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Strengthening the Biological Weapons Convention

Briefing Paper No 15 (Second Series)

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A CODE OF CONDUCT FOR THE LIFE SCIENCES: A PRACTICAL APPROACH

by Graham S. Pearson

Introduction

1. The States Parties to the Biological and Toxin Weapons Convention (BTWC) agreed¹ at the resumed Fifth Review Conference in November 2002 that the topic to be considered in the new process at which the States Parties would ‘*discuss, and promote common understanding and effective action*’ would in 2005 be:

- *The content, promulgation, and adoption of codes of conduct for scientists.*

2. An earlier Bradford Briefing Paper no. 13² by Brian Rappert examined the potential contribution of professional codes such as codes of ethics, codes of conduct and codes of practice. This Briefing Paper considers what the **aims** are of such a code of conduct for the life sciences and how these aims might be achieved. It then examines a practical approach based on legislation and regulations in the UK. Finally, it concludes by considering how such a practical approach might be adopted internationally.

The aims

3. The **aim** of the code of conduct for the life sciences is to ensure that activities involving *microbial or other biological agents, or toxins whatever their origin or method of production* are only of types and in quantities that have *justification for prophylactic, protective or other peaceful purposes*.

4. By focussing on this aim – and by accurately describing the aim – the risks that the involved community, whether government, life sciences, academia or industry, gain a misleading or inaccurate perception of the aim and thus misunderstand the importance of effective implementation will be minimized. From the point of view of gaining universal acceptance, an appeal for responsible and common sense behaviour is likely to be readily adopted.

Achieving these aims

5. In considering whether this aim is best achieved by something called a code of *conduct* or a code of *practice*, it is important to recognise that there are general perceptions relating to these two terms. There is a broad appreciation that a code of

¹United Nations, Fifth 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, Geneva, 19 November - 7 December 2001 and 11 - 22 November 2002, *Final Document*, BWC/CONF.V/17, 2002. Available at <http://www.opbw.org>

² Brian Rappert, *Towards a Life Sciences Code: Countering the Threats from Biological Weapons*, University of Bradford, Department of Peace studies, Briefing Paper No. 13, September 2004. Available at <http://www.brad.ac.uk/acad/sbtwc>

conduct is something to which individuals aspire as an objective but actual practice may fall short of that objective. On the other hand, codes of *practice* are widely utilised in the implementation of national regulations which require activities to be carried out in accordance with a set out code of practice and that whilst such a code of practice may itself not be mandatory, the onus is on the individuals to demonstrate that if they are not observing the code of practice then that the practice that they are observing is of a comparable standard – and will achieve the same objective – as the code of practice.

6. There is much to be said therefore for a code of *practice* to achieve the **aims** set out above as a code of *practice* is inherently enforceable.

Approaches to such a code of practice

7. It would be a mistake to assume that consideration is being given to such a code of *practice* against a clean page. In practice, the focus needs to be on a code of *practice* that can be **integrated** into the raft of regulations and codes of practice that **already** apply to activities involving *microbial or other biological agents, or toxins whatever their origin or method of production*.

8. The communities engaged in such work that need to be considered include the following:

- Academia in the life sciences fields
- Public, animal and plant health community
- Industry -- microbiology)
- -- biotechnology) both products and equipment
- -- pharmaceutical)
- Government departments

9. In the United Kingdom, there are already existing regulations and codes of conduct and practice which apply to **all** or **some** of the above communities. In the listing below the relevant UK government department or authority is indicated in parentheses (HSE – Health & Safety Executive, Defra – Department for Environment, Food and Rural Affairs, DTI – Department of Trade and Industry, MHRA – Medicines and Healthcare Products Regulatory Agency, Health – Department of Health):

- Health and Safety at Work (HSE) – all
- Protection of the environment (Defra) – all
- Export controls – “catch all” clause, intangible technology (DTI) – all

- Ethical considerations (Health) – some
- Animal experimentation (Home Office) – some
- Product safety and efficacy (MHRA) – some
- Proscribed drugs and precursors (Home Office) – some
- Genetic modification (Defra/Health) – some
- Security of and access to human pathogens and toxins (Home Office) – some

10. A logical approach would be to explore which of the existing regulations and codes of practice that already apply to **all** the communities is closest in its aims and objectives to those set out in paragraph 3 above – namely, to ensure that activities involving *microbial or other biological agents, or toxins whatever their origin or method of production* are only of types and in quantities that have justification for prophylactic, protective or other peaceful purposes. – and hence offer the prospect of the easiest integration. Given that the aims set out above have very wide applicability – to all *microbial or other biological agents, or toxins whatever their origin or method of production* -- there is advantage in building upon the existing regulations and codes of practice that have **widest** applicability as there should result in the most **effective** implementation of the aims. Of the three sets of regulations identified above – health and safety, environment and export controls -- the one which has **widest** application is that relating to health and safety. This is therefore examined further in this Briefing Paper.

Health and Safety at Work

11. Consideration of health and safety is embedded into **all** of the above communities. The UK Health and Safety at Work Act 1974 in its opening words states that the Act is “*to make further provision for securing the health, safety and welfare of persons at work, for protecting others against risks to health or safety in connection with the activities of persons at work, for controlling the keeping and use and preventing the unlawful acquisition, possession and use of dangerous substances...*” [Emphasis added]. Consequently, all work in the UK has to be considered from the point of view of the risk not only to those engaged in the work but also to those living in the community or who may be exposed to danger as a result of the activity. Parallel considerations apply to the safety of the transport of materials through the community. Enforcement is carried out primarily internally with requirements for risk assessment to be carried out prior to any novel activity -- and in some cases, requiring prior approval from the national authority which may be the Health and Safety Executive or a similar body.

12. The UK Health and Safety at Work Act 1974 sets out four basic provisions:

- (A) *Securing the health, safety and welfare of persons at work;*
- (B) *Protecting persons other than persons at work against risks to health or safety arising out of or in connection with the activities of persons at work;*
- (C) *Controlling the keeping and use of explosive or highly flammable or otherwise dangerous substances, and generally preventing the unlawful acquisition, possession and use of such substances;*
- (D) *Controlling the emission into the atmosphere of noxious or offensive substances from premises of any class prescribed for the purposes of this paragraph.*

It goes on to state that:

(3) For the purposes of this Part risks arising out of or in connection with the activities of persons at work shall be treated as including risks attributable to the manner of conducting an undertaking, the plant or substances used for the purposes of an undertaking and the condition of premises so used or any part of them.

13. In the UK, the implementation of the Health and Safety at Work Act 1974³ requirements in regard to risks relating to employees and to any other persons, whether at work or not, are elaborated in the Management of Health and Safety at Work Regulations 1999⁴ (known as the Management Regulations). The risk assessment provisions of the Management Regulations require that:

Every employer shall make a suitable and sufficient assessment of -

a. the risks to the health and safety of his employees to which they are exposed whilst they are at work; and

b. the risks to the health and safety of persons not in his employment arising out of or in connection with the conduct by him of his undertaking,

They are rather special⁵. They require employers and selfemployed people to assess the risks created by their undertaking so as to identify the measures they need to have in place to comply with their duties under health and safety law. As such, the assessment provisions of the Management Regulations are superimposed over all other workplace health and safety legislation including the general duties in the Health and Safety at Work Act.

14. This makes the Management Regulations risk assessment provisions very wide-ranging and all embracing. They are comprehensive in coverage of places, activities and other sources of hazard. They require any employer to assess all the risks in their workplace. That is, what could cause harm to the employer, their employees (if any) and members of the public, and the likelihood that harm will occur in practice. The employer then needs to decide on the precautions you must take to prevent the harm happening. There is also a requirement to record the results of the assessment as well as to review the assessment should there be any changes in the activity.

³ HMSO, *Health and Safety at Work Act 1974*. Available at: www.healthandsafety.co.uk/haswa.htm

⁴ HMSO, *The Management of Health and Safety at Work Regulations 1999*, Statutory Instrument 1999 No 3242. Available at <http://www.hmso.gov.uk/si/si1999/19993242.htm>

⁵ Health and Safety Executive, *A Guide to Risk Assessment Requirements*, INDG 218, Reprinted 01/04. Available at <http://www.hse.gov.uk/pubns/indg218.pdf>

15. In the case of biological agents, these requirements for risk assessment are further elaborated in the *Control of Substances Hazardous to Health Regulations 2002*⁶ and its associated *Approved Code of Practice and Guidance*⁷ which make it clear that no work shall be carried out which is liable to expose people to any substance hazardous to health unless “a suitable and sufficient assessment of the risk created by that work” has been made. In other words, the risk assessment has to be made first before any work is carried out. It should also be noted that an Approved Code of Practice has a particular status and role which is stated inside the approved code as follows:

This Code has been approved by the Health and Safety Commission, with the consent of the Secretary of State. It gives practical advice on how to comply with the law. If you follow the advice you will be doing enough to comply with the law in respect of the specific matters to which the Code gives advice. You may use alternative methods to those set out in the Code in order to comply with the law.

However, the Code has a special legal status. If you are prosecuted for breach of health and safety law, and it is proved that you did not follow the relevant provisions of the Code, you will need to show that you have complied with the law in some other way or a court will find you at fault.

In other words, if the advice and methods set out in the Code of Practice are followed then the law will be complied with. Alternative methods can be used, but in such circumstances, the onus is on the persons using the alternative methods to demonstrate that they have complied with the law.

16. In the COSHH 2002 Regulations, biological agents are defined as follows:

"biological agent" means a micro-organism, cell culture, or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health;

The guidance makes it clear that:

The definition of a ‘biological agent’ includes:

- a. micro-organisms such as bacteria, viruses, fungi, and the agents that cause transmissible spongiform encephalopathies (TSEs);*
- b. parasites, eg malarial parasites, amoebae and trypanosomes; and*
- c. the microscopic infectious forms of larger parasites, eg the microscopic ova and infectious larval forms of helminthes;*

⁶ HMSO, *The Control of Substances Hazardous to Health Regulations 2002*, Statutory Instrument 2002 No. 2677. Available at <http://www.legislation.hmsso.gov.uk/si/si2002/20022677.htm>

⁷ Health and Safety Executive, *Control of Substances Hazardous to Health (Fourth edition) Approved Code of Practice and Guidance*, 2002.

providing they have one or more of the harmful properties specified in the definition (cause any infection, allergy, toxicity or otherwise create a hazard to human health). Most are infectious but some agents can be harmful in other ways, for example, via the production of toxins or by inducing allergic responses.

In assessing the risks from biological agents, the Code of Practice requires particular consideration of:

- a. the hazard groups of any biological agents that may be present and what form they may be in, eg. Infectious stages or hardy spores;*
- b. how and where they are present, how they are transmitted and the diseases they cause;*
- c. the likelihood of exposure and consequent disease (including the identification of workers and non-workers, eg hospital patients, who may be particularly susceptible, for example because they are immunocompromised), drawing on evidence of the prevalence of infection or other ill effect, as experienced within a particular industry sector or workplace.*

14. These COSHH Regulations also require that steps be taken to ensure that the exposure of his employees to substances hazardous to health is either prevented or, where this is not reasonably practicable, adequately controlled. Moreover, in so far as prevention is concerned, substitution is the preferred solution whereby the employer shall avoid, so far as is reasonably practicable, the use of a substance hazardous to health at the workplace by replacing it with a substance or process which, under the conditions of its use, either eliminates or reduces the risk to the health of his employees.

15. Furthermore, the COSHH Regulations require the prior notification of biological agents. In particular, an employer shall not use for the first time one or more biological agents in Group 2, 3 or 4 at particular premises for any of the following activities:

- a. Research, development, teaching or diagnostic work in laboratories which involves working with a Group 2, Group 3 or Group 4 biological agent or material containing such an agent;*
- b. Working with animals which have been deliberately infected with a Group 2, Group 3 or Group 4 biological agent or which are, or are suspected of being, naturally infected with such an agent; and*
- c. Industrial processes which involve working with a Group 2, Group 3 or Group 4 biological agent.*

unless the Health & Safety Executive has been notified in writing of the intention to do so at least 20 working days in advance, or such shorter period as the Executive may allow and that the Health & Safety Executive has with that notification been provided with the following details:

- a. *The name and address of the employer and the address of the premises where the biological agent will be stored or used;*
- b. *The name, qualifications and relevant experience of any employee of that employer with specific responsibility for the health and safety of his fellow employees;*
- c. *The results of the risk assessment;*
- d. *The identity of the biological agent and, if the agent does not have an approved classification, the Group to which the agent has been assigned; and*
- e. *The preventive and protective measures that are to be taken.*

Before starting work, it is required that an acknowledgement of receipt be received from the Health and Safety Executive.

16. A further requirement is for the notification of the consignment of “*a Group 4 biological agent or anything containing, or suspected of containing, such an agent to any other premises*” or into Great Britain unless the Executive has been notified in writing of the intention to do so at least 30 days in advance.

17. **Analysis.** It is thus clear that in the United Kingdom, there are requirements that **risk assessments** be carried out in regard to the risks to those engaged in the work and to persons other than those at work prior to any work being carried out with biological agents. In addition, the Health and Safety Executive has to be notified before any work with Class 2, 3 or 4 biological agents commences and this notification has to include the results of the risk assessment.

Genetically Modified Organisms

18. The requirements⁸ in the UK for contained activities involving genetically modified organisms (GMOs) are similar in many respects to those for biological agents but include specific additional requirements. These require:

- a. Risk assessment in respect of human health and safety, and environmental protection of all activities involving GMOs.
- b. Establishment of a local genetic modification safety committee to advise on risk assessments for human health and safety and environmental protection relating to activities involving genetically modified microorganisms (GMMs).

⁸ HMSO, *The Genetically Modified Organisms (Contained Use) Regulations 2000*, Statutory Instrument 2000 No. 2831. Available at <http://www.legislation.hmso.gov.uk/si/si2000/20002831.htm>

- c. Advance notification to the Health and Safety Executive of an intention to use a premises for genetic modification for the first time.
 - d. Notification to the Health and Safety Executive of individual activities of classes 2, 3 or 4 involving GMMs. For all class 3 and 4 activities, consents are required before the activity can proceed.
 - e. Notification to the Health and Safety Executive of all individual activities involving genetically modified animals and plants which are potentially more harmful to human health than their non-modified parental organism(s).
19. The definition of genetic modification includes any alteration of the genetic material (DNA or RNA) of an organism using a method that does not occur naturally by mating and/or recombination. It is also made clear that microorganisms include all microorganisms. The requirements for risk assessments require consideration of any potentially harmful effects, the severity and the likelihood of the potential harmful effects. It is specified that the following matters are to be taken into account:
- a. *Any potentially harmful effects, in particular those associated with -*
 - i. *The recipient micro-organism,*
 - ii. *The inserted genetic material (originating from the donor organism),*
 - iii. *The vector,*
 - iv. *The donor micro-organism (where that donor micro-organism is used during the activity involving genetic modification), and*
 - v. *The resulting genetically modified micro-organism;*
 - b. *The characteristics of the activity;*
 - c. *The severity of the potentially harmful effects; and*
 - d. *The likelihood of the potentially harmful effects being realised.*

It is also specified that "potentially harmful effects" include -

- a. *Disease to humans including allergenic or toxic effects;*
- b. *Disease to animals or plants;*
- c. *Adverse effects resulting from the inability to treat disease or offer an effective prophylaxis;*

d. Adverse effects resulting from establishment or dissemination of the genetically modified micro-organisms in the environment;

e. Adverse effects resulting from the natural transfer of genetic material to or from other organisms;

f. Adverse effects resulting from the likely interaction of the genetically modified micro-organism with other organisms at the premises where the activity involving genetic modification is to be conducted.

20. The genetic modification safety committee (GMSC) is required to advise on risk assessments. The committee should represent both management and employees and it is important to include members who will not benefit directly from the decisions of the committee. The committee should have enough members with sufficient knowledge and experience to:

- Understand the risks to both human health and the environment arising from the proposed activity, and the extent to which those risks are uncertain;*
- Judge the adequacy of the risk assessment; and*
- Where appropriate, test its emerging conclusions by discussion so that the advice given is genuinely that of a committee and not an individual.*

Although the statutory purpose is solely to advise on risk assessment, the GMSC can also usefully be involved in ensuring good practice and that there is full discussion with all those concerned, on safety, training and laboratory discipline. Members' local knowledge and expertise can be particularly important. GMSCs are often involved in the formation of local rules and in the consideration of accidents and incidents. It is also made clear that a GMSC may be a subcommittee of a Safety Committee with wider responsibilities at the particular facility or activity.

21. The appropriate composition for a GMSC will depend on local circumstances and may include representatives with some or all of the following functions:

- A Chairman, preferably elected by the committee;*
- Representatives of management with responsibility for the work in genetic modification;*
- Representatives, of all persons having access to the genetic modification facilities or who might otherwise be exposed to genetic modification work, e.g. technical and ancillary staff, students or visiting workers;*
- The Biological Safety Officer ...;*

- Where appropriate, someone to liaise between the GMSC and a main safety committee;

- Co-opted members to supplement internal expertise where necessary, for example on specific viral vectors, medical or environmental considerations. Often these will be from another department, laboratory or outside body.

22. The notifications to be made to the Health and Safety Executive of individual activities of classes 2, 3 or 4 involving GMMs require the provision of considerable detailed information including a copy of the risk assessment. Details about the GMSC must be notified to HSE as part of the notification of first use of premises for genetic modification activities.

23. **Analysis.** It is clear that in the United Kingdom, there are requirements that **risk assessments** be carried out prior to any work being carried out involving genetic modification. A genetic modification safety committee is required to advise on such risk assessments. In addition, the Health and Safety Executive has to be notified of individual activities of classes 2, 3 or 4 involving GMMs. These notifications have to include a copy of the risk assessment. For all class 3 and 4 activities, consents are required before the activity can proceed.

Ethical Review Process

24. A good example in the UK of an existing requirement for an ethical review process is that required in relation to scientific procedures involving animals. The use of animals in scientific procedures is regulated by the Animals (Scientific Procedures) Act 1986⁹, which is widely viewed as the most rigorous piece of legislation of its type in the world. It puts into effect, and in some ways exceeds, the requirements of European Union Directive 86/609/EEC¹⁰ and offers a high level of protection to animals whilst recognising the need to use animals in medical research, the development of new medicines and scientific testing. It also has sufficient flexibility to allow the latest ideas and technology to be taken into account when deciding whether the use of animals is justified. The Act regulates scientific procedures which may cause pain, suffering, distress or lasting harm to "*protected animals*"; it refers to these as "*regulated procedures*". "*Protected animals*" are defined in the Act as all living vertebrate animals, except man, as well as one invertebrate species, the common octopus. The definition includes foetal, larval and embryonic forms which have reached specified stages of development. The Act recognises that scientific procedures can only be permitted when the benefits that the work is likely to bring (to man, other animals or the environment)

⁹ HMSO, *Animals (Scientific Procedures) Act 1986*. Available at <http://www.homeoffice.gov.uk/docs/cop-hcasp.html>

¹⁰ European Communities Council, *COUNCIL DIRECTIVE (86/609/EEC) of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes*. Available at http://europa.eu.int/comm/food/fs/aw/aw_legislation/scientific/86-609-eec_en.pdf

outweigh any pain or distress that the animals may experience, and where there are no alternatives.

25. The UK Act has a three-level licensing system:

- * Those carrying out procedures must hold personal licences, which ensures that those doing the work are qualified and suitable;
- * The programme of work must be authorised in a project licence;
- * Work must also normally take place at a designated user establishment.

As well as controlling the more obvious types of scientific procedures such as the use of animals for toxicity tests, drug development and fundamental research, the Act also covers the breeding of animals with harmful genetic defects, the breeding of genetically manipulated animals, the production of antisera and other blood products and the maintenance of tumours and parasites.

26. It is a requirement also that an ethical review process¹¹, acceptable to the Secretary of State, must be maintained at each designated establishment. This applies to breeding and supplying establishments as well as scientific procedure establishments. The aims of the process are:

- *To provide independent ethical advice to the certificate holder, particularly with respect to project licence applications, and standards of animal care and welfare;*
- *To provide support to named persons and advice to licensees regarding animal welfare and ethical issues arising from their work; and*
- *To promote the use of ethical analysis to increase awareness of animal welfare issues, and develop initiatives leading to the widest possible application of the 3Rs (replacement, reduction and refinement).*

Care was taken by the Home Office to describe the requirement as a ‘process’ rather than as an event or a committee. At establishments engaged in carrying out scientific procedures on animals, the process should be activated when work is at the concept stage, it should inform the planning process, continue once work is in progress, and reflect upon the lessons learned when work has been completed.

27. The ethical review process should allow (where appropriate) the following:-

- 1. Promoting the development and uptake of reduction, replacement and refinement alternatives in animal use, where they exist, and ensuring the availability of relevant sources of information;*

¹¹ Home Office, *The Ethical Review Process*, April 1998. Available at <http://www.homeoffice.gov.uk/docs/erpstatement.html>

2. *Examining proposed applications for new project licences and amendments to existing licences, with reference to the likely costs to the animals, the expected benefits of the work and how these considerations balance;*
3. *Providing a forum for discussion of issues relating to the use of animals and considering how staff can be kept up to date with relevant ethical advice, best practice, and relevant legislation;*
4. *Undertaking retrospective project reviews and continuing to apply the 3Rs to all projects, throughout their duration;*
5. *Considering the care and accommodation standards applied to all animals in the establishment, including breeding stock, and the humane killing of protected animals;*
6. *Regularly reviewing the establishment's managerial systems, procedures and protocols where these bear on the proper use of animals;*
7. *Advising on how all staff involved with the animals can be appropriately trained and how competence can be ensured.*

There should generally be a promotional role, seeking to educate users (in applying the 3Rs (replacement, reduction and refinement)) and non-users (by explaining why and how animals are used), as appropriate. There should be some formal output from the ethical review process for staff and colleagues in the establishment, made as widely available as security and commercial/intellectual confidentiality allow.

28. It is a requirement that a description of the proposed local ethical review processes must be agreed with the Home Office and any substantial changes may only be made with the knowledge and consent of the Secretary of State. It is also required that certificate holders, or their nominees, are required to countersign each request for a project licence confirming that the application has completed the local ethical review process and that suitable facilities will be made available. This signifies that corporate consideration has been given to the proposals and that the certificate holder has mobilised the expertise and advice available within and to the establishment. It is for the certificate holder to decide whether to countersign the proposal and thereby to support the application going forward to the Home Office. It is also required that details of the ethical review process and records of the outputs from the process shall, on request, be submitted to the Secretary of State or made available to an Inspector.

29. A review¹² of the Ethical Review Process was carried out by the Home Office in 2001 which concluded that in regard to the aim of the process *to provide independent*

¹² Home Office, *Review of the 'Ethical Review Process' in establishments designated under the Animals (Scientific Procedures) Act 1986*, November 2001. Available at <http://www.homeoffice.gov.uk/docs/erpreview.html>

advice to the certificate holder, particularly with respect to project licence applications and standards of animal care and welfare that:

- The existence, support and advice of ERPs have provided reassurance to certificate holders in the discharge of their responsibilities.*
- Many certificate holders now have a greater awareness of ethical, scientific and animal welfare issues, and of the work done in their establishments.*
- ERP has provided the stimulus for people to come together at a local level to focus specifically on matters relating to compliance with both the letter and spirit of the legislation and on issues relating to animal welfare.*
- ERP has raised the profile of ethics, animal welfare and the 3Rs, particularly with respect to local issues.*
- The discipline of an ERP has made some project licence holders/applicants more critical of their research and more aware of its implications for animal welfare throughout the duration of the programme of work.*
- The ERP has facilitated better communication between named persons (NVSs and NACWOs) and scientists, providing a better framework for the provision of expert advice to animal users, and a raised awareness of 'animal issues' within the establishment.*
- Lay members of ERPs have asked questions from a different perspective. They have constructively challenged existing assumptions and practices, with the result that improvements have been made with respect to licence applications and animal care and use.*
- ERPs have created a culture, or enhanced pre-existing cultures, in which continual, critical evaluation of costs and benefits, and implementation of best practice are 'second nature' to everyone involved in animal use.*

30. Analysis. The requirements are thus that any new application for a project license involving animals has to be subject to an **ethical review process** before that application will be formally considered by the Home Office who approve all licence applications. It is consequently a process which has to be carried out regularly whenever consideration is being given to a new project. It provides a good example of how an ethical review process can be devised which is part of the normal business of an organisation engaged in such work.

International Considerations

31. The previous sections have analysed the situation in the United Kingdom. However, the objective is to achieve an international strengthening of the Biological and Toxin Weapons Convention so consideration needs to be given to the international parallels to the laws and regulations that apply in the UK.

32. The various regulations in the UK relating to health and safety are consistent with the comparable EU regulations. In particular, the European Directive (98/24/EC)¹³ *Protection of the health and safety of workers from the risks related to chemical agents at work* and Directive (2000/54/EC)¹⁴ *Protection of workers from risks related to exposure to biological agents at work* set out the requirements for the determination and assessment of risks in a comparable way to that elaborated in the UK national regulations and codes of practice. In a similar way, the European Directive (98/81/EC)¹⁵ sets out the requirements for the contained use of genetically modified microorganisms and for the provision of risk assessments in a comparable way to that elaborated in the UK national regulations and code of practice. Likewise, the UK regulations for scientific procedures in animals are consistent with the European Directive (86/609/EEC)¹⁶ *on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes*.

33. In looking to the wider international scene, it is recognized that following the adoption of the Convention on Biological Diversity (CBD)¹⁷, the United Nations Environmental Programme had followed a twin track approach towards biosafety with the adoption of the UNEP International Technical Guidelines for Safety in Biotechnology in December 1995 to serve as an interim mechanism pending the agreement of the Protocol on Biosafety to the Convention on Biological Diversity. The Technical Guidelines could facilitate the development of national capacities to assess and manage biotechnology risks, the establishment of adequate information systems; and the development of human resources and relevant expertise pertinent to issues of biosafety at the national and regional levels. The second meeting of the Conference of the Parties to

¹³ European Council, *COUNCIL DIRECTIVE 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work*, Official Journal of the European Communities, L131/11, 5 May 1998. Available at http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_131/l_13119980505en00110023.pdf

¹⁴ European Council, *DIRECTIVE 2000/54/EC OF THE EUROPEAN PARLIAMENT AND COUNCIL of 18 September 2000 on the protection of the health and safety of workers from the risks related to exposure to biological agents at work*, Official Journal of the European Communities, L262/21, 17 October 2000.

¹⁵ European Council, *COUNCIL DIRECTIVE 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms*, Official Journal of the European Communities, L330/13, 5 December 1998. Available at http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_330/l_33019981205en00130031.pdf

¹⁶ European Communities Council, *COUNCIL DIRECTIVE (86/609/EEC) of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes*. Available at http://europa.eu.int/comm/food/fs/aw/aw_legislation/scientific/86-609-eec_en.pdf

¹⁷ United Nations Environment Programme, *The Convention on Biological Diversity*, Available at: <http://www.biodiv.org/convention/articles.aspH>

the CBD further noted in its decision II/5 that the UNEP Guidelines, without prejudice to the development of a protocol, could be used to complement it after its conclusion.

34. The UNEP International Technical Guidelines for Safety in Biotechnology¹⁸ contain a section on “Assessment and Management of Risks”. This sets out that an assessment of the risks to human health and the environment associated with the use of organisms with novel traits is based on consideration of the following key parameters, when applicable:

i. The characteristics relating to the organism with novel traits, taking into account:

- *The recipient/parental or host organism;*
- *The relevant information on the donor organism and the vector used;*
- *The insert and the encoded trait;*
- *The centre of origin, when known.*

ii. The intended use, i.e. the specific application of the contained use or deliberate release or placing on the market, including the intended scale and any management procedures and waste treatment;

iii. The potential receiving environment.

An Appendix gives examples of points that need to be considered in a risk assessment and includes the following advice:

The objective of risk assessment is to answer questions related to:

- *Identifying any hazards: what are the hazards, if any?*
- *Assessing the risks: if a hazard has been identified, what is the combined effect of the consequences and the likelihood of the hazard being realized? Can these be estimated?*
- *Managing the risks: To what extent can the risks be managed? Where indicated by the results of the risk assessment, either by applying adequate management strategies, including designing procedures and methods to minimize risks and their consequences, or by deciding not to proceed. Management strategies should be commensurate with the results of the risk assessment*
- *How do any identified risks compare with the risks that would be posed by the use, instead, of an organism not covered by these guidelines, if this is possible, or with risks that might be posed by doing nothing.*

¹⁸ United Nations Environment Programme, *UNEP International Technical Guidelines for Safety in Biotechnology*, December 1995. Available at: <http://www.biosafetyprotocol.be/UNEPGuid/Contents.html>

The impacts to be considered include those on human health, agricultural production, other organisms and the quality of the environment.

Full regard should be paid to the experience gained and to the relevant literature and consultation with available experts and public authorities.

The level of risk can be minimized either by applying risk-management strategies or by deciding not to proceed with the intended use of the organism with novel traits.

35. The Cartagena Protocol on Biosafety¹⁹ includes an Article 15 entitled Risk Assessment which states that:

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Annex III to the Protocol sets out in some detail what is involved in a Risk Assessment which includes the various points made in the UNEP International Guidelines. Annex III sets out that

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

a. An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

b. An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

¹⁹ United Nations Environment Programme, *Cartagena Protocol on Biosafety*. Available at: <http://www.biodiv.org/biosafety/protocol.asp>

c. An evaluation of the consequences should these adverse effects be realized;

d. An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

e. A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

f. Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

It is also made clear that a point to be considered in the risk assessment is “(g) **Information relating to the intended use.** Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms;”

36. **Analysis.** It is evident that **risk assessment** is required to be carried out extensively not only within the European Union but also globally under the UNEP International Guidelines adopted in 1995 and the Cartagena Protocol on Biosafety, which entered into force on 11 September 2003 and, as of 15 November 2004, has 110 States Parties. Such risk assessments are to evaluate the potential adverse effects on the environment taking into account risks to human health and taking into consideration, information relating to the intended use.

Towards a Code of Conduct for the Life Sciences

37. The previous sections have shown that the health and safety at work requirements in the UK require that **risk assessments** be carried out prior to any activities being carried out in regard to both persons at work and to persons other than persons at work. There are specific requirements detailed relating to the risk assessment of biological agents with prior notification of the Health and Safety Executive being required prior to first use of biological agents in Groups 2, 3 or 4. It is also shown that for work involving the genetic modification of microorganisms, there has to be a Genetic Modification Safety Committee which has to be able to give advice on the risk assessment of proposed new activities prior to such activities being carried out. Again there is a requirement to notify the Health and Safety Executive of individual activities in classes 2, 3 or 4 involving GMMs; copies of the risk assessment form part of these notifications.

38. The Ethical Review Process in relations to scientific procedures carried out on animals shows how a *process* requiring consideration of various ethical aspects can be carried out in such a way as to apply to all work of a particular type with a requirement that this process has been carried out before a formal application is submitted to the Home Office for approval of any new project.

39. There are thus already in the UK various procedures which could form the basis for an ethical process for the review of new projects in the life sciences. Judgments would need to be made as to the extent to which such an ethical process was subject to independent review or checking by a government authority or agency. The general approach in the UK in many areas of regulation – such as health and safety, genetic modification and quality control is through self regulation by the body carrying out the activity with the government authority having the right to review periodically the evidence that such self regulated activities have been carried out competently and effectively.

40. It is suggested that the ethical consideration of new projects in the life sciences could be **added** without any undue additional burden to the **risk assessments** that are already required by law in regard to health and safety of both persons at work and of other persons not at work – *the risks to the health and safety of persons not in his employment arising out of or in connection with the conduct by him of his undertaking*. After all, the principal concern that is behind the consideration of a code of conduct for the life sciences is that the work is not such that it is in breach of the prohibitions of the Biological and Toxin Weapons Convention with its central obligation in Article I that:

Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:

(1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

41. It is therefore suggested that the aim to ensure that activities involving *microbial or other biological agents, or toxins whatever their origin or method of production* are only *of types and in quantities that have justification for prophylactic, protective or other peaceful purposes* – are closely related to the health and safety requirement to assess the *risks ... arising out of or in connection with the conduct by him of his undertaking* and would appear to offer the prospect of being fairly easily integrated into an overall slightly wider consideration of health and safety. The modest extension which would be required in the hazard assessment relating to health and safety could simply relate to whether the proposed activity was **lawful** or not, with the term lawful embracing compliance with national obligations (implemented in national legislation) arising from the Biological and Toxin Weapons Convention. There would be merit when considering

such an extension to consider making it comprehensive so that it would embrace not only obligations relating to biological and toxin weapons but also to obligations relating to chemical weapons and proscribed drugs.

42. As the results of risk assessments are required to be provided to the Health and Safety Executive in regard to the notification of the first use of biological agents in Groups 2, 3 and 4 and copies of the risk assessment are to be provided to the Health and Safety Executive in regard to notifications of class 3 or class 4 activities involving genetic modification of microorganisms, the Health and Safety Executive would be able to ensure that these risk assessments had included consideration of whether it was lawful and consistent with the ethical considerations associated with ensuring that the prohibitions of the BTWC were not jeopardized.

A working assumption

43. It is useful at this stage to make a working assumption that the aims set out in paragraph 3 – namely, to ensure that activities involving *microbial or other biological agents, or toxins whatever their origin or method of production* are only of types and in quantities that have *justification for prophylactic, protective or other peaceful purposes* – are integrated into the implementation of health and safety – and to examine how well such an assumption would work from a practical point of view both nationally and internationally. First of all, the extension of the hazard assessment review process to include consideration of whether the proposed activity is lawful in respect of the obligations of legislation such as the Biological Weapons Act 1974, the Chemical Weapons Act 1996 and the corresponding proscribed drugs legislation would not be regarded as contentious by any of those concerned. It would rather be seen as a statement of the obvious and common sense. In other words, there would be considerable added value for very little additional effort in the existing process to review the health and safety aspects of proposed activities.

44. Looking at the international scene, it is clear that **risk assessments** are carried out in countries around the world and consequently the parallel argument to that which applies nationally in the UK would certainly apply throughout the expanded European Union. All of these countries share the common goals of ensuring effective implementation of the international treaties prohibiting chemical and biological weapons and those addressing proscribed drugs. In the wider international perspective, it is increasingly clear, as shown by the UNEP International Guidelines and the Cartagena Protocol on Biosafety, that countries around the world are concerned that activities in their countries are carried out safely and do not present a risk either to the workers engaged in such activities or to those who may be put at risk as a result of those activities. The adoption of the broader approach advocated here would appear to have much to be said for it in every country.

Conclusions

45. A code of conduct or practice that is uniquely focussed on the Biological and Toxin Weapons Convention is unlikely to attract the widespread national or international support that is essential if it is to be effective. Such an approach raises the question of what is the added value and how much effort has to be directed to gaining this added value. It should not be forgotten that the States Parties to the BTWC have long agreed politically in the Final Declarations of their successive Review Conferences -- from the Second Review Conference in 1986 onwards -- that:

The Conference notes the importance of:

- *legislative, administrative and other measures designed effectively to guarantee compliance with the provisions of the Convention within the territory under the jurisdiction or control of a State Party,*
- *legislation regarding the physical protection of laboratories and facilities to prevent unauthorised access to and removal of pathogenic or toxic material, and*
- *inclusion in textbooks and in medical, scientific and military educational programmes of information dealing with the prohibition of bacteriological (biological) and toxin weapons and the provisions of the Geneva Protocol*

and believes that such measures which States might undertake in accordance with their constitutional process would strengthen the effectiveness of the Convention.

If one considers the extent to which the third sub item has been accomplished by two of the Depositary States -- the UK and the US -- it is evident that the prospects for an effective code of conduct or practice based on similar language is slim indeed. For this reason, it is argued that an **integrated** approach should be pursued which brings significant **added** value to **all** States Parties in return for very **little** additional effort. Such an integrated approach can be readily achieved through a slight broadening of the considerations regarding health and safety that are already carried out to an increasing extent in countries around the world.

46. It is concluded a practical approach towards a code of conduct for the life sciences would be to slightly widen the **existing** requirements in **codes of practice** for the carrying out of **risk assessments** for biological agents and genetically modified microorganisms. It is evident that such codes of practice **already** require that risk assessments address not only the risks to those engaged in the activity but also to those not engaged in the activity and to the environment. Consequently, the **slight** extension to consider whether the activity presents a risk to the prohibitions enshrined in the Biological and Toxin Weapons Convention -- namely, to ensure that activities involving *microbial or other biological agents, or toxins whatever their origin or method of production* are only of types and in

quantities that have justification for prophylactic, protective or other peaceful purposes – in a code of practice would provide an effective strengthening of the BTWC prohibition regime. It would ensure that appropriate consideration was given to this aspect at the outset of each new activity and that such consideration carried out as part of the process of making a **risk assessment**. It is also recognised that this approach could readily be extended to embrace the comparable considerations relating to the Chemical Weapons Convention as well as to the international conventions relating to proscribed drugs²⁰.

47. The approach proposed here would be cost effective as the value added by the regular consideration of the BTWC prohibitions in the carrying out of **risk assessments** would add very little to the burden already required under health and safety legislation for the carrying out of risk assessments. It is clearly in the interests of all States Parties to the BTWC to take steps nationally to incorporate consideration of whether a proposed activity presents a risk to the prohibitions enshrined in the BTWC into their national processes and **codes of practice for carrying out risk assessments**.

²⁰ For an account of the anti-doping conventions see Graham S. Pearson, *Further Chemical Control Regimes: Anti-Doping*, CBW Conventions Bulletin, Issue No. 57, September 2002. Available at: <http://www.sussex.ac.uk/Units/spru/hsp/pdfbulletin.html>