁷⁷³ World Health Organization, *International Health Regulations*, 2nd ed. (Geneva: WHO, 2005), available at <http://www.who.int/ihr/publications/9789241596664/en/> (accessed 9/09/2015).

⁷⁷⁴ This objective has been internalised in Russia's policy on biosafety and biosecurity. See, for example, [in Russian] Genadii Onishchenko et al. 'Conceptual Bases of Biological Safety: Part 1', *Vestnik RAMN*, No.10 (2013), pp.4-13; G. Onishchenko and V. Kutyreva, *Biologicheskaya bezopasnost': termini i opredeleniya*, (Moscow: Meditsina, 2011).

⁷⁷⁵ World Health Organization, *Laboratory Biosafety Manual*, 3rd ed. (Geneva: WHO, 2004), available at http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/ (accessed 9/09/2015).

'Laboratory Biorisk Management Standard'.⁷⁷⁶ The document was prepared following a CEN Workshop with wide international participation, including experts from Russia. Whilst non-binding, the CEN Workshop Agreement constitutes an important stepping stone in the development of international laboratory biosafety and biorisk standards. In 2011 CWA 15973 was renewed for another three years and is currently being converted into an ISO standard.⁷⁷⁷

The origins of the Russian laboratory biosafety system date back to the late imperial period spanning the end of nineteenth and early twentieth century. During the Soviet era the system was formally codified and institutionalised and many of its elements have been preserved following the collapse of the USSR. Federal Act No.52 of 30 March 1999 'On Sanitary and Epidemiological Welfare' defines the legal framework for any activity involving biological material.⁷⁷⁸ Article 2 stipulates that any potentially hazardous services, products, or activity are subject to licensing and that any potentially hazardous biological and chemical substances and materials are subject to state registration. The Act further lays down the sanitary and epidemiological rules and requirements for conducting work involving biological material and biological and microbiological organisms, and toxins (Article 26); organising and performing prophylactic activities (Article 29); and enforcing quarantine (Article 31). It also outlines the specific licensing requirements for different potentially hazardous activities (Article 40), as well as the structure of and mechanisms for government sanitary and epidemiological oversight (Article 46). The Act is underpinned by

⁷⁷⁶ CEN Workshop Agreement, *CEN Workshop Agreement (CWA): 15793:2008 Laboratory Biorisk Management Standard*, (Brussels: CEN, 2008), available at http://www.absa.org/pdf/CWA15793_Feb2008.pdf (accessed 9/09/2015).

⁷⁷⁷ At a subsequent Workshop held in 2011, a follow-up document known as 'CWA: 15793: 2011 Laboratory Biorisk Management' was agreed. The 2011 document supersedes the previous version agreed in 2008 without making any substantive changes but for dropping the word 'Standard' from the title. See CEN, *CWA: 15793:2011 Laboratory Biorisk Management*, (Brussels: CEN, 2011), available at <http://globalbiorisk-public.sharepoint.com/links> (accessed 9/09/2015). On the progress of the conversion of the CEN Workshop Agreement into an ISO Standard, see Gary Burns, 'Development of an ISO Laboratory Biorisk Management Standard: Can ISO/AWI 35001 Help in Supporting the BTWC', a paper presented at the BWC 40th Anniversary Commemorative Events, 30 March 2015, Council Chamber, Palais des Nations, Geneva, Switzerland, available at <http://www.unog.ch/bwc/bwc40> (accessed 9/09/2015).

⁷⁷⁸ See [in Russian] Federal'nyi zakon RF, *O sanitarno-epidemiologicheskoy blagopoluchii naseleniya (s imeniyami i dopolnennyami, vstup. v silu s 24.07.2015)*, No.52-FZ, 30 March 1999, Moscow, available at http://www.consultant.ru/document/cons_doc_LAW_22481/ (accessed 9/09/2015). For a detailed discussion of the Act, see also Kalinina, *Mezhdunarodnye i natsional'nye problemy biologicheskoy bezopasnosti i perspektivy ikh resheniya*, op cit, p.263.

Government Resolution 569 of 15 September 2005, 'On the Implementation of State Sanitary and Epidemiological Oversight', according to which the responsibility for state sanitary and epidemiological supervision is vested in ROSPOTREBNADZOR.⁷⁷⁹ Any organisation conducting activities involving biological materials and/or organisms has to pass through a two-tiered certification process administered by ROSPOTREBNADZOR. First, it has to apply for a license in accordance with Federal Act No. 99-FZ of 4 May 2011, 'On the Licensing of Certain Types of Activity';⁷⁸⁰ second, as stipulated in the Sanitary and Epidemiological Regulations SP 1.2.1318-03, 'On the Procedure for Acquiring a Sanitary and Epidemiological Certificate for Conducting Work Involving Pathogenic Microorganisms (II-IV Group), Genetically-Modified Organisms, Toxins, and Helminths', it has to receive a Sanitary and Epidemiological Certificate.⁷⁸¹ The Certificate has to be renewed every five years.⁷⁸² The process of certification is done on the basis of the categorisation of pathogens. According to the Russian system of categorisation, pathogens are divided into four groups, according to which the ones deemed highly dangerous, such as Variola virus, Ebola virus, *Yersinia pestis*, and *Bacillus anthracis* are found in Groups I and II, and those deemed less dangerous are found in Groups III and IV. By contrast, in the system of classification adopted in the West, highly dangerous pathogens occupy categories III and IV. Life science research in Russia is subject to various sets of regulations, including:

- Sanitary Regulations, SP 1.2.036-95, 'On the Accounting, Storage, Transfer, and Transportation of Pathogenic Microorganisms, I-IV Group', issued 28 August 1995;⁷⁸³

⁷⁷⁹ See [in Russian] Postanovlenie Pravitel'stva RF, *O Polozhenii ob osushchestvlenii gosudarstvennogo nadzora v Rossiiskoi Federatsii*, No.569, 15 September 2005, published in *Rossiiskaya Gazeta*, No.3882, 23 September 2005, available at <http://www.rg.ru/2005/09/23/epidemiologiya-doc.html> (accessed 9/09/2015).

⁷⁸⁰ See [in Russian] Federal'nyi zakon RF, *O litsenzirovanii otдел'nykh vidov deyatel'nosti*, No.99-FZ, 4 May 2011, published in *Russkaia Gazeta*, No.5473, 6 May 2011, available at <http://www.rg.ru/2011/05/06/license-dok.html> (accessed 9/09/2015).

⁷⁸¹ See [in Russian] ROSPOTREBNADZOR, *Poryadok vydachi sanitarno-epidemiologicheskogo zaklyucheniya o vozmozhnosti provedeniya rabot s vzbuditel'yami infektsionnykh zabolovaniy cheloveka II-IV grupp (mikroorganizmami, vzbuditel'yami gel'mintozov i protozoozov i t.d.)*, v sootvetsvie s trebovayami saniranykh pravil SP 1.2.1318-03 'Poryadok vydachi sanitarno-epidemiologicheskogo zaklyucheniya o vozmozhnosti provedeniya rabot s vzbuditel'yami infektsionnykh zabolovaniy cheloveka I-IV grupp patogennosti (opasnosti), genno-inzhenerno-modifitsirovannymi mikroorganizmami, yadami biologicheskogo proizhozhdeniya', 24 April 2003, Moscow, available at <http://26.rospotrebnadzor.ru/rl/830/> (accessed 9/09/2015).

⁷⁸² Interview, 16 April 2014, Moscow.

⁷⁸³ See [in Russian] Postanovlenie Goskomsanepidnadzora RF, *Sanitarnye pravila SP 1.2.036-95: Poryadok ucheta, khraneniya, peredachi i transportirovaniya mikroorganizmov I-IV grupp patogennosti*, No.14, 28 August 1995, available at <http://www.ecobest.ru/snip/folder-1/list-77.html> (accessed 9/09/2015).

- Sanitary Regulations, SP 1.1.2193-07, 'Organisation and Exercise of Production Control on the Implementation of Sanitary Regulations and the Fulfilment of Prophylactic Activities', issued 27 March 2007;⁷⁸⁴
- Sanitary Regulations, SP 1.3.2322-08, 'Safety during Work Involving III-IV Group Pathogens and Parasites', issued 2 June 2009;⁷⁸⁵
- Order of the Ministry of Healthcare and Social Development, No 708n, 'Laboratory Practice Rules', issued 22 October 2010;⁷⁸⁶
- Sanitary Regulations, SP 1.3.3118-13, 'Safety during Work Involving I-II Group Pathogens', issued 28 November 2013.⁷⁸⁷

Non-compliance with the Sanitary Regulations is considered a criminal offence and subject to penalties. The Criminal Code⁷⁸⁸ makes the following provisions:

- Article 236, non-compliance with the sanitary and epidemiological regulations due to negligence leading to the accidental spread of disease – punishable by modes of punishment including a fine of up to 80 000 roubles and imprisonment of up to 5 years;
- Article 247, non-compliance with the rules pertaining to the handling of environmentally hazardous materials and wastes, including bacteriological materials and wastes – punishable by modes of punishment, including a fine of up to 300 000 roubles and imprisonment of up to 8 years;
- Article 248, non-compliance with the rules pertaining to the handling of microbiological or other biological agents or toxins – punishable by

⁷⁸⁴ See [in Russian] Postanovlenie Glavnogo gosudarstvennogo vracha RF, *Sanitarnye pravila SP 1.1.2193-07: Organizatsiya i provedenie proizvodstvennogo kontrolya za soblyudeniem sanitarnykh pravil i vypolneniem sanitarno-epidemiologicheskikh (profilakticheskikh) meropriyatiy*, No.13, 27 March 2007.

⁷⁸⁵ See [in Russian] Postanovlenie Glavnogo gosudarstvennogo vracha RF, *Sanitarnye pravila SP 1.3.2518-09: Bezopasnost'raboty s mikroorganizmami III-IV grupp patogennosti (opasnosti) i vzbuditel'yami parazitarnykh boleznei*, No.42, 2 June 2009.

⁷⁸⁶ See [in Russian] Prikaz Ministerstva zdravookhraneniya i sotsial'nogo razvitiya RF, *Ob utverzhdenii Pravil laboratornoi praktiki*, No.708n, 23 August 2010, Moscow, published in *Rossiiskaya Gazeta*, No.5319, 22 October 2010, available at <http://www.rg.ru/2010/10/22/laboratornaya-praktika-dok.html> (accessed 9/09/2015).

⁷⁸⁷ See [in Russian] Postanovlenie Glavnogo gosudarstvennogo vracha RF, *Sanitarnye pravila SP 1.3.3118-13: Bezopasnost'raboty s mikroorganizmami I-II grupp patogennosti (opasnosti)*, No.64, 28 November 2013, available at http://rospotrebnadzor.ru/documents/details.php?ELEMENT_ID=3552 (accessed 9/09/2015). On the regulations related to work involving pathogens classified as Group I-II, see also [in Russian] *Metodicheskie ukazaniya MU 1.3.1794-03: Organizatsiya raboty pri issledovaniyakh metodom PTsR materiala, infitsirovannogo mikroorganizmami I-II grupp patogennosti*, 5 December 2003.

⁷⁸⁸ Author's translation from Russian into English. See [in Russian] *Ugolovnyi kodeks Rossiiskoi Federatsii: po sostoyaniyu na 20 oktobrya 2013 goda*, (Novosibirsk: Normatika, 2013).

modes of punishment including a fine up to 300 000 roubles or imprisonment of up to 5 years.

b. Biosecurity

Along with the USA and the UK, Russia (then the Soviet Union) is a co-depository of the 1975 BTWC. Having inherited the Soviet Union's membership in the 1925 Geneva Protocol, Russia withdrew its reservations in 2001. Russia signed and ratified the CWC in 1993 and 1997, respectively. In accordance with the provisions made by the UN Security Council Resolution 1540, Russia has been submitting regular national reports on the progress of the implementation of measures and policies aimed at preventing non-state actors from acquiring WMD. The principal state agency tasked with coordinating and monitoring the activities related to the fulfilment of Russia's international obligations domestically is the Ministry of Industry and Trade. In 2005, a Government Committee on Biological and Chemical Security was established to serve as a coordinating body in the process of implementation of biosecurity policy. The Committee is chaired by the Minister of Healthcare.⁷⁸⁹ Alongside, several other arms of the government are involved in executing the national biosecurity policy, including the Radiation, Chemical, and Biological Protection (RCBP) Troops of the Ministry of Defence (*Voiska radiatsionnoi, khimicheskoi i biologicheskoi zashtity*), the Ministry of Emergency Situations (*Ministertsvo po delam grazhdanskoi oborony, chrezvychainym situatsiyam i likvidatsii posledstvii stikhiinykh bedstvii: MChS*), Ministry of Federal Services (*Federal'naya sluzhba bezopasnosti: FSB*), Federal Medical and Biological Agency (*Federal'noe mediko-biologicheskoe aginstvo: FMBA*), and the Federal Service for Surveillance in Consumer Rights Protection and Welfare (*Federal'naya sluzhba po nadzoru v sfere zashtity prav potrebitelei i blagopoluchiya cheloveka: ROSPOTREBNADZOR*). Two additional inter-agency bodies also play a part in promoting measures for countering biological threats, namely the National Antiterrorist Committee (*Natsionalnyi antiterroristicheskii komitet*)

⁷⁸⁹ See [in Russian] Pravitel'stvennaya komissiya po voprosam biologicheskoi i khimicheskoi bezopasnosti, available at <http://government.ru/department/153/about/> (accessed 9/09/2015).

and the Coordinating Scientific Council for Sanitary and Epidemiological Protection (*Koordinatsionnyi nauchnyi sovet po sanitarno-epidemiologicheskoi okhrane*).

The international prohibition on the development, production, stockpiling, acquisition, and retention of biological weapons is enshrined in Russia's Criminal Code. Of particular relevance are the following Articles:

- Article 189: Illicit export of raw materials, equipment, technologies, scientific and technological data, and services that could facilitate the development of WMD, armament, and military equipment – punishable by modes of punishment, including imprisonment of up to 3 years;
- Article 205, (3): Bioterrorism – punishable by modes of punishment, including imprisonment of 15 to 20 years, or life imprisonment;
- Article 225, (2): Negligence in safeguarding materials that could be used for the development of WMD – punishable by modes of punishment, including financial sanctions and imprisonment of up to 7 years;
- Article 226, (2): Theft of WMD or any materials thereof that could facilitate their development – punishable by imprisonment of 5 to 10 years;
- Article 226¹: Smuggling of poisonous, toxic, and radioactive materials, ammunitions, explosive devices, and materials and equipment that could facilitate the development of WMD, their means of delivery, or other type of armament – punishable by modes of punishment, including imprisonment of 3 to 7 years and a fine of up to 1 million rouble;
- Article 355: Development, production, stockpiling, acquisition or retention of WMD – punishable by imprisonment of 5 to 10 years;
- Article 356, (2): Use of WMD, prohibited under international law – punishable by imprisonment of 10 to 20 years.

Effort has been dedicated to develop and enforce export control measures for preventing the proliferation, smuggling and illicit trafficking of biological

materials for hostile purposes. In 2004, the Federal Service Technical and Export Control of Russia (*Federal'naya sluzhba po tekhnicheskomu i eksportnomu kontrolju: FSTEK*) was established.⁷⁹⁰ The FSTEK is the federal executive authority implementing national policy, organizing interdepartmental coordination and interaction, and exercising special and control functions in the sphere of state security concerning export control, among other issues. Whilst not being a member of the Australia Group,⁷⁹¹ Russia has employed an export control list based on the Group's recommendations. A revised version of the list that took into account the provisions of the BTWC and UNSC Resolution 1540 was approved by a Presidential Decree in 2007.⁷⁹² Relevant mechanisms include:

- Federal Act as of 18 July 1999 No.183-FZ: 'On Export Control' – the Act defines the principles of state policy and the legal basis for the conduct of government agencies in the sphere of export control, as well as the rights, obligations, and responsibilities of participants in foreign economic activity;⁷⁹³
- Resolution of the Government of the Russian Federation as of 16 April 2001 No.294: 'On Approval of the Regulations of Conducting a State-Funded Expert Examination of Foreign Economic Transactions with Goods, Data, Works, Services and Results of Intellectual Activity (Rights to Such Results) over Which Export Control Is Exercised',⁷⁹⁴
- Resolution of the Government of the Russian Federation as of 7 June 2001 No.447: 'On Approval of the Resolution for Control of Foreign Economic Activities Concerning Dual-Use Goods and Technologies

⁷⁹⁰ See [in Russian] Ukaz Prezidenta RF, *Voprosy Federal'noi sluzhby po tekhnicheskomu i eksportnomu kontrolyu*, No.1085, 16 August 2004, available at <http://fstec.ru/obshchaya-informatsiya/polnomochiya/98-eksportnyj-kontrol/zakonodatelstvo/ukazy/321-ukaz-prezidenta-rossijskoj-federatsii-ot-16-avgusta-2004-g-n-1085> (accessed 10/09/2015).

⁷⁹¹ See [in Russian] *Biobezopasnost': strategicheskie aspekty*, (Moscow: IMEMO, 2007); 'The Australia Group at a Glance: Fact Sheets and Briefs', *Arms Control Association*, October 2012, available at <https://www.armscontrol.org/factsheets/australiagroup> (accessed 10/09/2015). For general information on the Australia Group activity, see <http://www.australiagroup.net/en/index.html> (accessed 10/09/2015).

⁷⁹² See [in Russian] Ukaz Prezidenta RF, *Ob utverzhenii Spiska mikroorganizmov, toksinov oburudovaniya i tekhnologii, podlezhashtikh eksportnomu kontrolyu*, No.1083, 20 August 2007, published in *Rossiiskaya Gazeta*, No.4449, 24 August 2007, available at <http://www.rg.ru/2007/08/24/export-spisok-dok.html> (accessed 9/09/2015).

⁷⁹³ See [in Russian] Federal'nyi zakon RF, *Ob eksportnom kontrole*, No.183-FZ, 18 July 1999, available at <http://fstec.ru/obshchaya-informatsiya/polnomochiya/96-eksportnyj-kontrol/zakonodatelstvo/zakony/309-federalnyj-zakon-rossijskoj-federatsii-ot-18-iyulya-1999-g-n-183-fz> (accessed 9/09/2015).

⁷⁹⁴ See [in Russian] Postanovlenie Pravitel'stva RF, *Ob utverzhenii Pravil provedeniya gosudarstvennoi ekspertizy vneshekonomiceskikh sdelok s tovarami, informatsiei, rabotami, uslugami i rezul'tatami intellektual'noi deyatel'nosti (pravimi na nikh)*, v *otnoshnii kotorykh ustanovlen eksportnyi kontrol'*, No.294, 16 April 2001.

That Can Be Used in the Development of Weapons and Military Equipment’;⁷⁹⁵

- Resolution of the Government of the Russian Federation as of 21 June 2001 No.477: ‘On the System of Independent Expert Examination for Identification of Goods and Technologies for Export Control Purposes’ (to be implemented along with the preceding Resolution);⁷⁹⁶
- Resolution of the Government of the Russian Federation as of 29 August 2001 No.634: ‘On Approval of the Resolution for Control of Foreign Economic Activities Concerning Microorganisms, Toxins, Facilities and Technologies’;⁷⁹⁷
- Presidential Decree No.580, 5 May 2004: ‘On Approval of the List of Commodities and Dual-Use Technologies That Are Subject to Export Control and Can Be Used for the Development of Weapons and Military Equipment’;⁷⁹⁸
- Resolution of the Government of the Russian Federation as of 15 August 2005 No.517: ‘On the Procedure of Obtaining a Permit of the Export Control Committee of the Russian Federation for Foreign Economic Transactions with Goods, Data, Works, Results of Intellectual Activity (Rights to Such Results) That Can Be Used by Foreign States or Foreign Individuals for the Purpose of Creation of WMD and Means of Their Delivery, Other Kinds of Weapons and Military Equipment, or Acquired on behalf of Organisations or Individuals Participating in Terrorist Activities’;⁷⁹⁹

⁷⁹⁵ See [in Russian] Postanovlenie Pravitel'stva RF, *Ob utverzhdenii Polozheniya ob osushestvlenii kontrolya za vneshneekonomicheskoi deyatel'nost'yu v otnoshenii tovarov i tekhnologii dvojnogo naznacheniya, kotorye mogut byt' ispol'zovany pri sozdanii vooruzhenii i voennoi tekhniki*, No.477, 7 June 2001, available at http://base.spinform.ru/show_doc.fwx?rgn=27487 (accessed 9/09/2015).

⁷⁹⁶ See [in Russian] Postanovlenie Pravitel'stva RF, *O sisteme nezavisimoi identifikatsionnoi ekspertizy tovarov i tekhnologii, provodimoi v tselyakh eksportnogo kontrolya*, No.477, 21 June 2001.

⁷⁹⁷ See [in Russian] Postanovlenie Pravitel'stva RF, *Ob utverzhdenii Polozheniya ob osushestvlenii kontrolyu vneshneekonomicheskoi deyatel' nost'yu v otnoshenii mikroorganizmov, toksinov, oborudovaniya i tekhnologii*, No.634, 29 August 2001.

⁷⁹⁸ See [in Russian] Ukaz Prezidenta, *Ob utverzhdenii Spiska tovarov i tekhnologii dvojnogo naznacheniya, kotorye mogut byt' ispol'zovany pri sozdanii vooruzhenii i voennoi tekhniki i v otnoshenii kotorykh osushestvlyayetsya eksportnyi kontrol'*, No.580, 5 May 2004, available at <http://kremlin.ru/events/president/news/30894> (accessed 9/09/2015).

⁷⁹⁹ See [in Russian] Postanovlenie Pravitel'stva RF, *O poryadke polucheniya razresheniya Komissii po eksportnomu kontrolyu Rossiiskoi Federatsii na osushestvlenie vneshneekonomicheskikh operatsii s tovarami, informatsiei, rabotami, uslugami i rezul'tatami intellektual'noi deyatel'nosti (pravimi na nikh), kotorye mogut byt' ispol'zovany inostrannym gosudarstvom ili inostrannym litsom v tselyakh sozdaniya oruzhiya massovogo porazheniya i sredstv ego dostavki, inykh vidov vooruzheniya i voennoi tekhniki libo priobretayutsya v interesakh organizatsii ili fizicheskikh lits, prichastnykh k terroristicheskoi deyatel'nosti*, No.517, 15 August 2005.

- Resolution of the Government of the Russian Federation as of 15 September 2008 No.691: 'On Approval of the Resolution for Licensing Foreign Economic Transactions with Goods, Data, Works, Services and Results of Intellectual Activity (Rights to Such Results) over Which Export Control Is Exercised'.⁸⁰⁰

c. Genetically Modified Organisms

Russia is a State Party to the Convention on Biodiversity but has joined neither its Cartagena Protocol on Biosafety (2000) pertinent to the handling, transfer, and use of living modified organisms (LMOs) resulting from modern biotechnology, nor its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (2010).⁸⁰¹ As noted above, accession to the Cartagena Protocol is among the goals listed in the revised version of the state's biological security policy.

Work involving genetic engineering techniques in Russia is regulated by a Federal Act titled 'State Regulation in the Field of Genetic Engineering Activities', which was adopted in 1996 and amended in 2010.⁸⁰² After joining the WTO, Russia has embarked on developing a detailed legal framework on the use of GMOs, such as crops and animals. In 2013, the Government approved Resolution No.839 on the 'State Registration of Genetically Engineered/Modified Organisms Intended for Release into the Environment and Products Derived from the Use of Such Organisms or Containing Such Organisms'.⁸⁰³ Thus, any GMOs released in the environment are subject to a registration process, including those used for the production of raw food, feed and feed additives for animals, as well as breeding and growing modified

⁸⁰⁰ See [in Russian] Postanovlenie Pravitel'stva RF, *Ob utverzhdenii Polozheniya o litsenzirovanii vneshneekonomicheskikh operatsii s tovarami, informatsiei, rabotami, uslugami i rezul'tatami intellektual'noi deyatel'nosti (pravimi na nikh), v otnoshnii kotorykh ustanovlen eksportnyi kontrol'*, No.691, 15 September 2008, published in *Rossiiskaya Gazeta*, No.4757, 24 September 2008, available at <http://www.rg.ru/2008/09/24/export-litsenzirovanie-dok.html> (accessed 9/09/2015).

⁸⁰¹ For information on the Russia's participation in the Convention on Biological Diversity, see <https://www.cbd.int/> (accessed 9/09/2015).

⁸⁰² See [in Russian] Federal'nyi zakon RF, *O gosudartsvennom regulirovanii v oblasti genno-inzhenernii deyatel'nosti (s izmeneniyami i dopolneniyami ot 12 yulya 2000, No.96-FZ), No.86-FZ*, 5 July 1996, published in *Rossiiskaya Gazeta*, 12 July 2000, available at <http://www.rg.ru/2000/07/12/gennoinzh-dok.html> (accessed 9/09/2015).

⁸⁰³ See [in Russian] Postanovlenie Pravitel'stva RF, *O gosudarsvennoi registratsii genno-inzhenerno-modifitsirovannykh organizmov, a takzhe produktsii, poluchЕННОi s ikh primeneniem*, No.839, 23 September 2013, available at <http://government.ru/docs/6128/> (accessed 9/09/2015).

plants, animals, and microorganisms for agricultural use in the territory of Russia.⁸⁰⁴ Several agencies have been tasked with the implementation and oversight of the new rules. GMOs used in drug development for medical purposes are to be registered by the Ministry of Health which also administers the register of all GMOs and GM products; GMOs used for manufacturing medical products are to be registered by ROSZDRAVNADZOR; GMOs used in food production and raw food materials are to be registered by ROSPOTREBNADZOR; and GMOs used in agriculture are to be registered by Rosselkhoznadzor. For a GMO or a GM product to be registered, they have to pass five types of assessment, namely molecular-genetic, medical-biological, sanitary-epidemiological, biosafety, and environmental. The assessment on the environmental impact of GMOs and GM products is carried out by the Federal Service for Surveillance on Natural Resources Management (*Federal'naya sluzhba po nadzoru v sfere prirodopol'zovaniya: ROSPRIRODNADZOR*). GMOs used in assessments and scientific research are not subject to registration, as long as they are handled in accordance with the established sanitary and laboratory biosafety rules and procedures. Products obtained through the combination, treatment, or processing of already registered GMOs and GM products are not subject to registration provided that their genetic material has not been altered.

In April 2015, it was reported that the State Duma had approved at first reading a bill on the ban of cultivation and breeding of GM crops and animals within the borders of the Russian Federation.⁸⁰⁵ The bill excludes GMOs utilised for the purpose of conducting assessment and scientific research. The use of plant seeds obtained through genetic engineering techniques is also prohibited under the bill. It further stipulates that all imported GMOs and GM products are to be subject to registration and that the Government preserves the right to forbid the import of such products on the grounds of health and environmental safety. The envisaged liability for non-compliance with the bill takes the form of a fine of up to 500 000 roubles. The new bill

⁸⁰⁴ See Peter Roudik, *Restrictions on Genetically Modified Organisms: Russian Federation*, Legal Report for the Library of Congress, March 2014, available at <http://www.loc.gov/law/help/restrictions-on-gmos/russia.php> (accessed 9/09/2015).

⁸⁰⁵ See [in Russian] 'GD prinyala v I chtenii zakonoproekt o zaprete razvedeniya GMO v Rossii', *RIA Novosti*, 24 April 2015, available at <http://ria.ru/science/20150424/1060718919.html> (accessed 10/09/2015).

stands in stark contrast with the policy line that Russia has followed so far and in particular, with the measures taken after the country joined the WTO. Whilst at the time of writing, the bill remains under consideration by the Duma and little information has been revealed regarding the motivations and rationale that underpin it, it is possible to speculate that the radical regulatory change could be a reaction to the sanctions enforced against Russia by the EU and US in light of the crisis in Eastern Ukraine.

In accordance with the UN Declaration on Human Cloning adopted in 2005,⁸⁰⁶ Russia has amended its 2002 Act on the 'Temporary Ban of Human Cloning' which introduced a five-year moratorium on activities involving human cloning.⁸⁰⁷ The revised legal text passed in 2010 extended the moratorium for an indefinite period of time until law specifying the conditions and criteria for the application of cloning technologies for the purposes of human cloning is approved.⁸⁰⁸

d. Intellectual Property

Russia joined the World Intellectual Property Organisation in 1970 and has ratified most of the treaties it administers, including the Paris Convention (1965), the Budapest Treaty (1981), the UPOV convention (1998), the Patent Law Treaty (2009), and the World Intellectual Property Organization (WIPO) Copyright Treaty (2009).⁸⁰⁹ In 2012, Russia acceded to the WTO, fully committing itself to further strengthening its legal framework for the protection of intellectual property in accordance with the provisions of the TRIPS Agreement.⁸¹⁰

⁸⁰⁶ See United Nations General Assembly, *United Nations Declaration on Human Cloning*, A/RES/59/280, 23 March 2005, New York, available at <http://www.nrlc.org/uploads/international/UN-GADeclarationHumanCloning.pdf> (accessed 10/09/2015).

⁸⁰⁷ See [in Russian] Federal'nyi zakon RF, *O vremennom zaprete na klonirovanie cheloveka*, No.54-FZ, 20 May 2002, published in *Rossiiskaya Gazeta*, No.2958, 23 May 2002, available at <http://www.rg.ru/2002/05/20/klonirovanie-dok.html> (accessed 10/09/2015).

⁸⁰⁸ See [in Russian] Federal'nyi zakon RF, *O vnesenii izmeneniya v chatstyu 1 Federal'nogo zakona 'O vremennom zaprete na klonirovanie cheloveka'*, No.30-FZ, 29 March 2010, published in *Rossiiskaya Gazeta*, No.5145, 31 March 2010, available at <http://www.rg.ru/2010/03/31/klon-dok.html> (accessed 10/09/2015).

⁸⁰⁹ For a detailed record of Russia's participation in the WIPO-administered international agreements on the protection of intellectual property, see http://www.wipo.int/treaties/en/ShowResults.jsp?country_id=147C (accessed 10/09/2015).

⁸¹⁰ See Maxim Voltchenko and Tatiana Petrova, 'Russia: As Russia Joins the WTO, It Streamlines Official Fees and Is Expected to Improve IP Protection', *INTA Bulletin*, vol.67:15, 1 September 2012, available at <http://www.inta.org/INTABulletin/Pages/RUSSIAAsRussiaJoinstheWTO,ItStreamlinesOfficialFeesandIsExpectedto>

The existing legal base for intellectual property protection in Russia features several components, among which the Constitution, the Civil Code, the Patent Law, and subject-specific laws, such as those related to trademarks, copyrights, and information storage and protection.⁸¹¹ In 1992, shortly after the dissolution of the Soviet Union, Russia adopted a Patent Act which stipulated that the ownership rights of intellectual property (IP) accrued as a result of government-funded activity were to be assigned to the institutions in which that activity was conducted. The Act further specified that IP rights could only be assigned to legal entities such as research institutes, industrial enterprises, and commercial companies. By contrast, as far as military-oriented and dual-use R&D was concerned, all IP belonged exclusively to the state. Throughout the 1990s the legal framework for IP protection underwent significant revision in an attempt to accommodate the various conundrums raised by the consequences of privatisation. Thus, in 2003 the existing Patent Act was replaced with a new one, which set clear rules on how IP was to be assigned. Under the provisions of the new Act, the state can apply for a patent for discoveries made as part of a government contract. In all other cases, the organisation where the discovery has been made holds the right to apply for a patent. Two additional legal documents are of particular relevance with regard to IP protection. One is Government Resolution No 685 of 17 November 2005, 'On the Distribution of Rights to Results of R&D' which further confirmed the IP rights of organisations for discoveries made at state expense.⁸¹² The other is Federal Act No 217 of 2 August 2009, which allows for the commercialisation of government-funded research carried out

mprovelPPProtection.aspx (accessed 10/09/2015). For information on the TRIPS Agreement, see https://www.wto.org/english/tratop_e/trips_e/trips_e.htm (accessed 10/09/2015).

⁸¹¹ Irina Dezhina and Renaud Bellais, *The Russian National System of Innovation in Transition: Defence Legacy, Market Orientation and Emerging Challenges*, June 2004, CHEAR, Paris, France, p.5. See also [in Russian] Irina Dezhina, *Problemy prav na intellektual'nyu sobstvenost'*, Nauchnye trudy No.56-R, (Moscow: IEPP, 2003); A. Bendikov i Yu. Khrustalev, 'Intellektual'naya sobstvenost' v Rossii: problemy ispol'zovaniya i pravovoi zashchity', *Menedzhment v Rossii i za rubezhom*, No.3 (2001), available at <http://www.bizeducation.ru/library/management/innov/hrustalev.htm> (accessed 10/09/2015); L.Samatova, 'Problemy gosudarstvennogo regulirovaniya intellektual'noi sobstvennosti v usloviyakh innovatsionnogo razvitiya ekonomiki', *Aktual'nye problemy ekonomiki i prava*, No.3 (2011), pp.34-36; Irina Dezhina, *Gosudarstvennoe regulirovanie nauki v Rossii*, (Moscow: Magistr, 2008).

⁸¹² See [in Russian] Postanovlenie Pravitel'stva RF, *O poryadke rasporyazheniya pravami na nauchno-tekhnicheskoi deyatel'nosti*, No.685, 17 November 2005, published in *Rossiiskaya Gazeta*, No.3935, 25 November 2005, available at <http://www.rg.ru/2005/11/25/prava-dok.html> (accessed 10/09/2015). See also Loren Graham, *Lonely Ideas: Can Russia Compete?*, (Cambridge, MA: MIT Press, 2013).

in educational and research institutions with IP rights being retained by the institutions where the research has been performed.⁸¹³

Innovation Lift and Public-Private Partnerships

A range of initiatives has been launched to stimulate business investment and encourage active participation of the private sector in Russia's biotechnology. Between 2011 and 2013 an 'innovation lift' – a system of state institutions that support innovative projects at various stages of their development from inception to expansion and restructuring – came into operation.⁸¹⁴ It comprises a broad spectrum of components including open joint-stock companies (OJSC) such as the 'Russian Venture Company'⁸¹⁵ and Rosnano;⁸¹⁶ foundations such as Skolkovo Foundation,⁸¹⁷ the Fund for Assistance to Small Innovative Enterprises (*Fond sodeistvia razvitiu malykh form predpriatii v nauchno-tekhnicheskoi sfere*),⁸¹⁸ the Fund for Industrial Development (*Fond Razvitiya Promyshlenosti: FRP*), formerly RFTR;⁸¹⁹ and non-governmental organisations (NGOs) such as 'Russia's Support' (OPORA Rossii)⁸²⁰ and the Russian Venture Capital Association (*Rossiiskaya assotsiatsiya venchurnogo investirovaniya*).⁸²¹ Particularly active in the area

⁸¹³ See [in Russian] Federal'nyi zakon RF, *O vnesenii izmenenii v otdel'nye zakonodatel'nye akty Rossiiskoi Federatsii po voprosam sozdaniya byudzhetnymi nauchnymi i obrazovatel'nymi uchrezhdeniyami khozyaistvennykh obstestv v tselyakh prakticheskogo primeneniya (vnedreniya) rezul'tatov intellektual'noi deyal'nosti*, No.217-FZ, 2 August 2009, published in *Rossiiskaya Gazeta*, No.4966, 4 August 2009, available at <http://www.rg.ru/2009/08/04/int-dok.html> (accessed 10/09/2015). See also Loren Graham, *Lonely Ideas: Can Russia Compete?*, (Cambridge, MA: MIT Press, 2013).

⁸¹⁴ See Organisation for Economic Co-Operation and Development, *OECD Economic Surveys: Russian Federation 2013*, (OECD Publishing, 2014).

⁸¹⁵ For further information on the objectives and activities of the Russian Venture Company (*Rossiiskaya venchurnaya kompaniya*), see <http://www.rusventure.ru/en/company/brief/> (accessed 9/09/2015).

⁸¹⁶ For further information on the objectives, structure, and activities of Rosnano, see <http://www.rusnano.com/about/structure> (accessed 9/09/2015).

⁸¹⁷ For further information on the Skolkovo Foundation, see <https://sk.ru/foundation/about/> (accessed 9/09/2015). For analysis of Rosnano and Skolkovo, see Loren Graham, *Lonely Ideas: Can Russia Compete?*, (Cambridge, MA: MIT Press, 2013); Quirin Schiermeier, 'High Hopes for Russia's Nanotech Firms', *Nature*, vol.461 (2009), pp.1036-1037; Mark Rice-Oxley, 'Inside Skolkovo, Moscow's Self-Styled Silicon Valley', *Guardian*, 12 June 2015, available at <http://www.theguardian.com/cities/2015/jun/12/inside-skolkovo-moscows-self-styled-silicon-valley> (accessed 11/09/2015).

⁸¹⁸ For information on the Fund for Assistance to Small Innovative Enterprises, see [in Russian] <http://www.fasie.ru/> (accessed 9/09/2015).

⁸¹⁹ For further information on the activity of the Fund for Industrial Development, see <http://www.rftr.ru/> (accessed 9/09/2015). For analysis of the activity of Russian Foundations and Funds, see Loren Graham, *Lonely Ideas: Can Russia Compete?*, (Cambridge, MA: MIT Press, 2013).

⁸²⁰ For further information on the activity of OPORA Rossii, see [in Russian] <http://opora.ru/about/world> (accessed 9/09/2015). See also [in Russian] Frost and Sullivan, *Obzor rynka biotekhnologii v Rossii i otsenka perspektiv ego razvitiya, op cit.*

⁸²¹ For further information on the activity of the Russian Venture Capital Association, see <http://www.rvca.ru/eng/> (accessed 9/09/2015). See also [in Russian] Frost and Sullivan, *Obzor rynka biotekhnologii v Rossii i otsenka perspektiv ego razvitiya, op cit.* On the role of clusters in promoting science, see [in Russian] Vladimir Knyagin, 'Klasternyi put' k novoi ekonomike', *Polit.Ru*, 19 November 2012, available at <http://polit.ru/article/2012/11/19/cluster/> (accessed 10/09/2015); 'Territorii budeshtego: kak rabotayut innovatsionnye

of biotechnology is the Skolkovo Biomedical Cluster which not only provides companies with financial support in the form of grants but also offers them simplified customs procedures, professional mentor support, and discussion space. Similarly, Rosnano MedInvest, a subsidiary of Rosnano, and the Russian Venture Company have turned investing in biotechnology innovation into one of their chief priorities.

An example of the growing role of public-private partnerships as a vehicle for the development of an innovation-based economy is the introduction of Technology Platforms (*Tekhnologicheskie platformy*) patterned on those functioning in the EU. Yet unlike the EU technology platforms which tend to be bottom-up endeavours supported by private capital, the Russian ones are largely reliant upon the state as their primary source of funding. By design, technology platforms are communication tools directed at stimulating the development of novel commercially-viable technologies and products; attracting additional resources for R&D on the basis of a multi-stakeholder engagement featuring industry, science, civil society, and the state; and improving the normative and legal framework for the development of science, technology, and innovation.⁸²² Efforts to establish technology platforms in Russia commenced in 2010 when the Government Commission on High Technology and Innovation issued 'Order on the Formation of the List of Technology Platforms' (*Poryadok formirovaniya perechnya tekhnologicheskikh platform*).⁸²³ According to this document, technology platforms constitute a 'public-private partnership mechanism' and an 'important instrument of state science, technology, and innovation policy'. As

klastery v Rossii', *Russian Venture Chronicle*, No.2 (2014), pp.22-31, available at http://www.rusventure.ru/ru/newsletter/RussianVentureChronicle_October2014.pdf (accessed 10/09/2015); Anton Didikin, *Pravovoe regulirovanie innovatsionnoy deyatel'nosti v Rossii*, op cit.

⁸²² See [in Russian] Irina Dezhina, *Tekhnologicheskie platformy i innovatsionnye klastery: vmeste ili porozn'?*, Nauchnye trudy No.164, (Moscow: Gaidar Institute, 2013); Irina Dezhina, 'Technology Platforms in Russia: A Catalyst for Connecting Government, Science, and Business?', *Triple Helix*, vol.1:6 (2014), available at <http://link.springer.com/article/10.1186%2Fs40604-014-0006-x> (accessed 9/09/2015); Olga Zlyvko et al. 'Analysis of the Concept of Industrial Technology Platform Development in Russia and the EU', *International Economics Letters*, vol. 3:4 (2014), p.125-140.

⁸²³ See [in Russian] Pravitel'stvennaya komissiya po vysokim tekhnologiyami i innovatsiyam, *Poryadok formirovaniya perechnya tekhnologicheskikh platform*, Protocol No.4, 3 August 2010, available at http://economy.gov.ru/minec/activity/sections/innovations/formation/doc03082010_05 (accessed 9/09/2015). See also [in Russian] Pravitel'stvennaya komissiya po vysokim tekhnologiyami i innovatsiyam, *Perechen' tekhnologicheskikh platform*, Protocol No.2, 21 February 2012, available at http://economy.gov.ru/minec/activity/sections/innovations/formation/doc20120403_11 (accessed 9/09/2015).

such, they provide a number of incentives for businesses and enterprises, such as:

- Granting access to new resources for R&D;
- Helping define priority directions for the country's economic development;
- Assisting in the development of new technology regulations and standardisation;
- Optimising business planning (since member companies include both producers and consumers of new technologies);
- Offering option for more effective use of resources via outsourcing;
- Developing international cooperation.⁸²⁴

Three technology platforms have been set up in the area of biotechnology, namely 'Medicine of the Future' (*Meditsina budeshogo*), 'Bioindustry and Bioresources – BioTech 2030' (*Bioindustriya i bioresursy – BioTekh 2030*), and 'Bioenergy' (*Bioenergetika*). Among the nearly 400 participants in 'Medicine of the Future', there are 164 manufacturing plants, 114 academic institutions and 75 higher professional education institutions. The platform's overall strategic goal is the creation of an area of medicine of the future, based on a set of "breakthrough" technologies, which determine the prospects of emerging high-technology products and service markets, as well as the extensive use of advanced technologies in the medical and pharmaceutical industries. To this end, the platform seeks to promote networking and effective interaction between stakeholders in the medical and pharmaceutical sectors, including business, science, and the government; to develop long-term research, innovation, and production strategic programs in the field of medicine; to concentrate intellectual, financial and administrative efforts to develop new commercial products and services competitive both on the domestic and international market; to optimise the regulation of research and innovation activities, standardise technology regulations and procedures,

⁸²⁴ Irina Dezhina, 'Technology Platforms in Russia: A Catalyst for Connecting Government, Science, and Business?', *Triple Helix*, vol.1:6 (2014), p.2, available at <http://link.springer.com/article/10.1186%2Fs40604-014-0006-x> (accessed 9/09/2015).

and amend customs regulations in the field of biomedicine to accelerate the introduction of new products onto the market; to modernise healthcare and education by creating conditions for the utilisation of novel products and services; and to identify new areas of breakthrough technologies with application in medicine in order to reduce mortality and morbidity, increase the duration and quality of life, and provide population growth of Russia.⁸²⁵ The activity of the platform is jointly financed through several State and Federal Target Programmes, RFFI, and state corporations, such as RosNano and RosTechnologies.⁸²⁶

'Bioindustry and Bioresources – Biotech 2030' has a total of 99 participants featuring 46 businesses, 25 research institutes and 26 higher education teaching institutions. Among its funding sources the RFFI, RNF, Russian Venture Company, and Innovation Centre 'Skolkovo'. The platform's overarching objective is creating a modern bioindustry amounting to at least 3% of Russia's GDP. To accomplish this goal, the platform works in the following directions:

- Preparation of a concept for the development of Russia's bioindustry and bioresources base;
- Creation of new and further enhancement of already existing markets;
- Application of biotechnology in various sectors of the economy;
- International collaboration with similar foreign-based entities; and
- Education improvement and staff development in the area of biotechnology;

As far as technology development is concerned, the platform is dedicated to promoting the use of renewable sources of biomass to achieve sustainable industrial production and power supply with little negative impact on the

⁸²⁵ For further information on the Platform, 'Medicine of the Future', see [in Russian] <http://tp-medfuture.ru/aboutus/> (accessed 10/09/2015). For a detailed discussion of the three existing technological platforms in Russia, see Irina Dezhina, *Tekhnologicheskie platformy i innovatsionnye klasteri: vmeste ili porozn'?*, op cit. See also [in Russian] Irina Dezhina, 'Sostoyanie sfery nauki i innovatsii' in S. Sinel'nikov-Murylev et al. (ed.), *Rossiiskaya ekonomika v 2011 godu: Tendentsii i perspektivy*, (Moscow: Gaidar Institute, 2012), pp.375-410.

⁸²⁶ See Irina Kurzina, 'The Role of the Technology Platform 'Medicine of the Future' in Biomedical Innovations Development', 21 May 2014, Moscow, available at http://tp-medfuture.ru/wp-content/uploads/kurzina_i.pdf (accessed 10/09/2015).

environment. Priority areas of activity include biotechnology means of recycling renewable raw materials; use of renewable biomass as a raw base for the chemical and heavy industry; genomic and post-genomic, gene engineering and cell technologies for the development of new products (e.g. bioreagents, biomaterials, biofuels) and bioprocesses; biotechnology means of developing new food products; biotechnology means of more efficient mining; biotechnology means of recycling and waste management in agriculture; and agrobiotechnology.⁸²⁷

With a total number of 68 participants, technology platform 'Bioenergy' brings together state agencies, commercial companies, education and research institutions, and civil society representatives. Those include 23 businesses, 18 research institutes, 11 universities and 16 NGOs. The principal task of the platform is the consolidation of Russia's scientific, professional, business, and expert communities, and its institutional and resource potential for the effective development of bioenergy. Its priority R&D areas of activity entail generation of heat and electrical energy from biomass; production of biogas through organic waste processing; production of biofuels, such as biodiesel, bioalcohol, biogasoline, and biokerosin; peat bioenergy; active development and implementation of modern bioenergy technologies in all branches of the economy; ensuring sustainable development on the basis of bioeconomy and bioenergy; and export of Russia's bioenergy potential in the form of pellets, liquid biofuel, and biomethane.⁸²⁸

Life Science Budget

As part of its basic research programme covering all fields of science, Russia is expected to spend 834 billion roubles (13 billion US dollars) over the period until 2020.⁸²⁹ Yet the government expenditure on life science research in

⁸²⁷ For further information on the Platform, 'Bioindustry and Bioresources', see [in Russian] <http://biotech2030.ru/platforma/o-nas/> (accessed 10/09/2015). An English summary is available at <http://biotech2030.ru/about-us/> (accessed 10/09/2015).

⁸²⁸ For further information on the Platform, 'Bioenergy', see [in Russian] <http://www.tp-bioenergy.ru/> (accessed 10/09/2015). An English summary is available at <http://www.tp-bioenergy.ru/en/> (accessed 10/09/2015).

⁸²⁹ See Quirin Schiermeier, 'Russian Science Minister Explains Radical Restructure', *Nature*, 25 January 2015, available at <http://www.nature.com/news/russian-science-minister-explains-radical-restructure-1.16776> (accessed 20/05/15). For an overview of the Russian science funding policy, see [in Russian] Irina Dezhina, *Mekhanizmy gosudarstvennogo finansirovaniya nauki v Rossii, op cit*; Irina Dezhina, *Gosudarstvennoe regulirovanie nauki v Rossii*, (Moscow: Magistr, 2008); Evgenii Onishchenko, 'Byudzhet na nauku – 2015', *Troitskii variant*, No.164, 7

Russia remains low in comparison to other industrialised states, amounting to about 0.04 billion dollars annually.⁸³⁰ Moreover, the share of funding that Russia allocates to medical research is also much smaller. The primary sources of public financial support for life science research feature the RFFI, RNF, the RAN, and the Foundation for Advanced Research (*Fond perspektivnykh issledovaniy: FPI*).

Set up in 1992, RFFI is the oldest state foundation that provides funding for basic research in a range of fields, including biology and medical sciences. Its budget has been steadily increasing over the years reaching 9245 688.1 billion roubles in 2014.⁸³¹ 21 per cent of the money available in 2014 was spent on biology- and medicine-oriented projects, which was 6 per cent more than the share dedicated to physics and astronomy, and 8 per cent more than the share dedicated to chemistry.

The RNF was established in 2013 for the purpose of supporting basic research and staff development in virtually all areas of science. Among the main priorities of the Foundation is support for young scientists and post-doctoral researchers. The Foundation's expected budget for the period 2014-2016 is reported to be 47 billion roubles.⁸³²

In December 2014 the Presidium of RAN published a 'List of Priority Areas in Basic Research for 2015'.⁸³³ Life science research is covered in several categories, among which are:

- Nanostructures (physics, chemistry, biology, basic engineering) with an allocated budget of 140 million roubles;

October 2014, p.10-11, available at <http://trv-science.ru/2014/10/07/byudzheth-na-nauku-2015/> (accessed 11/09/2015).

⁸³⁰ See Roger Roffey, *Biotechnology in Russia: Why Is not a Success Story?*, *op cit*. See also [in Russian] Dmitrii Popov, 'Tol'ko 0.3% biotekhnologicheskikh startapov dokhodyat do rynka', *Russian Venture Chronicle*, No.2 (2014), pp.38-39, available at http://www.rusventure.ru/ru/newsletter/RussianVentureChronicle_October2014.pdf (accessed 10/09/2015).

⁸³¹ For an overview of the funding trends of the Russian Foundation for Basic Research, see [in Russian] <http://www.rfbr.ru/rffi/ru/funding> (accessed 10/09/2015).

⁸³² See [in Russian] 'Byudzheth Rossiskogo nauchnogo fonda na 3 goda sostavit 47 mrdld rub', *RIA Novosti*, 11 February 2014, available at <http://ria.ru/science/20140211/994340988.html> (accessed 10/09/2015).

⁸³³ See [in Russian] Postanovlenie Prezidiuma RAN, *Ob utverzhdenii Perechnya programm fundamental'nykh issledovaniy RAN po prioritentnym napravleniyam, opredelyaemyh RAN na 2015 god*, No.176, 23 December 2014, available at <http://www.ras.ru/presidium/documents/directions.aspx?ID=1080b82a-a4cb-48ad-8b41-a9615921e34a> (accessed 10/09/2015).

- Molecular and cell biology with an allocated budget of 170 million roubles;
- Mechanisms for integrating molecular systems in physiological processes with an allocated budget of 20 million roubles;
- Biodiversity in ecological systems with an allocated budget of 45 million roubles;
- Basic research for medical technology with an allocated budget of 200 million roubles.

The Biology Department of the Academy is further expected to receive 21 million roubles and the two former academies – RAMN and RASKhN – have an allocated budget of 100 million roubles each.

The FPI was founded in 2012. The federal act on the basis of which the FPI came into being followed a presidential decree urging the Government to promote and ensure the development of advanced high-risk and basic research, and applied research for the purposes of national security and state defence.⁸³⁴ As far as the life sciences are concerned, the Foundation finances projects in bionics, advanced medicine, and integrated biosystems. The estimated budget of FPI for 2015 and 2016 is reportedly 3.3 billion and 3.5 billion roubles, respectively.⁸³⁵

Life Science Professional Practice

The Russian science system remains divided along the lines of teaching and research. Universities and professional higher education schools are still predominantly seen as teaching institutions offering theoretical grounding in various disciplines. At the same time, research institutes have managed to

⁸³⁴ See [in Russian] Ukaz Prezidenta RF, *O realizatsii planov (programm) stroitel'stva i razvitiya Vooruzhenykh Sil Rossiiskoi Federatsii, drugikh voisk, voinskih formirovaniy i organov i modernizatsii oboronno-promyshlennogo kompleksa*, No.603, 7 May 2012, available at http://fpi.gov.ru/activities/documents/ukaz_prezidenta_rf_ot_7_maya_2012_g_n_603_o_realizatsii_planov_programm_stroitelstva_i_razvitiya_booruzhennykh_sil_rossiyskoy_federatsii_drugih_voysk_voinskih_formirovaniy_i_organov_i_modernizatsii_oboronno_promyshlennogo_kompleksa (accessed 10/09/2015).

⁸³⁵ See [in Russian] 'Byudzhet Rossiskogo nauchnogo fonda na 3 goda sostavit 47 mrd rub', *op cit.* On the negative impact of current financial crisis in Russia following the Western sanctions on the FPI's estimated budget, see [in Russian] 'Byudzhet 'kuznitsy innovatsii' VS Rossii iz-za krizisa sokreshten na 10%', *RIA Novosti*, 8 June 2015, available at <http://ria.ru/science/20150608/1068780073.html> (accessed 10/09/2015). For analysis of the broader impact of the sanction on Russian science, see [in Russian] Irina Dezhina, 'Sostoyanie nauki i innovatsii' in B. Mau et al. (ed.), *Rossiiskaya ekonomika v 2014 godu: Tendentsii i perspektivy*, (Moscow: Gaidar Institute, 2015).

preserve their image of bastions of knowledge production and experimental work. Thus, the concept of a research university virtually ubiquitous in the Anglo-Saxon world remains underdeveloped in Russia, even though some effort has been made to bring research institutes and universities closer. A case in point is the collaboration between Moscow State University (MGU) and the science-city of Pushchino.⁸³⁶ In 2013 MGU launched at its newly-established Faculty Biotechnology an integrated Master's degree in Biotechnology which combines theoretical and practical aspects of life science research. The overall duration of the programme is 6 years, in which the first 3 years of study entail lecture-based instruction at MGU with the final Bachelor's and both Master's years to be practically-oriented and carried out at Pushchino. A similar pattern of operation is observed at Novosibirsk State University (NGU) situated in Akademgarodok (Academy City) near Novosibirsk, which maintains close ties with the scientific complex of Koltsovo. For instance, in October 2015 Kolstovo Innovation Centre, an independent non-profit entity, is organising an international conference, OpenBio, designed to bring together and facilitate dialogue and cooperation among young scientists, science students, and representatives of business and funding institutions.⁸³⁷

Universities offer three types of degrees, namely Bachelor's, Master's, and Candidate of Science, which is roughly the equivalent of a PhD. Most Russian universities do not have life science faculties or departments as such but instead teach relevant courses within their schools of biology or medicine. Alongside, specialised universities such as First Moscow State Medical University (I.M. Sechenov Moscow Medical Academy), Moscow State Academy of Veterinary Medicine and Biotechnology, and Russian State Agrarian University deliver advanced professional training in life science-related disciplines. Yet it has been reported that despite the abundance of

⁸³⁶ Further information on the programme [in Russian] is available at <http://www.msu.ru/info/struct/dep/biotech.html> (accessed 10/09/2015). On the early reforms in higher education in Russia, see Irina Dezhina and Loren Graham, 'Science and Higher Education in Russia', *Science*, vol.286:5443 (1999), pp. 1303-1304. For an overview of the tendencies in science education in Russia, see [in Russian] Irina Dezhina and Viktoriya Kiseleva, *Tendentsii razvitiya nauchnykh shkol v sovremennoi Rossii*, Nauchnye trudy No.124R, (Moscow: IEPP, 2009); Irina Dezhina and Aleksei Ponomarev, '1000 laboratorii: Novye printsipy organisatsii nauchnoi raboty v Rossii', *Voprosy ekonomiki*, No.3 (2013), pp.70-82;

⁸³⁷ Further information about the event is available at <http://openbio.ru/> (accessed 10/09/2015). The page also contains information about the conference held in 2014.

courses and education programmes, the number of life science graduates trained to work in biotechnology laboratories remains low.⁸³⁸ This in turn puts an extra strain on industries as they have to spend additional time and resources on re-training their new employees. The need for a radical education reform and restructuring of the existing life science curricula is therefore evident. Moreover, there seems to be growing appreciation among universities that changes are all but inevitable. The introduction of the integrated Master's programme by MGU could be seen as a reaction to this recognition. Other universities have also joined the effort to help improve higher life science education and develop new standards and programmes. The participation of four Russian universities (Russian University of Chemical Technology, Kazan National Research Technological University, Moscow State University, and Novosibirsk State University) and two research institutes (RAN Institute of Molecular Genetics and RAN Institute of Microbiology) in the EU-funded project 'Reforming Higher Education in Biotechnology: Development and Improvement of Standards and Academic Curricula for Bachelor's and Master's Programmes' is indicative in this regard. Since 2011 NGU has also been involved in a collaborative project with Heilongjiang University at Harbin, China as a result of which a Chinese-Russian Institute has been established.⁸³⁹ The Institute administers joint Bachelor's and Master's programmes in six areas, including biology. Several universities have also been involved in the development of biosafety curricula, including NGU, I.M Sechenov Moscow Medical Academy, and Pushchino State University.⁸⁴⁰

Research institutes focus primarily on the practical aspects of life science practice. Teaching is limited and generally only research degrees such as Candidate of Science and Doctor of Science can be pursued there. Virtually all laboratories conducting studies involving pathogenic microorganisms are hosted within research institutes and all professionals with access to such

⁸³⁸ See [in Russian] Frost and Sullivan, *Obzor rynka biotekhnologii v Rossii i otsenka perspektiv ego razvitiya, op cit*, p.21.

⁸³⁹ Further information on joint programme is available [in Russian] at <http://fen.nsu.ru/fen.phtml?topic=ruchi> (accessed 10/09/2015).

⁸⁴⁰ Sergey Netesov, 'Russian Biosafety Experience during the Last Two Decades: Lessons and Achievements', a Paper presented at International Workshop, *Anticipating Biosecurity Challenges of the Global Expansion of High Containment Biological Laboratories*, 11-13 July 2011, Istanbul, Turkey, available at http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_065001.pdf (accessed 3/02/2016).

microorganisms are required to undergo appropriate laboratory biosafety training in accordance with the sanitary regulations.⁸⁴¹ The number of high-containment laboratories, BSL-3 and BSL-4, is limited.⁸⁴² Only in those facilities is work on highly dangerous pathogens from Group I and II allowed. Examples of institutes housing high-containment laboratories include the research facilities under the Ministry of Defence, with one located in Kirov, one in Sergiev Posad, and one in Yekaterinburg. Two entities – the State Research Centre of Applied Microbiology and Biotechnology at Obolensk, and the State Research Centre for Virology and Biotechnology ‘VECTOR’ at Koltsovo, the latter hosting the only BSL-4 laboratory on the territory of Russia – are under the auspices of ROSPOTREBNADZOR. The AP Service of ROSPOTREBNADZOR supervises the high-containment facilities situated at the five AP Institutes at Saratov (‘Microbe’), Irkutsk, Rostov, Stavropol, and Volgograd, the eleven regional AP Stations – Altay, Astrakhan, Chita, Dagestan, Elista, Kabardino-Balkaria, Khabarovsk, North-Western, Primorsky, Prichernomrsky and Tuva – and one mobile unit used during the Ebola outbreak in West Africa. The Ministry of Agriculture is in charge of three institutes with high-containment laboratories, namely the Federal Centre for Animal Health in Vladimir region, the National Research Institute of Veterinary, Virology, and Microbiology at Pokrov, and the Inter-Regional Veterinary Laboratory at Bryansk.

All research institutes with a high-containment laboratory on their premises are legally required to have their staff properly trained in laboratory biosafety with a focus on the safety procedures for handling, storage, and transfer of highly pathogenic microorganisms listed in Group I and II.⁸⁴³ The requirement for ensuring appropriate training extends to research staff, as well as to engineering, maintenance, and cleaning personnel.⁸⁴⁴ Temporary engineering and technical personnel has to obtain explicit authorisation by

⁸⁴¹ See Evgeniy Stavskiy et al, ‘Comparative Analysis of Biosafety Guidelines of the USA, WHO, and Russia (Organizational and Controlling, Medical and Sanitary – Antiepidemiological Aspects), *Applied Biosafety*, vol.8:3 (2003), pp.118-127; [in Russian] Ye. Kondrik et al. *Analiticheskoe obosnovanie kontseptsii biologicheskoi bezopasnosti*, (Obolensk: GNTs PM, 2003).

⁸⁴² See Tatyana Elleman, ‘Russian Federation’, *op cit*, p.198-199. For a detailed information on the research facilities within the framework of ROSPOTREBNADZOR, see N. Kalinina, *Mezhdunarodnye i natsional’nye problemy biologicheskoi bezopasnosti i perspektivy ikh resheniya*, *op cit*, p.264-269.

⁸⁴³ Interview, 15 April 2014, Moscow, Russia.

⁸⁴⁴ Evgeniy Stavskiy et al. ‘Comparative Analysis of Biosafety Guidelines of the USA, WHO, and Russia’, *op cit*, p.123.

the institute director, in order to be allowed in the facility. Such personnel can only perform their duties after all routine work has ceased and the premises have been disinfected. They have to be accompanied by an institute employee at all time. Details of visits (e.g. names and personal data of visitors, purpose of visit) of any kind to the facility are recorded in a designated registry.

Some institutes, including the AP Institutes, the Centre for Applied Microbiology at Obolensk, and 'Vector' are licensed to deliver accredited specialised training and retraining courses in this area.⁸⁴⁵ The programmes are practically-oriented and aim to equip professionals with the skills and knowledge necessary to ensure that work involving dangerous pathogens is carried out safely and in line with the existing rules and procedures. Case studies and problem-solving exercises are commonly used to enhance individuals' understanding of biosafety and facilitate the application of theoretical knowledge into practice.⁸⁴⁶ A pre- and post-assessment system for evaluating trainees' level of competence is in place. Alongside with face-to-face instruction, e-learning courses have been developed, which allow trainees to gain knowledge in a 'self-study' mode. Built-in assessment tools make it possible for instructors to monitor and evaluate trainees' performance and ensure quality control.⁸⁴⁷ Besides appropriate training, all researchers have to undergo a medical examination at the start of their contract. This includes appropriate vaccination against any pathogens with which they

⁸⁴⁵ All five institutes within the Anti-Plague System (Microbe – Saratov, Rostov-upon-Don, Irkutsk, Stavropol, and Volgograd) offer certified training courses both at beginners' level and as part of continuing professional development. The Institutes are also tasked with education resource and curricula development. See, for example, [in Russian] ROSPOTREBNADZOR Federal'noe kazennoe uchrezhdenie zdравookhraneniya 'Irkutskii ordena Trudovogo Krasnogo Znameni nauchno-issledovatel'skii protivochumnyi institut Sibiri i Dal'nego Vostoka', *Organizatsii i provedenie uchebnogo protsessa po podgotovke spetsialistov v oblasti biobezopasnosti i laboratornoi diagnostiki vozbuditelei nekotorykh opasnykh infektsionnykh boleznei*, 2012, Irkutsk. On the education and training activities carried out at VECTOR, see [in Russian] Mamed'yar Azaev, 'Prepodavanie osnov biobezopasnosti: Obrazovatel'naya deyatelnost' FBUN GNTs VB "Vektor"', paper presented at Seminar-Conference 'Biological Safety Principles at Microbiology Laboratories', 14-18 October 2013, Novosibirsk State University, Novosibirsk, available at http://biosafety.nsu.ru/?page_id=60 (accessed 11/09/2015).

⁸⁴⁶ [in Russian] T. A. Malyukova et al. 'Sovershenstvovanie podgotovki personala v tselyakh obespecheniya biobezopasnosti rabot s patogennymi biologicheskimi agentami', *Problemy osobo opasnykh infektsii*, vol.1:93 (2007), p.36. On the issue of biosafety training programmes, see also [in Russian] A.V.Boiko et al. 'Evaluation of Professional Qualification of the Personnel Authorised for Work with Pathogenic Biological Agents', *Problemy osobo opasnykh infektsii*, vol.2:108 (2011), pp.12-15; G.Onishchenko et al. 'Normirovanie kak element sistemy obespecheniya bezopasnosti rabot s biologicheskimi agentami I-II grupp patogennosti', *Problemy osobo opasnykh infektsii*, vol. 2:90 (2005), pp.5-11; T.A. Malyukova et al. 'Meditsinskie profilakticheskie meropriyatiya pri organizatsii provedeniya rabot s patogennymi biologicheskimi agentami I-II grupp: puti sovershenstvovaniya', *Problemy osobo opasnykh infektsii*, vol.4:88 (2004), pp.9-12.

⁸⁴⁷ Ibid.

intend to work.⁸⁴⁸ Employees who exhibit vaccination intolerance, or other side effects are allowed to conduct research only with a special institutional order. All members of staff are subject to daily medical surveillance and temperature measurement. They are further required to pass an annual medical check-up, including a mental health and drug test. A designated biosafety officer is in charge of monitoring compliance with these requirements. The biosafety officer has to keep a record of anyone who requests access to the laboratory and/or the pathogens collection. A two-person rule is in operation in all high-containment facilities. Work patterns are also monitored. For instance, if a member of staff is absent, they have to notify their line manager within two hours of their regular start office hours.⁸⁴⁹ Failure to call into work or report an absence more than two hours after the official start time triggers an investigation by the line manager who is obliged to establish why the employee is not at their workplace.

As discussed in Chapter 6, biosafety has a long-standing tradition in Russia, with its origins dating back to the late imperial period when the anti-plague laboratory at Fort Alexander I was established. Besides being actively engaged in the study of bacterial diseases and development of therapeutics, the laboratory also focused on training and capacity building in bacteriology and plague diagnostics. The expertise developed at Fort Alexander I was later transferred to Saratov where it largely laid the foundations for the establishment of the sanitary-epidemiological surveillance system of the Soviet Union. The backbone of the nationwide surveillance infrastructure was the AP system.

Human resource development and training were deemed areas of paramount importance, something evident in the emergence of specialised courses taught on the premises of the 'Microbe' Institute at Saratov as early as 1923.⁸⁵⁰ By the late 1940s completing a training course in biosafety had become a formal requirement for being allowed to work with pathogens. By

⁸⁴⁸ Evgeniy Stavskiy et al. 'Comparative Analysis of Biosafety Guidelines of the USA, WHO, and Russia', *op cit*, p.123.

⁸⁴⁹ *Ibid*

⁸⁵⁰ T. A.. Malyukova et al. 'Sovershenstvovanie podgotovki personala v tselyakh obespecheniya biobezopasnosti rabot s patogennymi biologicheskimi agentami', *op cit*, p.33.

the 1960s the sanitary regulations were further tightened, whereby work involving OOI could be carried only qualified individuals who had passed extensive prior biosafety training and had at least three years of practical experience in virology laboratories. Specialists working with OOI were further required to spend a set period in quarantine – that is, not to conduct any research – before they could undertake any travel if the latter entailed them being away from their place of residence for more than 24 hours.⁸⁵¹ All trained personnel were obliged to undergo a re-certification procedure every five years to demonstrate their biosafety competency – the rule is still in force in present-day Russia. Yet it is worth noting that despite the effort and time dedicated to the preparation of research personnel, laboratory accidents involving OOI still occurred, an aspect that highlights the challenge of eradicating the scope for human error, or technical failure.⁸⁵²

In terms of scope, biosafety training courses developed during the Soviet time were quite extensive, covering a vast array of aspects of professional activity. Since most of research practice was subject to state regulation, developing relevant habits and practices was not just a matter of professional responsibility but a legal requirement. The use of PPE is a case in point. Unlike in the USA where biosafety cabinets were introduced as early as the late 1940s, in the USSR most of laboratory research was carried out at the bench. Under those circumstances, even one tiny drop on the bench was considered an accident.⁸⁵³ Ensuring that staff were properly protected against potential biosafety risks therefore required high level awareness both of laboratory practices and PPE. To further reinforce the importance of PPE, the Sanitary Regulations contained (and still do in their present-day iteration) clear instructions on how the anti-plague suit (*protivochumnyi kostjum*) was to be worn and taken off. There are four types of anti-plague suit; each type is designed for a specific activity. The composition of a Type 1 suit, which is

⁸⁵¹ Interview, Novosibirsk, 7 April 2014.

⁸⁵² See S. Ya. Gaidamovich, 'Human Laboratory Acquired Arbo-, Arena-, and Hantavirus Infections', *Journal of the American Biological Safety Association* vol.5:1 (2000), pp.5-11; [in Russian] Nina Ruzanova, 'Virus kak na ladoni', *Rossiiskaya Gazeta*, No.3514, 30 June 2004, available at <http://www.rg.ru/2004/06/30/ebola.html> (accessed 3/02/2016).

⁸⁵³ *Ibid.*

required for work with OOI is described below, alongside with the official instructions on how the suit is to be put on and taken off.⁸⁵⁴

How to wear a Type 1 anti-plague suit?

(i) The anti-plague suit has to be put on in the designated for this purpose area in the following sequence:

(ii) A hood/head scarf. Put on the hood/head scarf so that it covers the forehead to the level of the eyebrows, the whole of the neck reaching underneath the chin, and most of the cheeks. Tie the laces at the back of the neck.

(iii) An anti-plague robe (gown). Put on the robe, so that the hood/head scarf remains inside it. Tie the collar and belt elastic laces in a bow that is visible in the front of the robe on the left-hand side; only after that tie the elastic laces of the sleeves.

(iv) A respirator. Place the respirator on the face, so that its upper end is aligned with the lower edge of the eyes, and its lower end reaches underneath the chin.

(v) Glasses. Before putting the glasses on, rub the lenses with a special pencil or dry soap, in order to prevent fogging.

(vi) Gloves. Check the gloves for defects before use.

(vii) Towel. Fix the towel on the right-hand side of the robe belt.

(viii) Boots. Put on the boots before entering the zone where pathogens are to be handled ('infectious zone'). Wear a pair of waterproof shoe covers underneath the boots.

How to take off a Type 1 anti-plague suit?

(i) The anti-plague suit has to be taken off in the designated for this purpose area in slow manner and in the sequence described below. Each time you take off an element of the suit, dip your hands in a disinfecting solution without removing the gloves.

(ii) Upon exiting the 'infectious zone', dip your feet without taking off the boots in disinfecting solution. Rub each boot from top to bottom for about 1-2 minutes with a tissue, or swab soaked in disinfecting solution. Only afterwards proceed with taking off the suit.

⁸⁵⁴ See [in Russian] Postanovlenie Glavnogo gosudarstvennogo vracha RF, *Sanitarnye pravila SP 1.3.3118-13: Bezopasnost' raboty s mikroorganizmami I-II grupp patogennosti (opasnosti)*, op cit..

- (iii) First, remove the towel and place it in a tank with disinfecting solution or in an autoclave.
- (iv) Take off the glasses using both hands by pulling it away from the face forwards, then upwards and finally backwards behind the head. Dip the glasses in, or rub them twice with ethyl alcohol (70 per cent).
- (v) Take off the respirator by pulling it away from the face, ensuring that its outer side does not touch the face. Place it in a container for decontamination.
- (vi) Undo the robe collar and belt laces, and lowering the upper edge of the gloves, undo the robe sleeve laces. Take off the robe by folding it inside out, and place it in a container for decontamination.
- (vii) Take off the hood/ headscarf folding its ends at the back of the head in one hand and place it in a container for decontamination.
- (viii) Take off the boots and waterproof shoe covers.
- (ix) Take off the gloves. Check for defects only after dipping them in disinfecting solution.
- (x) Treat your hands thoroughly with ethyl alcohol (70 per cent) and wash them with soap.

One researcher asserts: 'As a young scientist, I had to practise putting on my anti-plague suit multiple times – until I did it in the correct sequence, that is, as specified in the regulations'.⁸⁵⁵ Another one is more critical in their assessment: 'We were indeed well trained but it would have been more useful, had it been explained to us why we had to follow that precise sequence [when putting on and taking off the suit]. We were taught to follow instructions but we were not encouraged to think about, let alone, question them. And it would have been easier to remember the sequence in the first place if we had known the logic behind it!'⁸⁵⁶

Along with the USA, Russia is in possession of a collection of Variola strains, the virus that causes smallpox. When the WHO officially eradicated the virus in 1983, the US and Russia (then the Soviet Union) were allowed to retain

⁸⁵⁵ Interview, 15 April 2014, Moscow.

⁸⁵⁶ Interview, 28 May 2015, Odessa.

their collections and continue research work to help ensure preparedness in case of a reoccurrence of the disease.⁸⁵⁷ Thus, the Centre for Disease Control in Atlanta, Georgia in the USA and 'VECTOR' are the only two official repositories of the virus. All experimental work involving Variola strains is strictly overseen by the WHO Advisory Committee on Variola Virus Research which comprises members from all WHO regions. The Committee is assisted by a group of scientific experts from such areas as public health, fundamental applied research and regulatory agencies. 'VECTOR's collection comprises 120 strains with a total of 696 registered stored units. Among the WHO-approved project recently undertaken at the centre was an investigation of the susceptibility of mice to the Russian Variola virus. The study is aimed at developing animal models to test the efficacy of therapeutic and preventive products against smallpox.

Biosecurity, unlike biosafety is not yet fully integrated in the formal instruction of Russian life scientists. 'VECTOR's biosafety training programme contains some elements pertinent to biosecurity and the State Centre for Applied Microbiology at Obolensk has posted the BTWC in the 'Legal Documents' section of its official website. Likewise, the syllabus of one of the professional training courses, that is delivered at the 'Microbe' institute at Saratov features the following topic: 'The Threat of Bioterrorism: Counter-Terrorism and General Overview of the Biological Agents Most Likely to be Used for the Purposes of Bioterrorist Attacks'.⁸⁵⁸ As part of international collaboration within the framework of the ISTC (prior to Russia's withdrawal from the agreement noted in Chapter 7), a number of educational and awareness-raising tools and resources have been developed, such as 'English-Russian Harmonized Dictionary of Biological Safety and Security (*Anglo-russkii garmonizirovannyi slovar' po biologicheskoi bezopasnosti i okhrane*).⁸⁵⁹

⁸⁵⁷For information on the WHO smallpox research and preparedness, see <http://www.who.int/csr/disease/smallpox/research/en/> (accessed 10/09/2015). The issue of retaining strains of the Variola virus is a contentious one. See, for example, James Gallagher, 'Should the US and Russia Destroy Their Smallpox Stocks?', *BBC News*, 16 May 2011, available at <http://www.bbc.co.uk/news/health-13360794> (accessed 10/09/2015).

⁸⁵⁸ T. A. Malyukova et al. 'Sovershenstvovanie podgotovki personala v tselyakh obespecheniya biobezopasnosti rabot s patogennymi biologicheskimi agentami', *op cit*, p.36.

⁸⁵⁹ Sergey Netesov et al. *English-Russian Harmonized Dictionary of Biological Safety and Security*, (Moscow: MDV, 2010).

At university level, however, very little effort has been made to introduce seminars and courses on the biosecurity aspects of modern biotechnology. With the exception of Novosibirsk State University, Moscow State University, and Siberian Federal University (Krasnoyarsk) where university students are exposed to those issues as part of the bioethics curricula, biosecurity has hardly been embedded in the training of prospective life scientists. By contrast, over the past few decades, bioethics as related to the medical and clinical practice has been institutionalised.⁸⁶⁰ As early as 1992, a Russian National Bioethics Committee was set up under the auspices of RAN. The main aim of the Committee is the protection of the fundamental human rights and human dignity in the conditions of scientific and technological progress in the area of biology and medicine.⁸⁶¹ In 2007, a Federal Ethics Committee was established within the remit of ROSZDRAVNADZOR. The Committee is tasked with conducting ethics assessment of the materials used in clinical trials for testing new drugs and pharmaceuticals. Another national bioethics committee – the Russian Bioethics Committee (*Rossiiskii komitet po bioetike: RKB*) – was also created in that same year. RKB is under the auspices of the Federal Commission on UNESCO, which made the decision for its establishment. RKB's activities entail assessment of the legal, social, and ethical issues arising from scientific research and technology directed at humans; consultation and expert advice on the preparation of bills and legal acts in the field of bioethics; and analysis of the tendencies in the evolution of bioethical norms.⁸⁶² At local level, all laboratories conducting work involving

⁸⁶⁰ See Daniel Callahan, 'Bioethics as a Discipline', *Hastings Centre Studies*, vol.1:1 (1973), pp.66-73. Relevant international agreements on bioethics include Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, 4 April 1997, Oviedo, Spain, available at <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm> (accessed 11/09/2015); UNESCO, *Universal Declaration on the Human Genome and Human Rights*, 11 November 1997, Paris, France, available at http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html (accessed 11/09/2005); UNESCO, *Universal Declaration on Bioethics and Human Rights*, 19 October 2005, Paris, France, available at http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html (accessed 11/09/2005). Relevant international bodies tasked with dealing with bioethics issues include the International Bioethics Committee founded in 1993 and the Intergovernmental Bioethics Committee founded in 1998, both under the auspices of UNESCO. For further information, see <http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/international-bioethics-committee/> (accessed 11/09/2015). For an overview of the development of bioethics as a discipline in Russia, see [in Russian] Yurii Lopukhin, 'O bioetike: Bioetika v Rossii', *op cit.* G.L. Mikirtichan et al, 'Rossisskaya Federatsiya', *op cit.*

⁸⁶¹ See [in Russian] Yurii Khurstalev, *Bioetika: Filosofiya sokhraneniya zhizni i sberezheniya zdorov'ya*, (Moscow: GEOTAR, 2012), p.366.

⁸⁶² For further information on the goals, composition and activity of the Russian Bioethics Committee, see [in Russian] <http://www.bioethics.ru/rus/bioee/> (accessed 10/09/2015).

the use of animals are required to have a bioethics committee.⁸⁶³ The committee is responsible for reviewing project proposals and, where possible, for making recommendations for applying alternative methods for avoiding unnecessary animal suffering.

Whilst some effort has been made to promote closer ties between universities and business, as evident in Government Resolution No 218 of 9 April 2010, 'On the Measures for State Support for Fostering Cooperation between Higher Education Institutions and Organisations Working on High-Technology Production Projects', by and large, in the area of biotechnology those remain underdeveloped.⁸⁶⁴ A notable exception in this regard is the involvement of research institutes in vaccine production.⁸⁶⁵ Cholera and rabies vaccine is produced in the Anti-Plague Institute 'Microbe' at Saratov; plague vaccine is manufactured at the Anti-Plague Institute at Stavropol; and hepatitis A and measles vaccine are produced at 'VECTOR'. The Saint Petersburg Research Institute for Vaccine and Sera specialises in flu and herpetic vaccine production and the Chumakov Institute of Poliomyelitis and Viral Encephalitis in Moscow – in vaccine production against rabies, tick-borne encephalitis, yellow fever, and oral poliovirus. The Federal Centre for Animal Health and the National Russian Institute of Veterinary Virology and Microbiology manufacture a wide range of vaccines against zoonotic diseases such as foot-and-mouth disease (FMD), avian flu, anthrax, Newcastle disease, and sheep pox. Plague vaccine, anthrax vaccine, and smallpox vaccine are produced at Kirov, Yekaterinburg, and Sergiev Posad, respectively.

Soviet Inertia Revisited

As the discussion in the preceding sections illustrates, biotechnology is deemed a key state priority in Russia and a fundamental ingredient of

⁸⁶³ See, for example, the goals and activities of the Bioethics Committee established by Moscow State University available [in Russian] at <http://www.msu.ru/bioetika/> (accessed 10/09/2015).

⁸⁶⁴ See [in Russian] Postanovlenie Pravitel'stva RF, *O merakh gosudarstvennoi podderzhki razvitiya kooperatsii rossiiskikh vysshikh uchebnykh zavedenii i organizatsii, realizuyushchikh kompleksnye proekty po sozdaniyu vysokotekhnologichnogo proizvodstva*, No.218, 9 April 2010, published in *Rossiiskaya Gazeta*, No.5160, 16 April 2010, available at <http://www.rg.ru/2010/04/16/pravila-dok.html> (accessed 10/09/2015).

⁸⁶⁵ Tatyana Elleman, 'Russian Federation', *op cit*, p.199-200.

promoting economic and technological modernisation. The sheer number of policy instruments devised to stir innovation and facilitate knowledge-transfer and product-development in the life sciences and related disciplines is a clear indicator of the government's commitment to the goal of embedding cutting-edge biotechnology advances in such critical sectors as medicine, drug development, agriculture, and energy supply. Given the shared recognition within the Russian leadership of the need for replacing the existing economic model largely dependent on the extraction and export of natural resources, including gas and oil, with one based on the assimilation of novel technologies, this trend is likely to persist and potentially even intensify.

Yet the ongoing expansion of biotechnology in Russia does not take place in a vacuum but in a complex socio-political and economic context conditioned culturally and historically. Just as the globalising dynamics that have shaped the life sciences over the past few decades continue to permeate and influence the country's reality, local contingencies, power relations and competing agendas have a bearing on the trajectory of biotechnology advancement. Stiff global competition for economic growth, commercialisation, and quick implementation of biotechnology advances exacerbates realist fears, skews political calculations, and accelerates the drive for gaining scientific and technological advantage. Those dynamics are certainly not exclusively limited to the context of Russia; on the contrary, hardly any state finds itself insulated from such pressures. However, it is argued that the case of Russia is special, not least because of the legacy of a prolonged autocratic rule and the shadow of the biological weapons programme. When assessing the development of the Soviet Union, the historical and cultural context is difficult to overstate. The October Revolution and resultant rise of the Bolsheviks to power effectively set the scene for an experiment in state engineering on an unprecedented scale. Prior to 1917, Russia was largely an agrarian state which had parted with feudalism about half a century earlier. Industry was underdeveloped and the country's experience with capitalism was limited and bordering on non-existent. Its territory spread across two continents encompassing a multitude of peoples, ethnic groups, languages, and cultures. Some thirty years later, the Soviet

Union would emerge as one of the world's two superpowers and a possessor of the epitome of the most advanced technology at the time: the A-bomb. In national memory the horrors of the Stalinist purges, arbitrary arrests, and state-level harassment still tend to be juxtaposed with the victory in the Great Patriotic War. For its part, science and the life sciences in particular developed against the backdrop of the need for a rapid socio-economic post-war recovery and national defence enhancement. The synergy between these dynamics coupled with the attributes of a state apparatus which emphasised total control, submission, and ideological compliance gave rise to a system of knowledge production that was largely infused with and reflected the Soviet mentality of the day.

Even though the USSR ceased to exist more than two decades ago, its legacy still casts a shadow over the governance of the life sciences in Russia. Whilst science has officially demobilised, the culture that has sustained its development during the Soviet regime persists. State involvement, top-down regulation, secrecy and limited options for public deliberation on science policy raise questions regarding the extent to which the attempts to modernise the life science establishment and foster an ethos compatible with the changing biotechnology landscape have met with success. It suffices to mention that despite the enormous effort invested in promoting biotechnology research very little attention is given to the study of possible risks and related ethical, legal, and social concerns. Likewise, the level of engagement of both practising and prospective life scientists with the broader implications of their work remains low. Adapting the existing governance mechanisms in the realm of the life sciences to the changing innovation landscape requires a normative change that at this stage is hardly evident either in the established state-led approaches, or the life science professional culture. Against the backdrop of a rapidly evolving biotechnology sector and growing consolidation of multifaceted dynamics with complex interactions, fostering the type of professional ethos necessary to ensure the sustainable development of the life sciences in Russia remains a challenging task.

Conclusion and Research Implications

This research has sought to examine to what extent and by what means it is possible for Russia to reconcile its on-going expansion in biotechnology with the institutional and normative inertia arising from its Soviet past. The development of the life sciences in the USSR has in many respects been conditioned by the prevalent political and ideological ethos and economic and military contingencies, which have moulded a particular professional culture with its own attributes, relations of power and mentality. An inherent quality of cultures is stability, which makes them both robust and resilient. They are stable but not static, for 'stability is a special case of change and not the natural order of things'.⁸⁶⁶ For a culture change to be effective and sustainable therefore it is essential that the existing set of relations should adapt to the new reality and broader socio-political and economic context.

The governance of biotechnology in the 'new' Russia post-1991 is a vivid illustration of missed opportunities. The collapse of the Soviet Union offered prospects for building a liberal democratic order based on values such as individuality, freedom of expression, and private initiative – all long neglected and downplayed under the Communist Party. For once the future appeared brighter than ever, pregnant with hopes and expectations for a smooth transition to a freer, more open and in a way fairer society. As the outlook for a long-awaited change for the better gradually became dimmer and dimmer throughout the 1990s, so did the retrograde forces for re-establishing old habits and past patterns of organisation and order gather momentum, becoming stronger and stronger. On the brink of the new millennium, Russia emerged as a 'sovereign democracy' whereby underneath the delicate surface of what ostensibly was pictured as a reformed state with democratic institutions and a market economy, the Soviet heritage remained virtually intact, continuing to inform everyday policy and practice.⁸⁶⁷

⁸⁶⁶ A. W. DePorte, *Europe between the Superpowers: The Enduring Balance*, (New Haven, CT: Yale University Press, 1986), p.xv.

⁸⁶⁷ The concept of 'sovereign democracy' was first introduced in 2006 by the then Deputy Head of the Presidential Administration of the Russian Federation, Vladislav Surkov. See Richard Sakwa, 'Putin's Leadership: Character and Consequences', *Europe-Asia Studies*, vol.60:6 (2008), pp.879-897; Andrei Okara, 'Sovereign Democracy: A New Russian Idea or a PR Project', *Russia in Global Affairs*, vol.5: 3 (2007), pp.8-20; Viatcheslav Morozov, 'Sovereignty

If during the 1990s Russian science was in crisis struggling for survival, over the past decade and a half it has enjoyed a fresh revival and vigorous expansion. The area of biotechnology is a case in point. As illustrated in the preceding chapter, the sheer number and wide scope of high-level initiatives, programmes, and mechanisms highlighting the powerful drivers behind the growing expansion of the life sciences is indicative of Russia's firm commitment to enhancing its scientific prowess and deriving the maximum benefit attainable from the advent of new technologies. Given the explicit emphasis on the need for fostering sustainable domestic production to overcome the dependency on foreign imports in light of the international sanctions introduced amidst the Ukrainian crisis, the trend toward increasing consolidation of biotechnology development is likely to persist and further intensify. Yet a worrying aspect of the current trajectory of life science progress in Russia is the fact that the initiatives designed to facilitate the growth of biotechnology are barely matched with relevant measures for addressing the potential legal, social, ethical, and security concerns arising therefrom. Continuing state control over science, secrecy and lack of transparency breed distrust at international level. Equally, the absence of a life science ethos keenly aware and responsive to the challenges posed by the rapid proliferation of knowledge and technologies with multiple adaptive uses precludes the development and implementation of adequate governance mechanisms to ensure that biotechnology advances are utilised solely for peaceful, prophylactic and protective purposes. Until those conundrums are addressed, Russia's burgeoning biotechnology sector is likely to be viewed with suspicion and considered problematic in relation to its commitment to biological security and disarmament.

One aspect that merits attention is the active participation of Russia in the current Intersessional Programme of the BTWC 2012 – 2015. At the BTWC Meeting of Experts held in August 2014 Russia put forward a document titled 'Strengthening the B[T]WC through a Legally-Binding Instrument

and Democracy in Contemporary Russia: A Modern Subject Faces the Post-Modern World', *Journal of International Relations and Development*, vol.11 (2008), pp.152-180; [in Russian] Vladimir Putin, 'Demokratiya i kachestvo gosudarstva', *Kommersant*, 6 February 2012, available at <http://www.kommersant.ru/doc/1866753> (accessed 28/09/2015).

(Protocol)'.⁸⁶⁸ The proposal called for using the 1994 B[T]WC Special Conference negotiating mandate to develop a 'supplementary and additional Protocol' which would add 'value for States Parties by setting up enabling mechanisms of co-operation, assistance and protection and national implementation thereby strengthening the Convention and improving its implementation'. Among the key thematic areas of the Protocol was investigation of alleged use of biological weapons; investigation of suspicious disease outbreaks; promotion of international cooperation for peaceful purposes; assistance and protection against biological weapons; confidence building measures; national implementation; and monitoring of developments in science and technology relevant to the Convention. For the purposes of the administration and fulfilment of those and other related tasks, the proposal envisioned the establishment of an implementing agency – the Organisation for the Prohibition of Biological Weapons (OPBW) – modelled on the OPCW and comprising a Technical Secretariat, Executive Council and Conference of the States Parties. The proposal was once again discussed at the BTWC Meeting of Experts in August 2015 with a view of preparing a substantive document to be tabled in preparation for the Eight Review Conference of the BTWC to be held in the end of 2016.⁸⁶⁹ At that meeting, Russia also tabled a Working Paper jointly drafted with Belarus on measures for improving the structure of the intersessional process to make it more effective. Further, voicing concerns about the potential for misuse of dual-use research, Russia has suggested the creation of an 'ad-hoc expert working group to elaborate the criteria for referring the most sensitive research to the B[T]WC scope.'

If genuine, Russia's efforts to advocate for strengthening the BTWC constitute a positive signal of political will and commitment to the goal of ensuring that the life sciences are not subject to hostile misuse. Grounds for

⁸⁶⁸ See Russian Federation, *Strengthening the BWC Through a Legally Binding Instrument (Protocol)*, 5 August 2014, Palais des Nations, Geneva, Switzerland. Available at [http://www.unog.ch/__80256ee600585943.nsf/\(httpPages\)/f837b6e7a401a21cc1257a150050cb2a?OpenDocument&ExpandSection=9#_Section9](http://www.unog.ch/__80256ee600585943.nsf/(httpPages)/f837b6e7a401a21cc1257a150050cb2a?OpenDocument&ExpandSection=9#_Section9) (accessed 5/9/2015).

⁸⁶⁹ See Russian Federation, *Proposal by the Russian Federation for Inclusion in the Report of the Eighth Review Conference of the Biological Weapons Convention*, 11 August 2015, Palais des Nations, Geneva, Switzerland. Available at [http://www.unog.ch/__80256ee600585943.nsf/\(httpPages\)/46cac219b57f8b49c1257db20030bce8?OpenDocument&ExpandSection=11#_Section11](http://www.unog.ch/__80256ee600585943.nsf/(httpPages)/46cac219b57f8b49c1257db20030bce8?OpenDocument&ExpandSection=11#_Section11) (5/9/2015).

scepticism stem from at least two sources though. One is the formal explanation submitted by the Russian Federation with regard to the 2014 Report of the Meeting of the States Parties to the BTWC. According to the explanation, ‘the Russian Federation considers paragraphs 19 through 59 [the substantive paragraphs]... as having no approved status, and therefore, no commitments may arise therein.’⁸⁷⁰ Another is the rhetoric employed by the Russian delegation during the 2015 BTWC Meeting of Experts when accusations of dubious activities bordering noncompliance with the Convention were levelled against fellow States Parties.⁸⁷¹

In 2015 the BTWC is celebrating its 40th Anniversary since its entry into force. The Convention is the first international agreement to outlaw a whole class of WMD codifying the norm that the use of biological and/or toxin weapons ‘would be repugnant to the conscience of mankind’. Back in 1972 when the Convention was negotiated and opened for signature, the USSR was one of its three depository states. Russia therefore has a moral duty to act as a bulwark against the hostile misuse of the life sciences. So far, however, the country still has not fully lived up to this expectation. Whilst the formal legal architecture is in place domestically, more action is required to overcome the persisting institutional, infrastructural, and normative legacies inherited from the Soviet era and thus give a tangible expression to the vocal commitment to fostering a culture of biosecurity, both domestically and internationally.

This research has sought to uncover and analyse the existing culture of life science practice in present-day Russia. To this end, it has drawn upon the wide literature on the history of science in Imperial and, later, Soviet Russia looking both into the scope of scientific and technological advancement and the governance mechanisms for utilising scientific knowledge for social, political, economic, and military purposes. It has further reviewed the academic scholarship and official documents and reports on the history of the

⁸⁷⁰ Statement by the Russian Federation under the Standing Agenda Item, ‘Review of Developments in Science and Technology Relevant to the Biological and Toxin Weapons Convention’, 2 December 2014, Palais des Nations, Geneva, Switzerland.

⁸⁷¹ See Statement of the Russian Federation under the Standing Agenda Item, ‘Strengthening National Implementation’, 13 August 2015, Palais des Nations, Geneva, Switzerland. Available at [http://www.unog.ch/_80256ee600585943.nsf/\(httpPages\)/46cac219b57f8b49c1257db20030bce8?OpenDocument&ExpandSection=9#_Section9](http://www.unog.ch/_80256ee600585943.nsf/(httpPages)/46cac219b57f8b49c1257db20030bce8?OpenDocument&ExpandSection=9#_Section9) (accessed 5/09/2015).

Soviet biological weapons programme. The historical account has been then combined with an extensive analysis of the initiatives, measures and policies implemented in the area of biotechnology after the collapse of the USSR underpinned by primary research data obtained over the span of many hours of interaction with life scientists and government officials from Russia and the Former Soviet Union states, as well as by critical engagement with the limited literature on science governance in Russia after 1991. Thus, the research offers important insights into the multifaceted dynamics that have shaped and continue to shape the life science enterprise in Russia identifying both the strengths and shortcomings of the existing governance mechanisms in accommodating the whole gamut of ethical, security, social, and legal challenges arising from the rapid advancement of twenty-first century biotechnology. In particular, by drawing attention to the persistence of institutional and normative Soviet inertia, it highlights the limits of formal regulatory approaches to the development of a professional culture that could adequately accommodate the advent of novel multiple-use technologies.

The research consolidates several bodies of literature and primary research findings and, as such, provides a valuable starting point for further studies designed to examine the governance of biotechnology in Russia. One area that merits investigation is the role of scientist engagement in promoting a culture of biosecurity in the life sciences. According to the preamble of UNESCO's Constitution: 'since wars begin in the minds of men, it is in the minds of men that the defences of peace must be constructed'.⁸⁷² Good laboratory biosafety practice has a long-standing tradition in Russia dating back to the late imperial period. Education and training programmes in this area are in place and there are powerful professional norms re-enforcing compliance with the relevant laws and regulations. It may be useful therefore to examine the extent to which engaging life scientists with the dual-use problematic and the broader social, ethical, and legal implications of biotechnology could impact on their practices and contribute to the development of a professional ethos, based on a shared understanding of

⁸⁷² UNESCO Constitution, 16 November 1945, available at http://portal.unesco.org/en/ev.php-URL_ID=15244&URL_DO=DO_TOPIC&URL_SECTION=201.html (accessed 7/02/16).

the essential role of biosecurity in preventing the hostile misuse of the life sciences.

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Appendix 1

List of State Policy Documents and Programmes with Relevance to Biotechnology in Russia

Presidential Decree No.899

In 2011 the then Russian President Dmitry Medvedev signed Decree No.899 'On the Approval of Priority Directions for the Development of Science and Technology in the Russian Federation and the List of Critical Technologies'.⁸⁷³ The document defined eight priority areas on which the state agencies were to focus in order to promote the goal of modernising the economy and enhancing its competitiveness. The life sciences were listed under number 4. Among the twenty-seven critical technologies that merit specific attention and that should be vigorously pursued as stipulated in the second part of the document were biocatalytic, biosynthetic and biosensor technologies; biomedical and veterinary technologies; genomic, proteomic, and post-genomic technologies; cell technologies; NBIC technologies;⁸⁷⁴ bioengineering; and technologies for reducing the loss of life of socially significant disease.

State Coordination Programme for the Development of Biotechnology in the Russian Federation until 2020 (BIO 2020)

In 2005 the Ovchinnikov Society of Russian Biotechnologists published a *National Programme for the Development of Biotechnology in the Russian Federation, 2006 – 2015*.⁸⁷⁵ The Programme was developed in consultation with a wide range of stakeholders, including the State Duma, relevant

⁸⁷³ See [in Russian] Ukaz Prezidenta Rossiiskoi Federatsii, *Ob utverzhdenii prioritnykh napravlenii razvitiya nauki, tekhnologii i tekhniki v Rossiiskoi Federatsii i perechnya kriticheskikh tekhnologii Rossiiskoi Federatsii*, No.899, 7 July 2011, Moscow.

⁸⁷⁴ Derived from the convergence of Nanotechnology, Biotechnology, Information Technology, and Cognitive Science.

⁸⁷⁵ See [in Russian] Obshestvo biotekhnologov Rossii im. Yu.A. Ovchinnikov, *Natsional'naya programma 'Razvitie biotekhnologii v Rossiiskoi Federatsii na 2006-2015'*, 27 October 2015, available at <http://www.biorosinfo.ru/strategija-razvitija-biotekhnologicheskoi-otrasli-promyshlennosti-v-rossijskoj-federatsii-do-2020-g-strategija-bio-2020/> (accessed 9/09/2015). See also [in Russian] Obshestvo biotekhnologov Rossii im. Yu.A. Ovchinnikov, *Strategiya razvitiya biotekhnologii v Rossiiskoi Federatsii do 2020 (Strategiya Bio2020)*, 23 December 2010, Moscow.

ministries, the three big Science Academies at the time – RAN, RAMN, and RASKhN, research institutes, and private sector, and its draft was endorsed by the Expert Council on Biotechnology Industry of the Parliamentary Committee on Industry, Engineering and Knowledge-Based Technology. By design, it constituted an unprecedented undertaking aimed at raising awareness of the enormous potential, economic viability, and various benefits of biotechnology, highlighting the need for fostering public-private partnerships to ensure the long-term strategic advancement of the life sciences. Even though the programme was not ultimately implemented, it was an important first step toward the goal of consolidating the efforts to support biotechnology nation-wide.

In many respects, the 2005 *National Programme* has served as a basis for the development of another important document - the *State Coordination Programme for the Development of Biotechnology in the Russian Federation until 2020* – which was adopted in April 2012. The *State Coordination Programme* has institutionalised the government's commitment to promoting biotechnology drawing upon the proposals made in its draft predecessor.⁸⁷⁶ Among the objectives set in its ambitious agenda are:

- Raising the volume of consumption of biotechnology products 8.3 times;
- Raising the volume of production of biotechnology products 33 times;
- Reducing the import of consumer biotechnology products by half;
- Increasing the share of biotechnology exports more than 25 times;
- Raising the level of biotechnology production to 1% of the GDP by 2020 and to at least 3% by 2030.

In order to fulfil the aforementioned objectives, the Programme has envisaged a package of diverse measures. Those include:

⁸⁷⁶ See *State Coordination Program for the Development of Biotechnology in the Russian Federation until 2020*, No. VP-P8-2322, 24 April 2012, Moscow, English version available at http://owwz.de/fileadmin/Biotechnologie/Information_Biotech/BIO2020_Programme_full.pdf (accessed 9/09/2015). [in Russian] *Kompleksnaya programma razvitiya biotekhnologii v Rossiiskoi Federatsii na period do 2020*, No. VP-P8-3222, 24 April 2012, Moscow, available at <http://innovation.gov.ru/page/584> (accessed 9/09/2015).

- Incentive pricing (e.g. state procurements, setting new standards and technical regulations, financial support for industries);
- Enhancing the competitiveness of biotechnology enterprises (e.g. grants and interest-free loans to support R&D programmes at small and medium businesses; export promotion; development of innovation infrastructure);
- Improving education (e.g. creation of new educational standards and programmes);
- Development of science (e.g. increasing state funding, development of strategic research programmes);
- Development of a pilot production base;
- Promoting business-science-education cooperation;
- Support for biotechnology in the provinces;
- International collaboration.

The Programme is divided into two stages. During Stage 1 (2011-2015) the Programme has focused on the development of domestic demand and export of biotechnology products. In Stage 2 (2016-2020), it seeks to create the institutional conditions required for carrying out a 'deep' modernisation of the technological base of the relevant sectors of industry to enable the embedment of biotechnology methods in production. The principal coordinator of the Programme is the Ministry of Economic Development (*Ministerstvo ekonomicheskogo razvitiya: MINEKONOMRAZVITIYA*). Additional nine arms of the government are tasked to work alongside on its implementation. The Programme's overall budget is 1.2 trillion roubles, with 367 billion roubles allocated for bioenergy, 210 billion for industrial biotechnology, 200 billion for agricultural biotechnology, 150 billion for biomedicine, 106 billion for biopharmacy, 70 billion for marine biotechnology, 45 billion for forestry biotechnology, and 30 billion for environmental biotechnology.⁸⁷⁷

⁸⁷⁷ See [in Russian] Frost and Sullivan, *Obzor rynka biotekhnologii v Rossii i otsenka perspektiv ego razvitiya*, October 2014, Moscow, p.12. Full text of the report is available at <http://ww2.frost.com/news/press-releases/biotekhnologii-zadayut-vektor-innovacionnogo-razvitiya-ekonomiki-rossii/> (accessed 9/09/2015).

Blueprint for the Development of Biotechnology and Genetic Engineering

In 2013 the then Prime Minister Dmitry Medvedev signed Governmental Order No.1247-r approving the Plan (Blueprint) for the Development of Biotechnology and Genetic Engineering. That was yet another state document which recognised the need for addressing the unsatisfactory performance of Russia's biotechnology on the international scene and tackling its heavy dependence on foreign imports:

More than 80 percent of the biotechnology products used in Russia are imported and the volume of consumption is extremely low as compared to that in both developed and developing countries. Imported products feature 100 percent of the amino acids for the agricultural sector (lysine), up to 80 percent of the feed enzyme preparations, 100 percent of the enzymes for household chemicals, more than 50 percent of veterinary antibiotics, 100 percent of lactic acid, and 50 to 100 percent of the biological food ingredients.⁸⁷⁸

The Blueprint is conceptually linked to the *State Coordination Programme* outlined above and aims to facilitate the fulfilment of its core objectives set out for Stage 1. In particular, the Plan seeks to develop domestic demand and export of biotechnological products; to establish a technological and manufacturing basis for the organisation of new industry sub-branches which in the long-term could replace a significant part of the products currently manufactured by means of chemical synthesis with ones obtained through biological synthesis; and to establish a technological and pilot production base for the development of the biofuel industry. To this end, the Plan draws a list of indicators with clear targets to be met between 2012 and 2015, and then 2015 and 2018. For example, according to the Plan, the volume of consumption of biotechnology production in 2012 amounted to 128 billion roubles with the projected figures for 2015 and 2018 being 180 and 300

⁸⁷⁸ See [in Russian] Razporyazhenie Pravitel'stva RF, *Plan meropriyatii ("dorozhnaya karta") 'Razvitie biotekhnologii i gennoi inzhenerii'*, No.1247-r, 18 July 2013, Moscow, available at <http://government.ru/docs/3257/> (accessed 9/09/2015). For an unofficial English version, see Executive Order of the Government of the Russian Federation, *Action Plan ("Roadmap") 'Development of Biotechnology and Genetic Engineering'*, No.1247-r, 18 July 2013, available at: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Russian%20Government%20Roadmap%20for%20Development%20of%20Biotechnology_Moscow_Russian%20Federation_9-20-2013.pdf (accessed 9/09/2015).

billion roubles, respectively. Moreover, the Plan defines two packages of measures to be implemented. The first one, framework measures, is directed at such areas as promoting R&D; improving the education and qualification of scientific, engineering, technical, and management staff; improving the regulation of biotechnology; and creating coordination mechanisms. The second one, sector-specific measures, encompasses the policies to be developed with regard to the various fields of biotechnology.

Basic Principles of the State Policy in the Area of Healthy Nutrition Until 2020

In 2012 the Russian Government issued Resolution No.1873-r approving the 'Basic Principles of the State Policy in the Area of Healthy Nutrition Until 2020'.⁸⁷⁹ Among its key objectives and tasks the Policy listed 'development and implementation of innovation technologies, including biotechnology and nanotechnology in agriculture and food production.' In addition, the mechanisms through which the policy is to be executed feature investment in the promotion of basic research in the field of biotechnology and nanotechnology for the purpose of obtaining new food sources and methods for medical and biological analysis of their quality and safety.

State Programmes, Sub-Programmes, and Federal Targeted Programmes

The State Programme 'Science and Technology Development' adopted in 2012 set out the framework for the development of science and technology in Russia until 2020. Its implementing-agency-in-chief is *MINOBRANAUKI* which is to be assisted by *MINEKONOMRAZVITIYA*. The main objectives of the Programme are as follows:

- Creation of a competitive and cost-effective research and development sector and ensuring its leading role in the Russian economy's technological modernisation processes;
- Advancement of fundamental research;

⁸⁷⁹ See [in Russian] Razporyazhenie Pravitel'stva RF, *Osnovy gosudarstvennoi politiki Rossiiskoi Federatsii v oblasti zdorovogo pitaniya naseleniya na period 2020*, No.1873-r, 25 October 2010, published in *Rossiiskaya Gazeta*, No.5328, 3 November 2010, <http://www.rg.ru/2010/11/03/pravila-dok.html> (accessed 9/09/2015).

- Fostering larger than planned science and technological potential in high-priority areas of science and technology development;
- Ensuring the institutional development of the R&D sector and improving its structure, management, and financing system;
- Integration of scientific research with education;
- Establishment of modern equipment and production assets in the R&D sector;
- Integration of the Russian R&D sector into the system of international science and technological cooperation.⁸⁸⁰

The implementation of the Programme is estimated to cost 1,603 trillion roubles. Among the main instruments of the Programme is the Federal Targeted Programme, 'Research and Development in Priority Areas of Development of the Russian Scientific and Technological Complex for 2014-2020' drafted in 2013.⁸⁸¹ The Targeted Programme is tasked with creating scientific and technological groundwork orientated primarily toward inter-industry needs and a single infrastructure to support the R&D sector. To this end, it employs various implementation tools with regard to scientific and technological projects, including both state contracts and grant agreements in the form of subsidies for legal entities carrying out research projects.⁸⁸² The cost of the Targeted Programme for 2014-2020 is 239.03 billion roubles, of which 202.24 billion constitute a contribution from the federal budget and the remaining 36.79 billion roubles are to be derived from extra-budgetary sources.

In 2012 the Russian Government approved a State Programme titled 'Agricultural Development and Regulation of Agricultural Products,

⁸⁸⁰ See [in Russian] Postanovlenie Pravitel'stva RF, *Ob utverzhdenii gosudarstvennoi programmy Rossiiskoi Federatsii 'Razvitiya nauki i tekhnologii' na 2013-2020 goda*, No.301, 15 April 2014, available at <http://xn--80abucjiibhv9a.xn--p1ai/%D0%B4%D0%BE%D0%BA%D1%83%D0%BC%D0%B5%D0%BD%D1%82%D1%8B/4125> (accessed 9/09/2015). For the progress of the implementation of the Programme, see <http://government.ru/programs/211/events/> (accessed 9/09/2015). For an English summary, see <http://government.ru/en/docs/3346/> (accessed 9/09/2015).

⁸⁸¹ Here is an illustration of how State Programmes and Targeted Programmes are linked together. In this case, the State Programme serves as a framework within which the Targeted Programme is utilised for the attainment of particular goals and directing resources.

⁸⁸² [in Russian] Federal'naya tselevaya programma, *Issledovaniya i razrabotki po prioritetnym napravleniyam razvitiya nauchno-tekhnologicheskogo kompleksa Rossii na 2014-2020*, 21 May 2013, <http://fcpir.ru/> (accessed 9/09/2015). An English summary is available at <http://government.ru/en/docs/2129/> (accessed 12 May 2015).

Commodities, and Food Markets, 2013-2020' to be implemented by the Ministry of Agriculture (*Ministerstvo sel'skogo khozyaistva*).⁸⁸³ Other participants in the Programme include the Ministry of Culture (*Ministerstvo kul'tury*), Federal Road Agency (*Federal'noe dorozhnoe agenstvo*), and Federal Service for Veterinary and Phytosanitary Surveillance (*Federal'naya sluzhba po veterinarnomu i fitosanitarnomu nadzoru: ROSSELKHOZNADZOR*). Among the strategic goals of the Programme is guaranteeing food security; enhancing the competitiveness of domestic products both in and outside Russia; and fostering efficient and environment-friendly production models. To accomplish those goals, the Programme seeks to complete the following tasks:

- Creating incentives for the production of the main types of agricultural and food products;
- Implementing anti-epizootic measures with regard to quarantine and especially dangerous animal diseases;
- Supporting the development of agricultural and food market infrastructure;
- Making agriculture more cost-effective to ensure its sustainable development;
- Promoting biotechnology; and
- Encouraging innovation in the agricultural industry.

The State Programme comprises six sub-programmes and four targeted programmes. Particularly pertinent to the promotion of biotechnology is the sub-programme entitled, 'Technical and Technological Modernisation, Innovative Development'. Its chief objectives are enhancing the efficiency and competitiveness of agricultural production through technical and technological modernisation; fostering favourable economic conditions to support innovative development and attract investment; and bringing Russia's agricultural industry to leading positions in the area of agricultural biotechnology. The tasks required for the accomplishment of those goals

⁸⁸³ See [in Russian] Postanovlenie Pravitel'stva RF, *O Gosudarstvennoi programme razvitiya sel'skogo khozyaistva i regulirovaniya rynkov sel'skokhozyaistvennoi produkcii, syr'ya i prodovol'stviya na 2013-2020 gody*, No.717, 14 July 2012, Moscow, available at <http://government.ru/docs/16239/> (accessed 9/09/2015). An English summary is available at <http://government.ru/en/docs/3360/> (accessed 9/09/2015).

include the creation of appropriate institutional environment for the large-scale development and utilisation of innovation and adequate infrastructure for promoting agricultural biotechnology. Of the overall State Programme budget amounting to 2.126 trillion roubles, 31.6 billion roubles are to be dedicated to the completion of the sub-programme.

The State Programme entitled 'Development of Pharmaceutical and Medical Industry, 2013-2020' was launched in April 2014. Its principal coordinator is the Ministry of Industry and Trade (*Ministerstvo promyshlennosti i torgovli*) with other Programme participants featuring MINOBRANAUKI, Federal Service for Surveillance in Healthcare (*Federal'naya sluzhba ponadzoru v sfere zdravookhraneniya: ROSZDRAVNADZOR*), MINZDRAV, and Moscow State University. The overall objective of the programme is the formation of a world-class innovation-based pharmaceutical and medical industry in Russia. The main tasks to be completed to this end include:

- Enhancing the technological and manufacturing potential of the pharmaceutical and medical industry;
- Enhancing the innovative potential of the pharmaceutical and medical industry; and
- Improving the production of innovative medicines and medical products.⁸⁸⁴

Among the expected outcomes of the Programme is a seven-fold increase of the share of high-technological and knowledge-based products by 2020 in the overall volume of pharmaceutical and medical production as compared to 2011; an increase of up to 50 per cent of the share of domestically manufactured consumer medicines; and an increase in the export of pharmaceuticals and medical products to a level of at least 105 billion roubles. The Programme budget is 99.4 billion roubles. Three Sub-

⁸⁸⁴ See [in Russian] Postanovlenie Pravitel'stva RF, *Ob utverzdenii gosudarstvennoi programmy Rossiiskoi Federatsii 'Razvitie farmatsevticheskoi i meditsinskoj promyshlennosti' na 2012-2020*, No.305, 15 April 2014, Moscow, available at <http://government.ru/media/files/FixAD0zpgrA.pdf> (accessed 9/09/2015). An English summary of the Programme is available at <http://government.ru/en/docs/3370/> (accessed 9/09/2015).

Programmes and one Targeted Programme are to be implemented within the framework of the State Programme. Those are:

- Sub-Programme 1, Development of Pharmaceutical Manufacturing;
- Sub-Programme 2, Development of Medical Product Manufacturing;
- Sub-Programme 3, Improvement of the State Regulations Pertaining to the Circulation of Pharmaceutical Drugs and Medical Products; and
- Targeted Programme, Development of Pharmaceutical and Medical Industry in the Russian Federation until 2020 and beyond.⁸⁸⁵

The activities to be conducted as part of the Targeted Programme are divided in seven categories as follows:

1. Development of the scientific and technical potential of the pharmaceutical industry;
2. Development of the innovation potential of the pharmaceutical industry;
3. Development of the scientific and technical potential of the medical industry;
4. Development of the innovation potential of the medical industry;
5. Staff development and enhancement of the information infrastructure of the pharmaceutical and medical industry;
6. Investments to provide for the technological modernisation and the adoption of an innovation-based model of development in the pharmaceutical and medical industry;
7. Programme management.

As part of the Government State Programme, 'Development of Industry and Increasing Competitiveness, 2012-2020',⁸⁸⁶ a sub-programme titled

⁸⁸⁵ See in [Russian] Postanovlenie Pravitel'stva RF, *O Federal'noi tselevoi programme 'Razvitie farmatsevticheskoi i meditsinskoi promyshlennosti Rossiiskoi Federatsii na period do 2020 goda i dal'neisuyu perspektivu'*, No.91, 17 February 2011, Moscow, available at <http://fcpfarma.ru/catalog.aspx?CatalogId=744> (accessed 9/09/2015). For an overview of the Targeted Programme in English, see http://erawatch.jrc.ec.europa.eu/erawatch/opencms/information/country_pages/ru/supportmeasure/support_0017 (accessed 9/09/2015).

⁸⁸⁶ See [in Russian] Razporyazhenie Pravitel'stva RF, *Gosudarstvennaya programma Rossiiskoi Federatsii 'Razvitie promyshlennosti i povyshenie ee konkurentosposobnosti'*, No.1535-r, 29 August 2013, available at

'Industrial Biotechnology' is to be implemented.⁸⁸⁷ The agency tasked with the implementation of the sub-programme is the Ministry of Industry and Trade. The overall objective of the sub-programme is creating and developing modern industrial biotechnology sector competitive both on domestic and international markets. Among the tasks to be fulfilled to this end are the creation of an up-to-date legal, normative, technical, informational, and organisational base for the development of industrial biotechnology; formation and execution of comprehensive innovative projects in the area of industrial biotechnology; development of industrial biotechnology production export; and creation of technological base for industrial biotechnology. The sub-programme runs between 2014 and 2020 and its budget for the first three years of implementation (2014-2016) is 1.50 billion roubles.

Principles of the State Policy in the Area of Ensuring Chemical and Biological Security of the Russian Federation for the Period up to 2025 and beyond

Several key documents have identified biosecurity as a priority area that requires concerted action.⁸⁸⁸ The 'National Security Strategy of the Russian Federation until 2020' published in 2009 lists 'illicit activity in the field of biology' as one of the strategic challenges to ensure the state's national security.⁸⁸⁹ The proliferation of 'nuclear, chemical, and biological technology' and 'the development of [WMD] and their means of delivery' are also considered military threats. 'Principles of the State Policy in the Area of Ensuring Chemical and Biological Security of the Russian Federation for the Period up to 2025 and beyond' issued in 2013 is a comprehensive document setting out Russia's biosecurity policy. Among the potential biological threats specified in the 'Principles' is the spread of naturally occurring diseases resulting from the risk of the emergence of new and the re-emergence of

<http://government.ru/docs/11912/> (accessed 9/09/2015). For a reference to the State Programme in English, see <http://government.ru/en/docs/3341/> (accessed 9/09/2015).

⁸⁸⁷ The full text of [in Russian] *Podprogramma No.18: Promyshlennye biotekhnologii* is available at http://base.garant.ru/70643464/#block_18000 (accessed 9/09/2015). Author's translation.

⁸⁸⁸ See [in Russian] Eduard Yezhov, *Gosudarstvennaya nauchno-tekhnicheskaya politika: osnova tekhnologicheskoi bezopasnosti*, (Moscow: MAI, 1999); Aleksandra Simonova, *Protivodeistvie bioterrorizmu: mezhdunarodno-pravovoi aspekt*, (Moscow: Librokom, 2010); V. Sergiev and N. Filatov, *Infektsionnye bolezni na rubezhe vekov: osoznanie biologicheskoi ugrozy*, (Moscow: Nauka, 2006).

⁸⁸⁹ [in Russian] 'Strategia natsional'noi bezopasnosti Rossiiskoi Federatsii do 2020 goda', *op cit.* Author's translation.

already eradicated infectious diseases, and the growth of anti-microbial resistance; the accidental release of pathogens due to a failure in a laboratory containment system; and the deliberate release of pathogens featuring sabotage, illicit application of dual-use technologies, and bioterrorism. The main objectives of the policy are as follows:

- Improvement of measures aimed at ensuring the implementation of Russia's commitments under international treaties;
- Participation in the development and application of the Russian-Kazakhstan-Belarus Customs Union Technical Regulations which lay down safety requirements for products created with the use of biotechnologies;
- Improvement of the regulation on trans-border transfer of GMOs;
- Russia's accession to the Cartagena Protocol on Biosafety; and
- Elaboration of measures aimed at preventing the threat of use of biological weapons against the Russian Federation.⁸⁹⁰

The current 'Principles' aim to build upon Russia's earlier efforts to develop an effective nation-wide biosecurity system, as illustrated in the 'Principles of the State Policy in the Area of Ensuring Chemical and Biological Security of the Russian Federation for the Period up to 2010 and beyond' which appeared in 2003. The primary instrument for the implementation of the 2003 'Principles' has been the Federal Targeted Programme, 'National System for Chemical and Biological Security in the Russian Federation, 2009-2014', the goals of which have been the development of a methodology for threat assessment; modernisation of hazardous chemical biological facilities; research aimed at biological security; emergency response, and public and military protection; and curricula and staff development.⁸⁹¹ 4.09 billion

⁸⁹⁰ See Russian Federation, *Statement by the Russian Delegation at the Biological Weapons Convention Meeting of States Parties*, 9 December 2013, BWC/MSP/2013, Palais des Nations, Geneva, Switzerland, available at [http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/C2B97F73E1976622C1257C3C0068D2F0/\\$file/Russian+Federation.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/C2B97F73E1976622C1257C3C0068D2F0/$file/Russian+Federation.pdf) (accessed 9/09/2015).

⁸⁹¹ See [in Russian] Postanovlenie Pravitel'stva RF, *O Federal'noi tselevoi programme 'Natsional'naya Sistema khimicheskoi i biologicheskoi bezopasnosti Rossiiskoi Federatsii (2009-2014)'*, No.791, 27 October 2008, available at <http://base.garant.ru/2166728/> (accessed 9/09/2015). Full text of the Programme in Russian is available at <http://fcp.economy.gov.ru/cgi-bin/cis/fcp.cgi/Fcp/Passport/View/2010/255/> (accessed 9/09/2015). The English translation of the Programme Title has been taken from Tatyana Elleman, 'Russian Federation', *op cit*, p.195. For a detailed overview of the programme, see [in Russian] Nikolai Makhutov et al. *Bezopasnost' Rossii: Pravovye*,

Roubles have been spent on the Programme, including 2.85 billion on facility modernisation and 1.3 billion on research. The Federal Targeted Programme for the revised 'Principles', which will cover the period 2015-2020, is currently being developed.

RAN Basic Research Programme, 2013-2020

In 2012 the Government approved RAN's Programme of Basic Research for the period 2013-2020.⁸⁹² Among the key considerations underpinning the Programme is the need for the development of a modern system for the organisation of basic research on the basis of academic science; the need for effective utilisation of the potential of basic research as a strategic asset for the development of the society and state in general; and the need for ensuring the contribution of science to economic development, technological advancement, and national security. As the Programme was issued prior to the 2013 reform of the Academy, each of the three Academies pertinent to the life sciences – RAN, RAMN, and RASKhN – have been allocated a budget. For 2015, the estimated budget of RAN, RAMN, and RASKhN is 57185.82 million roubles, 5078.62 million roubles, and 7665.2 million roubles, respectively.

sotsial'no-ekonomicheskie i nauchno-tekhnicheskie aspekty: biologicheskaya bezopasnost', (Moscow: Znanie, 2009), particularly Chapter 12 and Appendix 2.

⁸⁹² See [in Russian] Razporyazhenie Pravitel'stva, *Programma fundamental'nykh nauchnykh issledovaniy gosudarstvennykh akademii nauk na 2013-2020 gody*, No.2237-r, 3 December 2012, Moscow, available at <http://www.ras.ru/scientificactivity/2013-2020plan.aspx> (accessed 9/09/2015).