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4

Regulating New Technologies: EU Internal Market Law, Risk, and Socio-Technical Order

*Mark L. Flear**

1. Introduction

New and innovative technologies appear in the news on a daily basis and encompass ‘red’ and ‘green’ technologies,¹ information and communications technology, and those that have largely yet to become a reality such as nanotechnology.² New technologies have the potential to meet pressing public needs such as growing sufficient or more nutritious food or the treatment of persistent or rare diseases (or indeed meeting private desires for new products and services). But they also give rise to concerns that science and technology are moving forward at such a fast pace that law and morality seemingly find it hard to keep pace, connect, and regulate. These concerns are reflected in much scholarly discussion on new technologies.³

In this chapter I challenge the latter account by arguing that, more than playing catch up with and being determined by technoscientific innovation, law also plays a leading role in the regulation of new technologies by variously orchestrating, orienting, shaping, and directing the conditions of possibility for their development and market availability.⁴ Specifically, I chart some of the main ways in

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¹ ‘Red’ new technologies intervene in human biology whereas so-called ‘green’ new technologies intervene in the environment.

² McHale, ‘Nanomedicine and the EU: Some Legal, Ethical and Regulatory Challenges’, 16(1) *Maastricht Journal of European and Comparative Law* (2009) 65.

³ For an overview see Brownsword, ‘So What Does the World Need Now? Reflections on Regulating Technologies’, in R. Brownsword and K. Yeung (eds), *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (2008).

⁴ In this sense internal market law is understood as part of and integrated within, while also being underpinned by, that which determines the conduct of conduct or what Foucault termed Regulating New Technologies: EU Internal Market Law, Risk, and Socio-Technical Order, First Edition, Mark L. Flear © Mark L. Flear 2017. Published 2017 by Oxford University Press

which European Union (EU) internal market law retains its regulatory capacity and efficacy by centralizing the harms or hazards relating to product safety as ‘the’ risks posed by new technologies through complementary techniques of negative integration and positive integration. I explain how the centralization of this notion of risk in EU-level regulation has several linked purposes and consequences. In particular, designing regulation and limiting the understanding of risk (through it) marginalizes and obscures other kinds of harms or hazards to which risk might pertain (be they physical, environmental, social, economic, moral, or political), as well as alternative (and probably wider) understandings of risk and framings of regulation (such as by human rights and bioethics, both of which are particularly prominent and important discourses in relation to new technologies—as underlined in my own work and that of others, both noted later in the chapter). The current regulatory design also depoliticizes and naturalizes the approach taken and its related (de)prioritizations of norms, values, and ends⁵—and this in turn helps to quell contestation about the focus and direction of scientific and technological development.⁶

In making that argument I point out how the focus and operation—and therefore the continued salience—of internal market law to risk regulation and its shaping of technoscientific trajectories relates to the EU’s broader strategic priorities. In these priorities new technologies are useful to the generation of a competitive and innovative market-based economy, and through it the construction and legitimation of the EU’s identity, socio-technical order and ultimately the project of European integration.⁷ The discussion in this chapter therefore adds to extant scholarly discussion of new technologies, including that within this collection. Others have looked at certain categories of new technologies⁸ or centralized alternative actors or concerns.⁹ My own work has examined aspects of EU positive integration techniques in relation to new health technologies¹⁰ and has brought together scholars from law and cognate disciplines to reflect on specific

‘governmentality’. See M. Foucault, *Power, Essential Works of Foucault 1954–1984, Volume 3* (2002), esp. ‘Governmentality’.

⁵ Depoliticization refers to the way in which the construction of governance and regulatory arrangements is masked, which means that they appear instead as natural occurrences. For discussion see W. Brown, *Regulating Aversion: Tolerance in the Age of Identity and Empire* (2006), at 15.

⁶ For reflection on the ongoing relevance of EU law, see, e.g., T. Tridimas, *European Union Law for the Twenty-First Century: Volume 1: Rethinking the New Legal Order* (2004).

⁷ For a similar argument on the relationship between law and identity, see Harding, ‘The Identity of European Law: Mapping Out the European Legal Space’, 6 *European Law Journal* (2000) 128.

⁸ S. Fovargue, *Xenotransplantation and Risk: Regulating a Developing Biotechnology* (2011); M. Lee, *EU Regulation of GMOs: Law and Decision-Making for a New Technology* (2008). Within this collection see Chapter 2.

⁹ F. Francioni (ed.), *Biotechnologies and International Human Rights* (2007); T. Murphy (ed.), *New Technologies and Human Rights* (2009). Within this collection see Chapters 3, 5, and 7.

¹⁰ Bache, Flear, and Herve, ‘The Defining Features of the European Union’s Approach to Regulating New Health Technologies’, in M. L. Flear *et al.* (eds), *European Law and New Health Technologies* (2013); Flear, ‘Clinical Trials Abroad: The Marketable Ethics, Weak Protections and Vulnerable Subjects of EU Law’, in A. Albers-Llorens *et al.* (eds), *Cambridge Yearbook of European Legal Studies, Volume 16 2013–2014* (2014); M. L. Flear, *Governing Public Health* (2015), esp. chs

examples.¹¹ In wider EU legal scholarship there has been a focus on negative integration, but it has given little attention to new technologies as a specific case study, or the joint workings of positive and negative integration techniques in that field. This chapter is therefore the first attempt to provide a comprehensive overview of those joint workings in the field of new technologies. It is also the first attempt to discuss how those specific techniques relate to the European integration project.

The argument I put forward in this chapter is built and advanced in the following way. In Section 2 I situate law within the EU's wider governance and in particular the programmatic concerns found in the EU's overarching architecture.¹² This is the starting point for explaining how EU internal market law comes to be concerned with the regulation of technological risk.¹³ In particular, it is by attention to the EU's programmatic concerns that it becomes clearer how the tightening relations between new technologies and internal market law not only demonstrate the EU's role in risk regulation but also the broader use and significance of that involvement. Subsequently, I deepen the analysis in two moves, first, in Section 3, by outlining the three key regulatory principles underpinning the negative integration mode of internal market law. The first principle is a focus on removing restrictions to free movement that subjects almost any national measures to scrutiny, supplemented by the second principle, which is that of mutual recognition. The final principle is the justification of national measures subject to a proportionality assessment, which actually operates to constrain the type, scope, and nature of permissible risk regulation at Member State level, albeit not yet so far as to narrow it to product safety.

In the course of the discussion on regulatory principles, the link with the positive integration mode of internal market law is made and this is elaborated in Section 4 through the second move that aims to deepen the analysis.¹⁴ In addition to legislation adopted under Article 114 of the Treaty on the Functioning of

2, 7, and 8; Flear, 'The EU Clinical Trials Regulation: Key Priorities, Purposes and Aims and the Implications for Public Health', 42 *Journal of Medical Ethics* (2016) 192.

¹¹ See, esp. the other chapters in M. L. Flear *et al.* (eds), *European Law and New Health Technologies* (2013).

¹² This chapter is therefore focused on the EU's regulatory order, which is one level of the multilevel system of governance. Within that system the EU level interacts with a range of other regulatory orders including those at the national level. See further L. Hooghe and G. Marks, *Multilevel Governance and European Integration* (2001).

¹³ Black's definition of regulation is 'the intentional use of authority to affect behaviour of a different party according to set standards, involving instruments of information-gathering and behaviour modification' (Black, 'Critical Reflections on Regulation', 27 *Australian Journal of Legal Philosophy* (2002) 1). As suggested earlier, I understand regulation as part of governmentality. Negative integration is deregulatory in the sense that it disapplies national laws that are deemed unjustifiably restrictive of free movement. But negative integration is also regulatory in that the disapplication of incompatible national laws affects the behaviour of market actors.

¹⁴ For further discussion of positive and negative integration see C. Barnard, *The Substantive Law of the EU: The Four Freedoms* (5th edn, 2016), chs 1 and 16; Scharpf, 'Negative and Positive Integration in the Political Economy of European Welfare States', in G. Marks *et al.* (eds), *Governance in the European Union* (1996).

the European Union (TFEU) positive integration is facilitated through several other kinds of supplementary regulatory techniques, including soft law, guidance, ‘steering’ through funding, and reliance on intellectual property rights. The first of these techniques pre-empts Member State responses to the regulation of technological risk only to some extent. The other techniques work with legislative harmonization under Article 114 TFEU in order to extend the reach of EU-level regulation—including its normative orientation, understanding, and framing of ‘risk’—but without pre-emptive effects (indeed, EU funding is founded on legal bases that preclude such effects).¹⁵ Taken together these techniques of positive integration promote uniformity in technoscientific development trajectories within the EU. The techniques narrow the meaning and framing of technological risk to being principally about product safety at different stages of product development and ultimately marketing within the internal market. At the same time the techniques bracket off and marginalize the other kinds of harms or hazards to which risk might pertain. These processes of centralization and marginalization in turn help to serve broader programmatic priorities and aims, most importantly for this chapter, the production, stabilization, anchoring, and legitimation of the EU’s identity, socio-technical order, and project of integration. I consider the techniques of negative and positive integration in terms of their role in the development of new health technologies from an idea through to circulation in the internal market.

To keep the chapter manageable, the discussion is limited in several ways. The chief limitation is a focus on just one category of new technologies; those related to health, or new health technologies (NHTs). A focus on novel and innovative *health* technologies is useful in that it underscores the weakness of Article 168 TFEU, the EU’s legal competence in the public health field, which is an area of supporting, coordinating, or supplementary competence under Article 6(a) TFEU, and essentially permits limited action in order to tackle serious cross-border threats to health. Although Article 168(5) TFEU provides that the EU legislature may ‘adopt incentive measures’ that are designed to, inter alia, ‘protect and improve human health and in particular to combat the major cross-border health scourges’, this specifically excludes ‘any harmonization of the laws and regulations of the Member States’.¹⁶ As we shall see later in this chapter, Article 114 TFEU provides far greater scope for the adoption of harmonization measures and these must

¹⁵ Noted later in this chapter. Further consideration of pre-emption, and its relationship with the supremacy of directly effective EU law, is beyond the scope of this chapter. The relevant Treaty provisions (and applicable secondary legislation) discussed later in this chapter are (in the absence of specific decision by the CJEU arguably) directly effective (Case 26/62, *Van Gend & Loos*, [1963] ECR 1 (ECLI:EU:C:1963:1)) and therefore take precedence over conflicting national laws and administrative practices (Case 11/70, *Internationale Handelsgesellschaft*, [1970] ECR 1125 (ECLI:EU:C:1970:114); Case 106/77, *Simmmenthal SpA*, [1978] ECR 629 (ECLI:EU:C:1978:49)). For a discussion of these doctrines and their relationship to pre-emption, see S. Douglas-Scott, *Constitutional Law of the European Union* (2002), at 169–171.

¹⁶ In addition, Art. 168(7) TFEU provides the responsibility of the Member States for the ‘definition of their health policy and for the organization and delivery of health services and medical

relate to the establishment and functioning of the internal market. The weakness of Article 168 as compared to Article 114 helps to explain the continuing salience of internal market law to new technologies as well as how that in turn facilitates the achievement of the EU's broader programmatic priorities and aims (although, as we shall see, in at least one instance—clinical trials—internal market legislation gains support from Art. 168).

NHTs are not a single category in EU law. The Patients' Rights Directive is the only piece of legislation that refers to 'health technologies', identifying them as including medicinal products, medical devices, or medical and surgical procedures as well as measures for disease prevention, diagnosis, or treatment used in healthcare.¹⁷ Elsewhere EU marketing legislation distinguishes between 'medicinal products'¹⁸ and 'medical devices'.¹⁹ A range of sub-categories exist—encompassing 'biotechnology medicine', 'biotechnology-derived pharmaceutical',²⁰ 'advanced therapy medicinal products' (ATMPs),²¹ and

care' is respected. Legislation under Art. 114 TFEU and Art. 168 TFEU is adopted using the ordinary legislative procedure set out in Art. 294 TFEU.

¹⁷ Art. 3(1) Directive 2011/24/EU on the Application of Patients' Rights in Cross-Border Healthcare, OJ 2011 L 88/45.

¹⁸ Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, OJ 2001 L 311/67 (Community code (as amended)), has two limbs to its definition of 'medicinal product'. These are medicinal product by 'presentation' ('any substance or combination of substances presented for treating or preventing disease in human beings'—Art. 1(2) Community code) and by 'function' ('any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis').

¹⁹ Defined by Directive 93/42/EEC Concerning Medical Devices, OJ 1993 L 169/1 to include 'any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings' for one or more of several purposes. Art. 1(2) provides that these purposes are: 'diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; [or] control of conception'. To fall within this definition, the device must 'not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means', but it 'may be assisted in its function by such means'.

²⁰ The terms 'biotechnology medicine' or 'biotechnology-derived pharmaceutical' are generally used (EMA, *S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals*, CHMP/ICH/302/95) to cover the medicines derived from the processes listed in section 1 of the Annex (recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, hybridoma, and monoclonal antibody methods) to Regulation (EC) 726/2004 Laying Down Community Procedures for the Authorization and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency, OJ 2004 L 311/67.

²¹ ATMPs are still classed as medicinal products and are included in section 1a of the Annex to Regulation (EC) 726/2004, *ibid*. The definition of ATMPs, under Regulation (EC) 1394/2007 on Advanced Therapy Medicinal Products and Amending Directive 2001/83/EC and Regulation (EC) 726/2004, OJ 2007 L 324/121, includes gene therapy medicinal products, somatic cell therapy medicinal products, tissue-engineered products, and combined ATMPs. It appears that only

‘nanomedicine’²²—and the ensuing discussion refers to all of these categories (some of which are not especially ‘new’²³).

A key reason for the focus on NHTs is the need to provide a sufficiently detailed discussion and analysis of the complementary techniques of negative integration and positive integration in order to make the chapter’s core argument. As such the discussion does not provide a detailed substantive analysis of the application of internal market law to specific NHTs or other new technologies.²⁴ In addition, some legislation that is obviously centrally related to technological risk (and not simply product safety matters), such as the so-called REACH legislation,²⁵ and which is applicable to some new technologies, is not discussed because it is not applicable to NHTs.²⁶ Other areas of law that are only very indirectly related to the regulation of NHTs and technological risk, such as competition law, are also not discussed.²⁷

There is a related limitation in terms of what is included in the discussion on positive integration techniques. The analysis does not encompass all applicable EU legislation or indeed all techniques of positive integration. Instead, the discussion focuses on some of the most important techniques clustered around particular types of regulatory activity from the inception of an idea through to its development and ultimately marketing in the internal market: stimulating and steering innovation through funding; intellectual property law and the fostering of technological development; regulating research processes; and finally product

one ATMP has been authorized by the EMA, ChondroCelect (this is a tissue-engineered product for which TiGenex gained EU marketing authorization on 5 October 2009). For discussion, see Mahalatchimy, ‘Access to Advanced Therapy Medicinal Products in the EU: Where Do We Stand?’, 18 *European Journal of Health Law* (2011) 305.

²² EMA, *Reflection Paper on Nanotechnology-Based Medicinal Products for Human Use*, EMEA/CHMP/79769/2006, uses the term ‘nanomedicinal product’. Moreover see Dorbeck-Jung *et al.* (eds), ‘Governing Nanomedicine: Lessons from within, and for, the EU Medical Technology Regulatory Framework’, 33 (Special Issue 2) *Law and Policy* (2011) 215–303.

²³ E.g. recombinant insulin and growth hormone (defined as ‘biotechnology medicines’) have been on the market in the EU since the 1980s.

²⁴ For examples, see N. Hoppe, ‘Human Tissue-Derived Health Products: The Problems of EU Law’ and B. Dorbeck-Jung, ‘Therapeutic Nanoproducts as Drivers of Legal Governance Innovation in the European Union’, both in Flear *et al.* (eds), *supra* note 11.

²⁵ Regulation (EC) 1907/2006 Concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency, Amending Directive 1999/45/EC and Repealing Regulation (EEC) 793/93 and Regulation (EC) 1488/94 as well as Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ 2006 L 136/3; Directive 2006/121/EC Amending Directive 67/548/EEC on the Approximation of Laws, Regulations and Administrative Provisions Relating to the Classification, Packaging and Labelling of Dangerous Substances in order to Adapt it to Regulation (EC) 1907/2006 Concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and Establishing a European Chemicals Agency, OJ 2006 L 136/281.

²⁶ See Art. 2(5)(a) Regulation (EC) 1907/2006, *ibid.*, which states that the REACH legislation does not apply to the extent that a substance is used in medicinal products and Art. 2(6), which states that it does not apply to medical devices, covered by the *leges speciales* discussed in this chapter.

²⁷ E.g. anti-monopoly laws can determine the feasibility of research into NHTs, see Hancher, ‘The EU Pharmaceuticals Market: Parameters and Pathways’, in E. Mossialos *et al.* (eds), *Health Systems Governance in Europe: The Role of EU Law and Policy* (2010).

safety as a continuing concern.²⁸ The techniques falling within these types of activity (which are to some extent overlapping and mutually supportive) are most directly related to regulating technological risk instantiated as product safety or supporting those efforts in order to optimize the internal market. The techniques deployed at these points of technoscientific development and market availability demonstrate and highlight the continuing importance of internal market law to the regulation of new technologies.

Overall, in what follows I underline the way in which internal market law continues to play a leading role in the regulation of new and innovative technologies. In reflection on this core finding, in Section 5 I point to a concern that has seemingly been overlooked in extant legal scholarship on new technologies. That is, I highlight the (re)alignment, (re)configuration, and (re)orientation of EU law to and within market-oriented norms, values, and rationalities that shape technoscientific innovation and trajectories. I suggest that this can in turn be explained by the way in which EU law and innovation are increasingly tied to the pursuit and legitimation of the EU's project of European integration. In short, EU law is connecting with and shaping new technologies, but its focus on product safety is about increasing market availability and through it producing a particular market-oriented identity for the EU, rather than meeting pressing health needs.

2. Internal Market Law, the Regulation of Technological Risk, and the Programmatic Level of Governance

Internal market law remains of central importance to the EU's regulation of new technologies—and that in turn relates to and facilitates the EU's broader programmatic priorities. The internal market is defined by Article 26(2) TFEU as 'an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured'.²⁹ New technologies fall principally within the free movement of goods.³⁰ Moreover, the internal market is described as '*one of the pillars of the European Union*' and it is situated within the EU's overarching

²⁸ There are seven broad types: funding; protection of intellectual property; regulation of research processes; data protection; marketing and product safety legislation; post-market monitoring and surveillance, and product liability; and pricing, reimbursement, and coverage in national healthcare systems. The selection is drawn from and reorganizes material from across these types. See further Bache, Flear, and Hervey, 'The Defining Features of the European Union's Approach to Regulating New Health Technologies', in Flear *et al.* (eds), *supra* note 11.

²⁹ The establishment of the internal market is required by Art. 3(3) Treaty on European Union (TEU).

³⁰ Arts 28–36 TFEU. E.g. pharmaceuticals are a good for these purposes, i.e. 'products which can be valued in money and which are capable, as such, of forming the subject of commercial transactions' (Case 7/68, *Commission v. Italy (Art Treasures case)*, [1968] ECR 423 (ECLI:EU:C:1968:51)). Goods must also 'possess tangible physical characteristics' (Advocate General Fennelly in Case C-97/98, *Jägerskiöld v. Gustafsson*, [1999] ECR I-7319 (ECLI:EU:C:1999:515)). So, the organization of lotteries does not constitute an activity relating to goods (Case C-275/92, *Customs Excise v. Schindler*, [1994] ECR I-1039 (ECLI:EU:C:1994:119)).

architecture and objectives that are reflective of its imagined socio-technical order and directed at perpetuating its integration project: '[t]he internal market is essential for prosperity, growth and employment in the EU, contributing to the achievement of its objectives under the Lisbon strategy. As an integrated, open and competitive area, it in fact promotes mobility, competitiveness and innovation, interacting in particular with the EU sectoral policies'.³¹

Under the Lisbon Strategy³² research was presented as 'the driver for the production and exploitation of knowledge [making it] above all a linchpin in the implementation of the Lisbon strategy to make Europe the most dynamic and competitive, knowledge-based economy in the world, capable of sustaining economic growth, employment and social cohesion'³³ by 2010. EU funding of projects in new technologies, especially in relation to research and development was, and as I discuss later continues to be, seen as integral to the creation of a European Research Area, which aims to 'reinvigorate research in Europe',³⁴ and is linked to the Lisbon Strategy as part of the so-called 'knowledge triangle' of research, education, and innovation.³⁵ Importantly, while EU funding is limited by the principle of 'European added value',³⁶ it is directed at enabling discourse between researchers in different Member States in order to foster economic competitiveness of European industry, and integration.³⁷

The Lisbon Strategy was subsequently refocused on growth and jobs,³⁸ linking research and development of new technologies even more closely to the central goal of economic optimization. In 2010 this refocusing was intensified in the light of the recent global (and European) financial and economic crisis in the European Commission's 'Europe 2020' strategy for economic growth.³⁹ Further, references to health in Europe 2020 bolster the link between it and the economy.

³¹ *Internal Market: General Framework*, available at http://europa.eu/legislation_summaries/internal_market/internal_market_general_framework/index_en.htm (last visited 22 December 2016) (emphasis added).

³² Council of the European Union, *Presidency Conclusions—Lisbon European Council, 23rd and 24th March* (2000). See Armstrong, 'Governance and Constitutionalism After Lisbon' in JCMS Symposium: EU Governance After Lisbon, 46 *Journal of Common Market Studies* (2008) 413, at 413–414.

³³ European Commission, *Building the ERA of Knowledge for Growth*, COM(2005) 118 final, at 2 (emphasis added).

³⁴ European Commission, *Towards a European Research Area*, COM(2000) 6 final, at 5.

³⁵ European Commission, *Putting Knowledge into Practice: A Broad-based Innovation Strategy for the EU*, COM(2006) 502 final.

³⁶ E.g. Decision 1982/2006 Concerning the Seventh Framework Programme of the European Community for Research, Technological Development and Demonstration Activities (2007–2013), OJ 2006 L 412/1.

³⁷ Gusma'o, 'Research Networks as a Means of European Integration', 23 *Technology in Science* (2003) 386.

³⁸ W. Kok, *Facing the Challenge: The Lisbon Strategy for Growth and Employment. Report from the High Level Group Chaired by Wim Kok* (2004).

³⁹ See, generally *Europe 2020*, available at http://ec.europa.eu/europe2020/index_en.htm (last visited 22 December 2016). Also see European Commission, *Smart Regulation in the European Union*, COM (2010) 543 final; European Commission, *Europe 2020 Flagship Initiative Innovation Union*, COM (2010) 546 final.

In particular, given its importance in terms of the discussion to which we will return in due course, health is given a specific mention in the strategy's broad objectives. For example, health is integral to smart and inclusive growth because, *inter alia*, 'keeping people healthy and active for longer has a positive impact on productivity and competitiveness'. Moreover, the drive for innovation is noted as helping to 'make the healthcare sector more sustainable and find new cures for health conditions'. In addition, as health 'employs 1 in 10 of the most qualified workers in the EU', it contributes to improving work skills and creating employment. Finally, the potential impact of the increase in older people also justifies the emphasis on health, since 'financing rising healthcare costs and access to a dignified and independent life for the aging population will be central to the political debate'.⁴⁰

The Innovation Union,⁴¹ one of Europe 2020's flagship initiatives, is particularly revealing in that it 'aims to maximise the EU's capacity for innovation and research and channel it towards societal challenges. The Commission aims to make the EU a world-leader in developing innovative ways to promote *active and healthy ageing*—a challenge common to all European countries.'⁴² Noteworthy here is how innovation is linked to research, and this is then directed at societal challenges, but these are used to promote the optimization of ageing; i.e. an ageing population is to be an economically active one that contributes towards the wider economy. Improving the sustainability of social and healthcare systems is part of this set of linked objectives, but the direct link to economic optimization reveals this to be the ultimate aim of societal optimization including in relation to health. It is to: 'boost and improve the competitiveness of the markets for innovative products and services that respond to the ageing challenge both at EU and global level, thus creating new opportunities for businesses'.⁴³ Returning to internal market law, these efforts are clearly directly relevant. In furthering the goal of economic optimization, so that EU citizens and businesses 'can make the most of the advantages of the single market', the EU '*concentrates on dismantling barriers still impeding its operation. It seeks to harmonize legislation in order to improve its response to the challenges of globalisation and to adapt to advances, such as the new technologies*'.⁴⁴

The barriers that are the subject of this drive towards harmonization arise principally from laws and wider measures promulgated and produced at the Member State level. All EU Member States regulate new technologies in order to reduce their attendant risks and maximize their benefits. As Brownsword explains, regulators 'need to tailor their interventions to the perceived risk profile presented by a particular technology'.⁴⁵ This involves determining matters such as when risk

⁴⁰ *Europe 2020—for a Healthier EU*, available at http://ec.europa.eu/health/europe_2020_en.htm (last visited 22 December 2016).

⁴¹ *Innovation Union*, available at http://ec.europa.eu/research/innovation-union/index_en.cfm (last visited 22 December 2016).

⁴² *Europe 2020—for a Healthier EU*, *supra* note 40 (emphasis added).

⁴³ *Ibid.*

⁴⁴ *Internal Market: General Framework*, *supra* note 31 (emphasis added).

⁴⁵ R. Brownsword, *Rights, Regulation and the Technological Revolution* (2008), at 118.

arises (whether it is when the technology fails, or is abused—or works); the degree of risk (low or high); the kind of harms or hazards to which the risk pertains (physical, environmental, social, economic, moral, and political) and the potential for their ranking as more or less serious; and, finally, how risk relates to precaution (whether precaution occurs at risk assessment or somehow operates in risk management).⁴⁶ Generating a risk profile for new technologies depends on the specific technology in question and there are related questions about whether to regulate at all and, if so, the form, type, and extent of regulation. The problems for legal and regulatory decision-making are exacerbated where there is scientific uncertainty or even a lack of knowledge as well as (and often related to) broader disagreement about the factors that can or should go together in building a risk profile—raising questions about how risks ‘should be framed, which methodologies should be adopted, [and] which values prioritized’.⁴⁷

The central problem for internal market law is the potential for disparate national attempts to regulate the risks posed by new technologies, which would erect barriers, fragment the internal market, and undermine the interpenetration of trade—and ultimately the production and legitimation of the EU’s identity, socio-technical order based on a competitive and innovative economy, and its core project of European integration. Consequently, the EU seeks to dismantle barriers through complementary techniques of negative integration and positive integration, and as we shall see in different albeit related ways both of these engage with the risk posed by new technologies.

3. Negative Integration: Free Movement, Mutual Recognition, Justification of National Measures Subject to Proportionality, and the Necessity of (Minimum) Harmonization

A. Free Movement

In terms of negative integration, the relevant Treaty provisions target and prohibit both fiscal⁴⁸ and non-fiscal barriers. The latter are more important for this chapter given that outright bans on products or regulation of their salient features, means of distribution, and marketing are more likely (as demonstrated by the examples noted below). In that regard Article 34 TFEU provides that ‘[q]uantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States’. In interpreting this provision, and indeed the others that relate to internal market law,⁴⁹ the Court of Justice of the European Union

⁴⁶ *Ibid.*, at 118–119. ⁴⁷ *Ibid.*, at 119–120.

⁴⁸ These include ‘customs duties and charges having equivalent effect’ prohibited under Art. 28 TFEU and in order to underpin a customs union with a common external tariff barrier and the prohibition on ‘discriminatory internal taxation’ under Art. 110 TFEU.

⁴⁹ Arts 56–62 TFEU for services, Arts 45–48 TFEU for workers, Arts 49–55 TFEU for establishment, and Arts 63–66 TFEU for capital.

(CJEU) has been mindful of its significance for the *telos* of European integration project in terms of both its production and its legitimation,⁵⁰ and with that in mind has adopted a purposive or teleological interpretation,⁵¹ i.e. one that literally seeks to engender integration through law.⁵² This can be seen in the CJEU's expansive definition of quantitative restrictions (QRs) as 'measures which amount to a total or partial restraint of, according to the circumstances, imports, exports, or goods in transit'.⁵³

This was followed by the even more wide-ranging and all-encompassing definition of measures having equivalent effect to quantitative restrictions (MEQRs) with the *Dassonville* judgment ruling that they comprise 'all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade'.⁵⁴ Subsequently *Cassis de Dijon* clarified what *Dassonville* implied: MEQRs include national measures that make no distinction between domestically produced and imported goods, i.e. product requirements, in particular because they can impose a further regulatory burden on goods imported from another Member State and produced in accordance with its standards.⁵⁵ In *Keck* there was a further refinement of the scope of Article 34 TFEU such that 'certain selling arrangements'⁵⁶ were found to fall outside it.⁵⁷

⁵⁰ M. Adams and H. de Waele (eds), *Judging Europe's Judges: The Legitimacy of the Case Law of the European Court of Justice* (2013).

⁵¹ Koopmans, 'The Theory of Interpretation and the Court of Justice', in D. O'Keefe and A. Bavasso (eds), *Judicial Review in EU Law* (2000); A. Stone Sweet, *The Judicial Construction of Europe* (2004).

⁵² M. Cappelletti et al. (eds), *Integration through Law: Europe and the American Federal Experience* (1986).

⁵³ Case 2/73, *Geddo v. Ente Nazionale Rizi*, [1973] ECR 865 (ECLI:EU:C:1973:89).

⁵⁴ Case 8/74, *Procureur du Roi v. Dassonville*, [1974] ECR 837 (ECLI:EU:C:1974:82).

⁵⁵ Case 120/78, *Rewe-Zentrale AG (Cassis de Dijon)*, [1979] ECR 649 (ECLI:EU:C:1979:42).

⁵⁶ Joined Cases C-267 and 268/91, *Keck and Mithouard*, [1993] ECR I-6097 (ECLI:EU:C:1993:905), at para. 16 (emphasis added).

⁵⁷ That is, provided the measures applied universally and are neutral in effect. The measures in question must 'apply to all relevant traders operating within the national territory and so long as they affect in the same manner, in law and in fact, the marketing of domestic products and of those from other Member States' (*ibid.*). See, e.g., Joined Cases C-401 and C-402/92, *Tankstation*, [1994] ECR I-2199 (ECLI:EU:C:1994:220); Case C-292/92, *Hünernmund*, [1993] ECR I-6787 (ECLI:EU:C:1993:932); Joined Cases C-69 and 258/93, *Punto Casa*, [1994] ECR I-2355 (ECLI:EU:C:1994:226); Joined Cases C-418–421, 460–462 and 464/93, 9–11 and 14–15/94, *Semeraro Casa Uno*, [1996] ECR I-2975 (ECLI:EU:C:1996:242). An alternative market access-based test was put forward in the opinion of Advocate General Jacobs in Case C-412/93, *Leclerc-Siplec*, [1995] ECR I-179 (ECLI:EU:C:1995:26). However, CJEU judgments have pursued a related route of ensuring neutrality in the effects of selling arrangements, which leads to an analysis of whether relevant national measures inhibit market access, and if they do, the measure falls back within Art. 34 TFEU as an MEQR that might be saved in the usual way. See, e.g., Cases C-34–36/95, *De Agostini*, [1997] ECR I-3843 (ECLI:EU:C:1997:344); Case C-405/98, *Gourmet International Products*, [2001] ECR I-1795 (ECLI:EU:C:2001:135); Case C-254/98, *TK-Heimdienst*, [2000] ECR I-151 (ECLI:EU:C:2000:12); Case C-322/01, *DocMorris*, [2003] ECR I-14887 (ECLI:EU:C:2003:664). There are, however, exceptions where the market access test has been preferred: Case C-441/04, *A-Punkt*, [2006] ECR I-2093 (ECLI:EU:C:2006:141) (catching (truly because not just legally, but also factually) non-discriminatory selling arrangements) and cf. Case C-108/09, *Ker-Optika*, [2010] ECR I-12213 (ECLI:EU:C:2010:725) and Case 439/09, *Pierre Fabre Dermo-Cosmétique SAS*, [2011] ECR I-9419 (ECLI:EU:C:2011:649), both concerning Member State rules on distribution contracts, which were deemed contrary to the Treaty provisions

In addition, the CJEU developed mutual recognition as the central regulatory principle in *Cassis de Dijon*.⁵⁸ There were several drivers behind this development, inter alia economic malaise and disaffection with the slow pace of European market integration, and the limited capacity of the CJEU and national courts (adjudicating on EU law matters) to deal with a potentially burdensome caseload prompted by the wide range of measures falling foul of the Treaty. Mutual recognition provides that goods that are lawfully marketed in one Member State are to be allowed to circulate throughout the internal market; in other words, there is a presumption in favour of free movement. This regulatory approach maximizes the autonomy of national regulators, but they must also have regard to and trust their counterparts in other Member States, with whom they must cooperate.⁵⁹ Mutual recognition also provides the scope for regulatory competition and a wider range of new technologies (with different risk profiles) to be produced and sold within the internal market.⁶⁰ That is because the principle of mutual recognition permits a multiplicity of national approaches to regulating technological risk. The approaches adopted might go beyond product safety to encompass different kinds and understandings of harms or hazards that are not necessarily focused on product safety.

B. Derogations and Justifications

Nevertheless, the principle of mutual recognition is subject to limitation and that is because it remains possible for national regulators to limit the free movement of goods from other Member States where there are acceptable reasons for doing so (from the point of view of internal market law). In this regard national regulators can use the Treaty-based derogations in Article 36 TFEU to justify and preserve measures that are found to be QRs or MEQRs. In addition, objective public interest justifications created by the CJEU in *Cassis de Dijon* and added to in subsequent cases are available to save MEQRs that constitute either indistinctly applicable (and often indirectly discriminatory) or non-discriminatory hindrances to market access.⁶¹ As such, it remains possible for national regulators

on goods because they undermined free movement. For a potential remoteness test, i.e. a measure that has an insignificant effect on market access, see Case C-20/03, *Burmanjer*, [2005] ECR I-4133 (ECLI:EU:C:2005:307). There appears to be a recent move to capture ‘any other measure’ which is neither a product requirement nor a selling arrangement, but prohibiting or (severely) restricting the use of goods, see Case C-110/05, *Commission v. Italy (Trailers)*, [2009] ECR I-519 (ECLI:EU:C:2009:66) (concerning the prohibition of motorcycles from pulling trailers); Case C-142/05, *Mickelson*, [2009] ECR I-4273 (ECLI:EU:C:2009:336) (a limitation on the use of personal watercraft only on general navigable waterways).

⁵⁸ Case 120/78, *Cassis de Dijon*, *supra* note 55.

⁵⁹ The ‘principle of sincere cooperation’ in Art. 4(3) TEU.

⁶⁰ Armstrong, ‘Mutual Recognition’, in J. Scott and C. Barnard (eds), *Law of the Single European Market: Unpacking the Premises* (2002).

⁶¹ The move from a discrimination model to a market access model of what constitutes a ‘restriction’ is indicative of the CJEU’s choice to regulate the internal market in a particular way via negative integration. For discussion see M. P. Maduro, *We the Court: The European Court of Justice and the European Economic Constitution* (1998).

to regulate technological risk, but only to the extent that their free movement restrictive measures can be justified by grounds found in these derogations and justifications. Importantly, this means that the reasons for the adoption of a measure at the national level might not fit into the accepted categories of derogations and justifications: for the purposes of EU internal market law, national reasons are not necessarily acceptable justifications for restrictions on free movement. In addition, successful recourse to the derogations and justifications is subject to an assessment that the national measures adopted and that are restrictive of free movement are proportionate to the regulatory aims pursued. Since a national measure that conflicts with directly effective EU free movement law must be dis-applied unless it can be saved by a derogation or justification, the kinds of harms or hazards that can be subject to (legitimate) regulation by the Member States is effectively constrained.

To summarize the derogations and justifications, Article 36 TFEU provides that Article 34 TFEU:⁶² ‘shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants’.⁶³ It is conceivable that national regulation of new technologies might be justified on any of these finite grounds—and in the following I assume for the moment that there are no legislative harmonization measures. To focus on NHTs, the ground of public morality is in principle available to Member States in order to justify a prohibition on the marketing of products containing, consisting, or derived from, for example, embryonic stem cells.⁶⁴ In relation to the latter ground, it remains ‘for each Member State to determine in accordance with its own scale of values and in the form selected by it the requirements of *public morality* in its territory’.⁶⁵ Consistency in the treatment of domestically and imported goods is essential for the successful use of this derogation⁶⁶ (just as it is for the others).

Although not necessarily useful as a way of justifying national measures regulating NHTs that are restrictive of free movement, public security remains important for the justification of national regulation of wider new technologies. Indeed, it is conceivable that, for instance, new information and communication technologies might have a ‘dual use’ (i.e. having both military and civilian uses)⁶⁷ and could therefore be strategically sensitive to both the internal and external security of the state. Hence in *Richardt* the CJEU found that bubble memory circuits imported from the United States (US) into one Member State and then another,

⁶² As well as Art. 35 TFEU which prohibits quantitative restrictions on exports and all measures having equivalent effect.

⁶³ It continues ‘the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property’.

⁶⁴ Cf. the discussion on marketing and product safety and public morality as an exceptional ground for limiting free movement under harmonization, see Section 4D.

⁶⁵ Case 34/79, *Henn and Darby*, [1979] ECR 3795 (ECLI:EU:C:1979:295), at para. 15 (emphasis added).

⁶⁶ Case 121/85, *Conegate*, [1986] ECR 1007 (ECLI:EU:C:1986:114).

⁶⁷ Case C-70/94, *Fritz Werner*, [1995] ECR I-3189 (ECLI:EU:C:1995:328).

where they would then be exported to Russia, could be subject to inspection in the second Member State in order to verify the nature of the goods.⁶⁸ To take a contemporary example, in the wake of the massacre of journalists of the *Charlie Hebdo* satirical magazine in Paris, the British Prime Minister suggested that in his view it was not acceptable that ordinary people could use mobile applications or ‘apps’ and other devices in order to have conversations on which the security services were unable to eavesdrop. A national measure to overcome this problem could involve requiring app developers to build backdoors into their software that permit the interception of messages by authorities or an outright ban on the app.⁶⁹ Public security might be put forward in order to justify such measures where they produce barriers to the free movement of apps between Member States.⁷⁰

Moving to consider the potential use of public health to save measures that regulate NHTs and fall foul of Article 34 TFEU (and again assuming the absence of EU harmonization legislation), one example is a ban on the use of the plastic di (2-ethylhexyl) phthalate (DEHP) in medical devices due to fears that it is likely to be carcinogenic (i.e. that it causes cancer). France in fact banned such products where used on paediatric, neonatal, and maternity units through a law that came into force on 1 July 2015 and (at the time of writing) the United Kingdom (UK) is considering the evidence for introducing a ban.⁷¹ To give one other example, Member States might seek to ban direct-to-consumer genetic testing products that do not involve supervision by a medical professional (a ban on the provision of services based on the data produced by such products would likely fall to be considered within the free movement of services⁷²). For instance, one such product, 23andme, has been banned in the US by the Food and Drug Administration on the grounds of public health,⁷³ but after a number of changes to deal with those concerns this product is now being marketed in the UK.⁷⁴ Other EU Member States might argue that such products lead to, say, excessive, irrational, or wasteful use of public resources, or incorrect diagnosis when (as such products usually promise) diagnosis can be carried out without the supervision of the medical profession.

⁶⁸ Case C-367/89, *Richardt*, [1991] ECR I-4621 (ECLI:EU:C:1991:376).

⁶⁹ ‘David Cameron in “Cloud Cuckoo Land” Over Encrypted Messaging Apps Ban’, *The Guardian*, 13 January 2015.

⁷⁰ In addition to public security, Art. 346(1)(b) TFEU provides that Member States can take measures in the interests of their security where they relate to the production of or trade in arms, munitions, and war material. Such measures must not adversely affect the conditions of competition in the internal market for goods that are not intended for military purposes.

⁷¹ *Warning Over Plastics Used in Treating Premature Babies*, BBC News, 13 November 2014, available at <http://www.bbc.co.uk/news/health-30034760> (last visited 22 December 2016).

⁷² Here the provision of services is likely to be seen as the main activity, with the free movement of goods being ancillary (on this point see Case C-275/92, *Customs Excise v. Schindler*, *supra* note 30).

⁷³ Food and Drug Administration, *23andMe, Inc. 11/22/13*, available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm> (last visited 22 December 2016).

⁷⁴ *Controversial DNA Test Comes to UK*, BBC News, 2 December 2014, available at <http://www.bbc.co.uk/news/science-environment-30285581> (last visited 22 December 2016).

Public health grounds were argued in *DocMorris* where the CJEU stated that ‘the health and life of humans rank foremost among the assets or interests protected by [Art. 36 TFEU]’ and ‘it is *for the Member States*, within the limits imposed by the Treaty, to decide what degree of protection they wish to assure’.⁷⁵ In *DocMorris* that meant a prohibition on internet sales of non-prescription drugs could not be justified. In contrast, a prohibition could be justified with respect to prescription drugs since there was a need to check the authenticity of doctors’ prescriptions to ensure the medicine reached the patient either directly or via an authorized person, and to prevent problems arising from the use of different languages (such as purchasing the wrong medicine or incorrect use). Concerns over DEHP or the unsupervised use of genetic testing technologies and the interpretation of their results are therefore likely to provide reasonable grounds for regulatory interventions at the Member State level and attempts to justify them on public health grounds.

Public policy (which is not the same as the public interest justifications available as mandatory requirements) is restrictively interpreted⁷⁶ and has not usually succeeded as a stand-alone defence, except in order to ‘protect . . . the fundamental interests of the State’,⁷⁷ and has instead been more successful when used in combination with other derogations, such as public health.⁷⁸ Further concerns about genetic testing technologies may arise and be articulated in terms of public policy, such as where the capacity to test for certain diseases is deemed problematic because it might produce genetic discrimination or compound existing different treatment of affected individuals or groups.⁷⁹

As for the objective public interest justifications, the CJEU has, for example, identified the ‘effectiveness of fiscal supervision, protection of public health, fairness of commercial transactions, [and] defence of the consumer’⁸⁰ as starting points for the non-exhaustive range of mandatory requirements (with similar objective public interests being developed in relation to the other freedoms⁸¹). Consequently, where Member State measures such as the examples noted earlier are indistinctly applicable or non-discriminatory it becomes possible to justify them on the basis of objective public interest justifications that overlap with the derogations in Article 36 TFEU or on additional public interest grounds. Consumer protection is one such ground, yet while it might seem an appropriate justification for measures that aim to regulate technological risk, the protection of public health has been more widely used in such cases.⁸² In addition, the environment

⁷⁵ Case C-322/01, *DocMorris*, *supra* note 57, at para. 103 (emphasis added).

⁷⁶ Case 177/83, *Ringelhan*, [1984] ECR 3651 (ECLI:EU:C:1984:334).

⁷⁷ Case 7/78, *Thompson*, [1978] ECR 2247 (ECLI:EU:C:1978:209), at para. 34.

⁷⁸ Case C-434/04, *Ahokainen*, [2006] ECR I-9171 (ECLI:EU:C:2006:609), at para. 28.

⁷⁹ For discussion see Montgomery, ‘Strategies of Regulation: Illustrations from the Work of the Human Genetics Commission’, in Flear *et al.*, *supra* note 11.

⁸⁰ Case 120/78, *Cassis de Dijon*, *supra* note 55, at para. 8.

⁸¹ See further: Barnard, *supra* note 14, ch. 13.

⁸² The following cases were *not* concerned with safeguarding consumers against technological risk but demonstrate its potential to justify national measures by analogy: Case 178/84, *Commission v. Germany (Beer Purity)*, [1987] ECR 1227 (ECLI:EU:C:1987:126) (ensuring beer purity); Case

has been recognized as an objective public interest that is worthy of protection as a mandatory requirement,⁸³ although it is less clear whether it is protected under Article 36 TFEU (in terms of animal or plant health).⁸⁴ Given that several EU Member States have banned the growth of seeds that are classed as genetically modified organisms (often simply referred to as GMOs) and most often used in food production, it is not inconceivable that protection of the environment or indeed public health might be used to justify a ban on the importation of products derived from those sources such as vaccines produced by specially engineered plants.⁸⁵

C. Proportionality

The limitations on the prohibition of restrictions on the free movement of goods are, as noted earlier, subject to the principle of proportionality. In *DocMorris* the CJEU described proportionality in the following way:

national rules or practices likely to have a restrictive effect, or having such an effect, on the importation of pharmaceutical products are compatible with the Treaty only to the extent that they are necessary for the effective protection of health and life of humans. A national rule or practice cannot benefit from the derogation provided for in [Art. 36 TFEU] if the health and life of humans may be protected just as effectively by measures which are less restrictive of intra-Community trade.⁸⁶

Thus, even where the risk profile of the specific technology at issue provides reasons for its regulation on the grounds of the protection of public health, the measures adopted by national regulation must be the least restrictive to free

C-315/92, *Clinique*, [1994] ECR I-317 (ECLI:EU:C:1994:34) (preventing consumers from being misled into believing that Clinique was selling medicinal as opposed to cosmetic products); Case C-470/93, *Mars*, [1995] ECR I-1923 (ECLI:EU:C:1995:224) (similar to the latter case, this one was to do with preventing consumers from being misled into believing a chocolate bar was bigger than it was, i.e., due to a '+10 free' that was larger than the size of the chocolate bar it covered). Decision 1082/2013/EU on serious cross-border threats to health and repealing Decision 2119/98/EC, OJ 2013 L 293/1 applies and further shapes the exercise of Member State discretion in terms of the regulatory interventions adopted in order to tackle and ameliorate the threat. Member States are required to communicate their plans prior to serious cross-border threats, notify any changes to their plans especially in the event of the emergency arising, and finally to explain and justify their responses (entailing consideration of their proportionality).

⁸³ E.g. see Case 142/05, *Mickelsson*, *supra* note 57 (restricting the use of jet skis on inland waterways seemed to be justified on environmental protection grounds).

⁸⁴ E.g. contrast the justification of stricter standards for aircraft registered in another Member State than for domestic aircraft on the basis of 'public health and environmental protection' (Case C-378/96, *Aber-Waggon*, [1998] ECR I-4473 (ECLI:EU:C:1998:357), at para. 19; see also Case C-379/98, *PreussenElektra*, [2001] ECR I-2099 (ECLI:EU:C:2001:160)) with the finding that 'the protection of the environment cannot serve to justify any restriction on exports, particularly in the case of waste destined for recovery' (Case C-209/98, *FFAD*, [2000] ECR I-3743 (ECLI:EU:C:2000:279), at para. 48).

⁸⁵ Paul and Ma, 'Plant-Made Pharmaceuticals: Leading Products and Production Platforms', 58 *Biotechnology and Applied Biochemistry* (2011) 58.

⁸⁶ Case C-322/01, *DocMorris*, *supra* note 57, at para. 104.

movement. Public health is particularly salient to the regulation of technological risk. The enduring concern of the CJEU in shaping and applying the proportionality assessment in relation to this reason for limiting free movement, perhaps more so than for the other possible reasons, has been its possible misuse. In other words, the CJEU has been careful to ensure that public health and the other justifications available under Article 36 TFEU or as mandatory requirements are not used, in the words of that provision, as ‘a means of arbitrary discrimination or a disguised restriction on trade between Member States’.⁸⁷

Consequently, resort to public health as a reason for maintaining Member State regulation of technological risk requires evidence of genuine health concerns that in the case of challenge is carefully scrutinized by the CJEU. In *Medicinal Herbs* the CJEU explained it needed a ‘detailed assessment, on a case by case basis, of the risk alleged by the Member State invoking [Art. 36 TFEU]’.⁸⁸ In the case of medical devices containing DEHP, for instance, any challenge to and defence of the French ban on such products (again assuming the absence of EU harmonization legislation) could make use of the EU’s own assessment, which classifies DEHP as possibly carcinogenic to humans.⁸⁹ In *Frans-Nederlandse Maatschappij voor Biologische Producten (Frans-Nederlandse)* the CJEU found that, in the absence of harmonization, where there are uncertainties in the present state of scientific research it is for the Member States to decide what degree of protection of the health and life of humans they intend to assure. As such, in that case ‘a Member State is not prohibited from requiring plant protection products to be subject to prior approval, even if those products have already been approved in another Member State’.⁹⁰

Sandoz concerned the addition of certain vitamins, in particular vitamins A and D, to muesli bars and analeptic beverages. The CJEU found the internal market principles also applied to them as:

substances . . . which are not as a general rule harmful in themselves but may have special harmful effects solely if taken to excess as part of the general nutrition, the composition of which is unforeseeable and cannot be monitored. In view of the uncertainties inherent in the scientific assessment, national rules prohibiting, without prior authorisation, the marketing of

⁸⁷ Seen in Case 40/82, *Commission v. United Kingdom (Turkeys)*, [1984] ECR 0283 (ECLI:EU:C:1984:33) in which the CJEU held the ‘real aim of the 1981 measures [in which there was a slaughter policy applied to flocks infected with Newcastle disease and a ban on the importation of poultry meat and eggs from all other Member States except Denmark and Ireland] was to block, for commercial and economic reasons, imports . . . in particular from France’, from where there has been a huge increase in imports (at para. 37). In relation to public morality, see Case 34/79, *Henn and Darby*, *supra* note 65.

⁸⁸ Case C-88/07, *Commission v. Spain (Medicinal Herbs)*, [2009] ECR I-1353 (ECLI:EU:C:2008:567), at para. 93 (emphasis added).

⁸⁹ *Scientific Committee on Emerging and Newly-Identified Health Risks, Preliminary Opinion on the Safety of Medical Devices Containing DEHP Plasticised PVC or Other Plasticisers on Neonates and Other Groups Possibly At Risk (2014 update)*, available at http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_047.pdf (last visited 22 December 2016).

⁹⁰ Case 272/80, *Frans-Nederlandse Maatschappij voor Biologische Producten*, [1981] ECR 3277 (ECLI:EU:C:1981:312), at para. 16.

foodstuffs to which vitamins have been added are justified on principle within the meaning of Art. 36 of the Treaty on grounds of the protection of human health.⁹¹

As this example illustrates, a precautionary approach can be adopted for the justification of measures under public health.⁹² Following a detailed assessment that reveals the persistence of uncertainty regarding the extent of the risk to human health, Member States do not have to wait for the reality and seriousness of technological risk to be fully demonstrated before protective measures can be taken.⁹³

However, in departing from the prohibition on restrictions on the free movement of goods (or indeed the other freedoms) Member States must have continuing regard to the requirements of free movement, in particular that in order to be justified the measure in question must be proportionate to the objective pursued. As the CJEU put it in *Frans-Nederlandse*:

The authorities of the importing state are however *not entitled unnecessarily to require technical or chemical analyses or laboratory tests* when the same analyses and tests have already been carried out in another Member State and their results are available to those authorities or may at their request be placed at their disposal.⁹⁴

In this way, mutual recognition requires that Member States do not duplicate the regulatory interventions of other Member States. Where there is such duplication it is likely to be found disproportionate—or even a disguised restriction on trade.

The importance of free movement subject to proportionate limits was also echoed in the CJEU's affirmation of this ruling in *Sandoz*, where it held that scientific uncertainty did not provide Member States with unlimited discretion. Rather, proportionality 'requires that the power of the Member States to prohibit imports of the products in question from other Member States should *be restricted to what is necessary to attain the legitimate aim of protecting health*'.⁹⁵ That meant that there must remain scope for authorizations to market where they are compatible with the need to protect health, that is, where 'when the addition of vitamins to foodstuffs meets a real need, especially a technical or nutritional one'.⁹⁶

D. Necessity of (Minimum) Harmonization

Negative integration has proven essential in bringing down barriers to the free movement of new technologies (and other goods), not least through mutual recognition as a central regulatory principle. The limited possibility of justifying national measures that are restrictive of free movement subject to proportionality means that the scope of permissible risk regulation is effectively constrained.

⁹¹ Case 174/82, *Sandoz*, [1983] ECR 2445 (ECLI:EU:C:1983:213), at para. 17 (emphasis added).

⁹² European Commission, Communication on the Precautionary Principle, COM(2000) 1 and Art. 191 TFEU on the environment.

⁹³ Case C-192/01, *Commission v. Denmark*, [2003] ECR I-9693 (ECLI:EU:C:2003:492).

⁹⁴ Case 272/80, *Frans-Nederlandse*, *supra* note 90, at para. 16 (emphasis added).

⁹⁵ Case 174/82, *Sandoz*, *supra* note 91, at para. 18 (emphasis added).

⁹⁶ *Ibid.*, at para. 19.

But this constraint on regulation is not to the extent that the measures adopted cannot regulate a more diverse range of harms or hazards than those that pertain to product safety. Negative integration would be insufficient on its own for the achievement of a truly integrated internal market. Indeed, as highlighted by the examples noted earlier, although the CJEU has limited the circumstances in which Article 36 TFEU and mandatory requirements can be invoked by Member States, their use threatens to fragment the internal market. In addition, where national regulation is found to be incompatible with free movement law and cannot be saved, regulatory gaps can emerge. Consequently, national measures that survive scrutiny under negative integration as well as those that do not are subject to the complementary mode of positive integration. This is classically understood as entailing the adoption of legislation at the EU level. However, for the purposes of this chapter positive integration encompasses several regulatory techniques in addition to legislation. Before detailing those techniques in Section 4 let us briefly outline legislation, as the core technique.

As mentioned earlier, Article 114 TFEU provides the main basis for the adoption of legislation aimed at the establishment and functioning of the internal market. The concerns noted earlier over the need to tailor regulatory interventions to the perceived risk profile presented by a particular technology therefore also arise at the EU level. However, EU interventions are circumscribed by the conditions for the use of Article 114 TFEU or indeed any other legal base. These comprise the question of whether the competence to regulate is in principle applicable, and the application of the principles of subsidiarity (relevant to this as an area of shared competence under Article 4(2)(a) TFEU⁹⁷) and proportionality,⁹⁸ which pertain to the matters of whether the competence can in fact be used and, if so, the extent of permissible regulation. In using Article 114 TFEU to regulate technological risk there is a subsidiary requirement in Article 114(3) TFEU which provides that the Commission ‘in its proposals . . . concerning health, safety, environmental protection and consumer protection, *will take as a base a high level of protection, taking account in particular of any new development based on scientific facts*’ (emphasis added). In this way scientific and technical knowledge and expertise are underscored and valorized as the foundation and a key justification for EU legislation, which is a key technique for regulating the dangers or threats attendant on the circulation of products. Article 114(3) is a more specific instantiation of the general requirement under, in particular, Article 9 TFEU that the ‘the Union shall take into account requirements linked to . . . *a high level of . . . protection of human health*’ (emphasis added) in the definition and implementation of its policies and activities.

Article 114(10) TFEU provides that legislation adopted under that legal basis must include a ‘safeguard clause’ in ‘appropriate cases’ that authorizes the Member States to take provisional measures subject to EU control ‘for one or more of the non-economic reasons referred to in Art. 36’. In addition, it remains possible for a Member State to maintain a measure ‘on grounds of major needs referred to in

⁹⁷ Art. 5(3) TEU.

⁹⁸ Art. 5(4) TEU.

Art. 36 [TFEU], or relating to the protection of the environment or the working environment' on a temporary basis under Article 114(4) TFEU,⁹⁹ or even introduce 'after the adoption of the harmonization measure' a new temporary measure based on 'new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State' under Article 114(5) TFEU.¹⁰⁰ In the event that either Article 114(4) or 114(5) applies, Article 114(7) TFEU requires the Commission to 'immediately examine whether to propose an adaptation to that [harmonization] measure'.

However, as mentioned above, before Article 114 TFEU can be used it is first necessary to demonstrate that the legal base is indeed applicable. In *Tobacco Advertising I* the CJEU found that Article 114 can only be used to adopt a measure where it is genuinely intended to improve the conditions for the establishment and functioning of the internal market and had that effect. Provided that is the case, the legislation adopted must either contribute to the elimination of obstacles to the exercise of the fundamental freedoms constitutive of the internal market or contribute to the removal of distortions of competition arising from diverse national rules (a broader ground which can serve to justify legislation where one Member State regulates but another does not, generating additional costs and market fragmentation).¹⁰¹ Since several of the measures regulated by the directive at issue in the case did not meet these criteria and the relevant provisions could

⁹⁹ Further, in this case the Member State 'shall notify the Commission of these provisions as well as the grounds for maintaining them'.

¹⁰⁰ The Member State must 'notify the Commission of the envisaged provisions as well as the grounds for introducing them'. Art. 114(6) TFEU provides that the Commission 'shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market'. Approval is automatic where the Commission does not make a decision within this period. The Commission is permitted to extend the six-month period for a further six months, but only when it is 'justified by the complexity of the matter and in the absence of danger for human health'.

¹⁰¹ Case C-376/98, *Germany v. European Parliament and Council (Tobacco Advertising I)*, [2000] ECR I-8419 (ECLI:EU:C:2000:544), which was applied in the follow-up Case C-380/03, *Germany v. European Parliament and Council (Tobacco Advertising II)*, [2006] ECR I-11573 (ECLI:EU:C:2006:772) and affirmed in Case C-491/01, *British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd*, [2002] ECR I-11453 (ECLI:EU:C:2002:741). *Tobacco Advertising I* was widely seen as a response to Case C-300/89, *Commission v. Council (Titanium Dioxide)*, [1991] ECR I-2867 (ECLI:EU:C:1991:244) in which the CJEU preferred Art. 114 TFEU as the basis for environmental legislation instead of Art. 192 TFEU (although in other choice of legal bases cases the CJEU opted for the more specific basis over Art. 114 TFEU: Case C-155/91, *Commission v. Council (Waste Directive)*, [1993] ECR I-939 (ECLI:EU:C:1993:98); Case C-269/97, *Commission and Parliament v. Council (Beef Labelling)*, [2000] ECR I-2257 (ECLI:EU:C:2000:183)). This implied an expansive definition of the internal market (through the marginalization of more specific legal bases) and arguably usurped the wishes of the Member States as masters and drafters of the Treaties, who had denoted Art. 114 TFEU a *residual* legal basis (with Art. 114(1) TFEU stating the provision applies '[s]ave where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Art. 26'). However, subsequent cases indicate the CJEU might be relaxing its interpretation of when Art. 114 TFEU can be used to regulate economic life, see e.g., Case C-210/03, *Swedish Match*, [2004] ECR I-11893 (ECLI:EU:C:2004:802); Case C-434/02, *Arnold André*, [2004] ECR I-11825 (ECLI:EU:C:2004:800).

not be severed, the directive had to be annulled.¹⁰² More importantly for the present discussion, under this approach disparate national measures that regulate new technologies and their various risks (be they physical, environmental, social, economic, moral, or political) can easily justify and trigger EU-wide harmonizing legislation (particularly where the CJEU has ruled that a restriction on free movement or distortion of the conditions of competition exists). The CJEU noted that exclusion on the adoption of harmonizing legislation in the public health field under Article 168(5) TFEU does not mean that legislation adopted under other legal bases (such as Art. 114) could not have any impact on the protection of human health. The ease with which legislation can be adopted under Article 114 has been demonstrated by a subsequent ruling that a revised tobacco advertising directive that omitted the problematic provisions met the criteria for legislation under Article 114.¹⁰³ Such harmonizing legislation is important for the achievement of broader regulatory aims: diverse Member State measures would not only put at risk the internal market itself, but they would in turn imperil the production and legitimation of the EU's socio-technical order and project of European integration.

The subsidiary aim of Article 114 TFEU of protecting certain public interests (especially health and safety) ensures that EU (re)regulation might not provide an exact replacement for diverse Member State measures.¹⁰⁴ EU (re)regulation is focused on removing obstacles to free movement and distortions of competition, and only a narrow range of harms or hazards need to be given particular consideration in proposals for legislation (under Art. 114(3) TFEU), or can remain regulated either by Member State measures adopted as a 'safeguard' (under Art. 114(10) TFEU), or can be maintained or introduced on a temporary basis where the harmonization legislation does not provide the requisite protection (under Art. 114(4) TFEU and Art. 114(5) TFEU respectively). But these special measures can typically be justified only on the non-exhaustive grounds provided for under Article 36 TFEU rather than the objective public interests protected by the mandatory requirements. Overall, therefore, Article 114 TFEU reduces the scope of permissible EU risk regulation within the internal market. Article 114 essentially provides the foundation for the narrowing of technological risk to product safety matters and renders this as the dominant frame for the legislative instruments eventually

¹⁰² Directive 98/43/EC on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Advertising and Sponsorship of Tobacco Products, OJ 1998 L 213/9.

¹⁰³ Case C-380/03, *Tobacco Advertising II*, *supra* note 101, concerning the validity of using Art. 114 TFEU in order to adopt Directive 2003/33 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Advertising and Sponsorship of Tobacco Products, OJ 2003 L 152/16.

¹⁰⁴ Reregulation might occur where the EU legislature produces instruments that replace Member State measures—simple regulation would occur where there are no such measures to replace. Reregulation might be required where the CJEU finds Member State measures in contravention of the free movement provisions and incapable of being saved by a derogation and/or justification (or capable of being saved but disproportionate), which means that they must be set aside, but with the potential effect of creating a regulatory gap (e.g. where proportionate measures are not put in place or cannot be crafted).

adopted by the EU legislature (as well as the supplementary techniques discussed in Section 4). This legal basis also thereby supports the particular market-based orientation of the EU's identity.

In the case of 'full' or 'pre-emptive' legislative harmonization measures, the EU is said to 'occupy the field', further national legislation is automatically precluded, and pre-existing national measures are automatically superseded by the new EU law. Yet this approach is now quite rare. The advent of mutual recognition in the CJEU's jurisprudence in the 1980s became a central component of the Commission proposal¹⁰⁵ for the insertion of both the aforementioned Article 26 TFEU and Article 114 TFEU into the Treaty by the Single European Act, as well as a new approach to harmonization that focused on essential technical and safety standards¹⁰⁶ (and increased choice over the type of legislative instrument available, albeit with a long-running preference for the flexibility provided by directives over the rigidity of regulations—a preference that is beginning to change, most notably in relation to the legislation on clinical trials and medical devices).¹⁰⁷

Given this regulatory preference it remains for the CJEU to determine the extent to which harmonization covers the field in question and pre-empts Member State regulation. In other words, it is for the CJEU to decide whether there is space left for autonomous Member State regulation and therefore the continued application of (and the necessity of ensuring compliance with) the Treaty principles. As the CJEU explained in *DocMorris*:

[Art. 34] continues to apply in relation to the manufacture and marketing of specialised pharmaceutical products as long as harmonization of national rules has not been fully achieved in those areas . . . In that regard, it should be noted that the sale of medicinal products to end consumers has not been subject to full Community harmonization.¹⁰⁸

Nevertheless, the limits on the application of Article 34 TFEU remain important. Elsewhere, in *Schwarz* the CJEU affirmed its previous rulings on limitations by reference to Article 36 TFEU: 'in the *absence of harmonization*, [it is for Member

¹⁰⁵ In the following: European Commission, Completing the Internal Market: White Paper, COM(85) 310.

¹⁰⁶ Council Resolution 85/C 136/01 of 7 May 1985 on a New Approach to Technical Harmonization and Standards; European Commission, Communication on Enhancing the Implementation of the New Approach Directives, COM(2003) 240 final. For commentary see Pelkmans, 'The New Approach to Technical Harmonization and Standardization', 25(3) *Journal of Common Market Studies* (1987) 249. Legislation is now most commonly adopted under Art. 114 TFEU. It is easier to adopt legislation under the latter than the alternative (and original) legal basis of Art. 115 TFEU, which requires unanimity in the Council of the European Union (by contrast Art. 114 TFEU provides for the adoption of legislation under Art. 294 TFEU, the ordinary legislative procedure, which requires a qualified majority in the Council of the EU and therefore makes it easier to adopt legislation).

¹⁰⁷ Under Art. 288 TFEU a directive 'shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods' whereas a regulation 'shall have general application. It shall be binding in its entirety and directly applicable in all Member States'. Art. 114(1) TFEU provides the EU legislature with the scope to 'adopt measures for the approximation' of Member State measures and therefore includes directives and regulations.

¹⁰⁸ Case C-322/01, *DocMorris*, *supra* note 57, at para. 102.

States] to decide on their intended level of protection of human health and life, always taking into account the requirements of the free movement of goods within the Community'.¹⁰⁹ In other words, proportionality remains central, which in this case meant that a requirement that goods sold from vending machines had to be packaged was proportionate to the objective of protecting public health, since there was a risk of 'contamination of the delivery tray by pathogenic germs and their transmission onto the goods removed by the customer . . . [which was] by no means merely theoretical'.¹¹⁰

4. Techniques of Positive Integration: Some Examples in the Field of New Health Technologies

A. Stimulating and Steering Innovation through Funding

As noted earlier, legislation adopted under Article 114 TFEU is a key technique of positive integration, particularly in relation to marketing within the internal market. However, there are several others that are salient to the regulation of technological risk *prior* to marketing and earlier in the technoscience product development pipeline. These additional techniques support the centralization of harms or hazards relating to product safety in legislation, while facilitating the marginalization of other kinds of harms or hazards to which risk might pertain (physical, environmental, social, economic, moral, or political), as well as alternative understandings of risk and framings of regulation. In that regard, shaping knowledge through involvement in research is foundational to steering the trajectory of technoscience; knowledge is the foundation for the exercise of power and the basis for the production of products and services and their regulation. Consequently shaping knowledge through funding is a core priority within the overarching architecture of EU governance, as I mentioned earlier.

Indeed, in the seventh (and final) Framework Programme (FP), FP7,¹¹¹ even basic research—including on health and medical treatments¹¹²—was framed as a driver of future growth instead of as a means of increasing knowledge and understanding *per se*. The same frame is found in (the current) Horizon 2020.¹¹³ And this common frame is reflective of the legal basis of each in the EU's competence

¹⁰⁹ Case C-366/04, *Schwarz*, [2005] I-10139 (ECLI:EU:C:2005:719), at para. 32 (emphasis added).

¹¹⁰ *Ibid.*, at para. 35.

¹¹¹ Decision 1982/2006/EC, *supra* note 36.

¹¹² E.g. nanotechnologies are highlighted in the FP7 objectives, in such references as 'the development and validation of new therapies . . . diagnostic tools and medical technologies'. See *Proposed Priorities for Innovative Health Research 2012*, available at http://ec.europa.eu/research/health/pdf/fp7-health-2012-orientation-paper_en.pdf (last visited 22 December 2016).

¹¹³ Regulation (EU) 1291/2013 Establishing Horizon 2020—the Framework Programme for Research and Innovation (2014–2020) and Repealing Decision 1982/2006/EC, OJ 2013 L 347/104.

for research and technological development in Article 182(1) TFEU,¹¹⁴ which under Article 4(3) TFEU is shared with the Member States. This basis is directed at ‘encouraging . . . [EU research] to *become more competitive, including in its industry*, while promoting all the research activities deemed necessary by virtue of other Chapters of the Treaties’,¹¹⁵ such as those relating to the internal market and public health. Within Horizon 2020 (and FP7 before it), the ‘added value’ (and justification) of EU funding is constructed as supporting translational research; i.e. bringing innovations into the internal market.¹¹⁶ In terms of basic research, ‘[r]esearch on the brain and related diseases’, nanotechnology, and research on the genes behind kidney disease risk,¹¹⁷ are noted as key areas for funding.¹¹⁸ Moreover, EU funding is partly about reducing the risks attendant to research in new technologies (such as the high costs involved), rather than the risk posed by new technologies to consumer safety, and helping to support the translation of research into products.

It is Article 168(5) TFEU that provides the legal basis for funding provided under the EU’s health programme. Health programme funding is now in its third iteration (for 2014–2020)¹¹⁹ and is limited to supporting actions under *Together for Health* and in turn the priorities of Europe 2020, for which it is noted that the ‘promotion of good health at Union level is also an integral part’.¹²⁰ The focus on economic optimization is underlined in statements such as, ‘*in line with the objectives of the Europe 2020 Strategy*, the Programme should focus on a set of well-defined objectives and actions with clear, *proven Union added value*, and concentrate support on a smaller number of activities in *priority areas*’.¹²¹ Those priority areas include: promoting health; protecting EU citizens from cross-border threats to their health; contributing to the development of health systems that are innovative, efficient, and sustainable; and finally, facilitating improvements to

¹¹⁴ Art. 173(3) TFEU (industry) forms the second basis for Regulation (EU) 1291/2013 *ibid.*, and Art. 166(1) European Community Treaty (replaced by Art. 182(1) TFEU) forms the sole basis for Decision 1982/2006, *supra* note 36 above.

¹¹⁵ Art. 179(1) TFEU (emphasis added).

¹¹⁶ Defined in Art. 26(2) TFEU as, ‘an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured’. The establishment of the internal market is required by Art. 3(3) amended TEU.

¹¹⁷ A number of projects contributed towards this research, including ANEUPLOIDY (understanding the importance of gene dosage imbalance in human health using genetics, functional genomics, and systems biology), EUROSPAN (European special populations research network: quantifying and harnessing genetic variation for gene discovery), GENECURE (applied genomic strategies for treatment and prevention of cardiovascular death in uraemia and end-stage renal disease), and EPIC (European prospective investigation into cancer, chronic diseases, nutrition, and lifestyle).

¹¹⁸ European Commission, Amended Proposal for a Council Decision Concerning the 7th Framework Programme of the European Atomic Energy Community (Euratom) for Nuclear Research and Training Activities (2007–2011) (Presented by the Commission Pursuant to Art. 250(2) of the EC Treaty), COM/2006/0364 final.

¹¹⁹ Regulation (EU) 282/2014 on the Establishment of a Third Programme for the Union’s Action in the Field of Health (2014–2020) and Repealing Decision 1350/2007/EC, OJ 2014 L 86/1.

¹²⁰ Rec. 2, *ibid.*

¹²¹ Rec. 5, *ibid.* (emphasis added).

the safety of and access to healthcare.¹²² These priorities are, however, framed by Europe 2020, and as with Horizon 2020 funding, this is seen in the focus on promoting translational research: ‘The Programme should promote synergies, while avoiding duplication with related Union programmes and actions, *by promoting, where relevant, the uptake of innovative breakthroughs resulting from research in the health sector*’.¹²³

The European Group on Ethics in Science and New Technologies (EGE) plays an important role in justifying funding.¹²⁴ For example, in its *Opinion on the Ethical Aspects of Nanomedicine* the EGE justifies EU funding and investment into research and development and seeks to develop the EU’s nanoregulation through the leveraging of risk and scientific uncertainty.¹²⁵ As Harvey and Salter point out, novel science ‘gives bioethical expertise access to new governance territory; *bioethical expertise gives sciences access to political acceptability*’.¹²⁶ The EGE’s focus has been on providing bioethical justification for risk-orientated regulation that aims to foster and direct, rather than circumscribe, innovation in new technologies in general. Indeed, the EGE is an important actor and means of providing legitimacy and generating support and the more general social licence for innovation, especially in areas where social and broader ethical implications of new technologies—and not just technological risk defined narrowly as product safety—is a pressing public concern.¹²⁷ The EGE’s role points to the role of expert deliberation around bioethics in facilitating the narrowing of the scope and type of harms and hazards that are the focus of technological risk regulation to product safety.

Overall, funding is a way of regulating through ‘steering’¹²⁸ rather than ‘command and control’, in that it is used to stimulate and support the development of certain types of NHTs (rather than others), which is particularly important since the exercise of EU competence in respect of funding considered here does not pre-empt Member State action.¹²⁹ Funding helps to shape and support research priorities throughout the EU and therefore the trajectory of technoscientific product development and market availability. Research funding is in turn embedded

¹²² Summarized in European Commission, *The Third Health Programme 2014-2020 Funding Health Initiatives*, available at http://ec.europa.eu/health/programme/docs/factsheet_healthprogramme2014_2020_en.pdf (last visited 22 December 2016).

¹²³ Rec. 21, *supra* note 119 (emphasis added).

¹²⁴ E.g. EGE, *The Ethics Review of hESC FP7 Research Projects (Opinion No. 22)*.

¹²⁵ See, e.g., EGE, *Ethical Aspects of Nanomedicine (Opinion No. 21)*.

¹²⁶ Harvey and Salter, ‘Anticipatory Governance: Bioethical Expertise for Human/Animal Chimeras’, 21 *Science as Culture* (2012) 291, at 309 (emphasis added).

¹²⁷ Busby, Hervey, and Mohr, ‘Ethical EU Law? The Influence of the European Group on Ethics in Science and New Technologies’, 33 *European Law Review* (2008) 803.

¹²⁸ This ‘steering’ is what Daintith calls ‘government by dominium’. See: Daintith, ‘The Techniques of Government’, in J. Jowell and D. Oliver (eds), *The Changing Constitution* (1994).

¹²⁹ As a reminder, in respect of Horizon 2020 funding, Art. 4(3) TFEU states ‘the exercise of . . . [EU] competence shall not result in Member States being prevented from exercising theirs’. Similarly, in respect of health programme funding, Art. 6(a) TFEU provides that it is limited to providing support to the Member States.

within a network that constructs the EU's identity, and its narrative about itself (including in terms of what it regulates, how, and why).¹³⁰

B. Intellectual Property Law and the Fostering of Technoscientific Development

The EU's intellectual property law helps to mediate and manage technological risk and steer behaviour and the trajectory of technoscience, and it does so through the incentive of exclusive intellectual property rights, such as patent protection.¹³¹ By regulating technological risks that relate to harms and hazards highlighted by bioethics (and linked to human rights), EU law in this area supports the focus on technological risk rendered as product safety seen elsewhere in the product development pipeline. A central objective of patent protection under the Legal Protection of Biotechnological Inventions Directive is the stimulation of innovation that, like research funding, recognizes the risks of developing new technologies and seeks to minimize them. For example, it is noted that 'in the field of genetic engineering, research and development require a considerable amount of high-risk investment and *therefore only adequate legal protection can make them profitable*'.¹³² In other words, pre-emption of diverse Member State patent protection regimes and the establishment of a single EU regime for biotechnological inventions is about trying to mitigate risks to developers rather than to, for example, health and safety, i.e. ensuring that those developing inventions have their investment of time and research safeguarded, in order that it can be justified (usually to private investors or shareholders), and that they rather than a competitor derive the reputational and (especially) the economic benefits (profits).

With Article 114 TFEU as the legal basis of this legislation, patent protection is ultimately oriented towards markets and the Directive is justified by the idea that differences in the legal protection of biotechnological inventions between Member States would create barriers to trade in the internal market.¹³³ Although this rationale was challenged in *Netherlands v. Parliament and Council (Biotechnology)*¹³⁴ the CJEU found that the Directive 'in fact aims to protect damage to the internal market'.¹³⁵ In particular, the main justification for harmonization is the need to foster and shape the technoscientific development pipeline and through it the

¹³⁰ Tourney, 'Narratives for Nanotech: Anticipating Public Reactions to Nanotechnology', 8 *Techne* (2004) 88.

¹³¹ Odell-West, 'Multilevel European Patent Law as an Indirect Form of Regulation of New Health and Enhancement Technologies', in M. L. Flear *et al.*, *supra* note 11; Hervey and Black, 'The European Union and the Governance of Stem Cell Research', 12 *Maastricht Journal of European and Comparative Law* (2005) 3.

¹³² Rec. 2 Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, OJ L 213/13 (emphasis added).

¹³³ Recs 5, 6, and 7, *ibid.*

¹³⁴ Case C-377/98, *Netherlands v. Parliament and Council (Biotechnology)*, [2001] ECR I-7079 (ECLI:EU:C:2001:523).

¹³⁵ At para. 18.

internal market and to protect against risks to the economy and legal integration rather than to health and safety or the environment: ‘uncoordinated development of national laws on the legal protection of biotechnological inventions in the [EU] could lead to further disincentives to trade, to the detriment of the industrial development of such inventions and of the smooth operation of the internal market’.¹³⁶

Hence, the Directive also provides that it is not possible to patent certain products and processes.¹³⁷ Under Article 6 that includes where commercial exploitation would be contrary to *ordre public* or morality.¹³⁸ Article 6(2)(c) provides an indicative list of processes to which the exclusion applies and that includes ‘the use of human embryos for industrial or commercial purposes’. Consistent with its earlier decision, in *Brüstle* the CJEU observed that while the ‘the text of the Directive does not define human embryo’, the term ‘must be regarded, for the purposes of application of the Directive, as designating *an autonomous concept of European Union law which must be interpreted in a uniform manner throughout the territory of the Union*’.¹³⁹ Having determined that there must be an EU-specific meaning of ‘human embryo’, the CJEU built on the indicative list in Article 6(2)(c) by referring to the rationale for the Directive, including the specific reference in its recitals that ‘processes, the use of which offend against human dignity . . . are obviously also excluded from patentability’,¹⁴⁰ to hold that the Directive’s ‘context and aim . . . show that the EU legislature intended to *exclude any possibility of patentability* [of human embryos] where respect for human dignity could thereby be affected’.¹⁴¹ Consequently, the CJEU ruled that it ‘follows that the concept of “human embryo” within the meaning of Art. 6(2)(c) of the Directive must be understood in a wide sense’.¹⁴²

Of course, the creation of a definition of ‘human embryo’ in EU internal market law is an important consequence of the Directive.¹⁴³ But the CJEU’s insistence that there had to be such a definition, and one that it has revisited and refined in *International Stem Cell Corporation*,¹⁴⁴ is also important in that it indicates the

¹³⁶ Rec. 7 Directive 98/44/EC, *supra* note 132.

¹³⁷ Art. 4 mentions plant and animal varieties, essentially biological processes and Art. 5(1) mentions simple discovery of genes, both *ibid*.

¹³⁸ Art. 6, *ibid*. The morality clause in Art. 53(a) European Patent Convention has been revised so that it corresponds to the Directive, see Rules 23b–23e of the Implementing Regulations. For critical comment on this change, see D. Beyleveld and R. Brownsword, *Human Dignity in Bioethics and Biolaw* (2001), 197–199.

¹³⁹ Case C-34/10, *Oliver Brüstle v. Greenpeace*, [2011] ECR I-9821 (ECLI:EU:C:2011:669), at para. 26 (emphasis added).

¹⁴⁰ Rec. 38 Directive 98/44/EC, *supra* note 132.

¹⁴¹ Case C-34/10, *Oliver Brüstle*, *supra* note 139, at para. 34 (emphasis added).

¹⁴² *Ibid.*, at para. 34.

¹⁴³ *Ibid.*, at para. 27, citing Recs 3 and 5–7 Directive 98/44/EC, *supra* note 132.

¹⁴⁴ *Ibid.*, at para. 36, the CJEU held that the classification ‘human embryo’ applies to, e.g., ‘a non-fertilized human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilized human ovum whose division and further development have been stimulated by parthenogenesis’. The criterion for determining whether these fall within the term ‘human embryo’ is that they are ‘capable of commencing the process of development of a human being just as an embryo created by fertilization of an ovum can do so’. In Case C-364/13, *International Stem*

way in which internal market law continues to connect with and regulate NHTs. Specifically, this *exception* to the Directive centralizes human dignity as a key concern and leverages it as a legitimating support for EU involvement in the field and, therefore, the market-oriented approach aimed at fostering the competitiveness of its domestic biotechnology industry. In terms of the latter, this decision seems to steer the EU's domestic industry towards certain types of research such as that using adult stem cells,¹⁴⁵ as well as certain kinds of behaviour like secrecy over manufacturing processes,¹⁴⁶ and investment in companies based outside the EU, i.e. which are not subject to the Directive.¹⁴⁷

The EU's intellectual property law supports the narrowing of technological risk to product safety by providing goods with a 'bioethical stamp' that ensures they are deemed respectful of human dignity and can, therefore, be legitimately marketed within the internal market. In addition, the EU also regulates research through intellectual property¹⁴⁸ by providing rights to the results (now known as the 'results'¹⁴⁹). There are detailed provisions on

Cell Corporation v. Comptroller General of Patents, judgment of 18 December 2014, not yet published (ECLI:EU:C:2014:2451), the CJEU followed the opinion of its Advocate General in order to qualify this criterion further. The CJEU held that the criterion must be understood as meaning a non-fertilized human ovum must have the 'inherent capacity to develop into a human being' (at para. 28). As such 'where a non-fertilized human ovum does not fulfil that condition, the mere fact that that organism commences a process of development is not sufficient for it to be regarded as a "human embryo"' (at para. 29). Thus, where 'an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis did have the capacity to develop into a human being' it is to be classified as a 'human embryo' and cannot be patented (as in Case C-34/10, *Oliver Brüstle*, *supra* note 139, at para. 31). But where 'according to current scientific knowledge, a human parthenote, due to the effect of the technique used to obtain it, is not as such capable of commencing the process of development which leads to a human being', it is not to be classified as a 'human embryo' and can be patented (as in Case C-364/13, *International Stem Cell Corporation*, at para. 33 and para. 37).

¹⁴⁵ Abbott, 'Stem Cells: The Cell Division', 480 *Nature* (2000) 7377.

¹⁴⁶ *Stem Cells Unpatentable if an Embryo is Destroyed*, available at <http://www.patentbaristas.com/archives/2011/10/24/eus-court-of-justice-stem-cells-unpatentable-if-an-embryo-is-destroyed/> (last visited 22 December 2016). Cf. Langer, 'The European Court of Justice Bars Stem Cell Patents in Land Mark Decision', *The Bolt, Berkeley Technology Law Journal* (2012), who argues that the ruling may not have much effect at all (see <http://btlj.org/2012/01/05/the-european-court-of-justice-bars-stem-cell-patents-in-landmark-decision/> (last visited 22 December 2016)).

¹⁴⁷ E.g. the wide definition of 'human embryo' precludes the grant of patents on any products or therapies that rely on human embryonic stem cells derived from the destruction of a human embryo, however far removed from the original cell line. Such products might include those developed in order to treat incurable diseases of the eye and the cornea by the Institute of Ophthalmology at University College London. By contrast, the US-based company that brought Case C-364/13, *International Stem Cell Corporation*, *supra* note 144, and which has developed similar products from a non-fertilized human ovum that, due to the effect of the technique used to obtain it, is not as such capable of commencing the process of development which leads to a human being, will be able to obtain a patent and generate a return on their investment (assuming the products are purchased in the internal market).

¹⁴⁸ For a discussion of intellectual property as an indirect mode of regulation in this area see Hervey and Black, 'The European Union and the Governance of Stem Cell Research', 12 *Maastricht Journal of European and Comparative Law* (2005) 3.

¹⁴⁹ Under Horizon 2020 'results' means any tangible or intangible output of the action, such as data, knowledge or information, that is generated in the action, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property

ownership,¹⁵⁰ dissemination and use,¹⁵¹ and access rights.¹⁵² One way in which these are important is in the situation which arises when the Commission objects to the transfer of ownership or grant of exclusive licence of ‘results’ to ‘third parties established in a third country not associated with Horizon 2020’.¹⁵³ Overall, therefore, internal market law is shaping and supporting technoscientific trajectories and the behaviour of those involved in research and development—and it continues to do so by engaging with and regulating research processes.

C. Engaging with Research Processes

EU legislation also concerns research processes and like other stages in the product development pipeline it is primarily concerned with product safety through risk assessment and risk monitoring, licensing, and inspection carried out by EU-mandated competent authorities of the Member State, and these focus on harmonizing Member State regimes and pre-empting divergences in approaches in relation to certain matters (i.e. it appears harmonization is not exhaustive). Two particularly important areas of engagement are the regulation of preclinical research through ‘good laboratory practice’¹⁵⁴ (GLP) and clinical research through ‘good clinical practice’ (GCP), and together these strengthen the role of internal market law in shaping and directing innovation in technoscience. Specifically, this legislation requires Member States to set standards for the planning, performance, reporting, and archiving of research and to establish systems of monitoring and inspection. In terms of GLP, EU law¹⁵⁵ draws on the Organisation for Economic Co-operation and Development’s (OECD’s) work on good laboratory and clinical practice¹⁵⁶ and on International Standards for audit, accreditation, and technical competence.¹⁵⁷ In practice, much regulation is carried out through

rights’. See Art. 2(1)(19) Regulation (EU) 1290/2013 Laying Down the Rules for Participation and Dissemination in ‘Horizon 2020—the Framework Programme for Research and Innovation (2014–2020)’ and Repealing Regulation (EC) 1906/2006, OJ 2013 L 347/81. Under FP7 ‘results’ were known as ‘foreground’, see Art. 39(1) Regulation (EC) 1906/2006 Laying down the Rules for the Participation of Undertakings, Research Centres and Universities in Actions under the Seventh Framework Programme and for the Dissemination of Research Results (2007–2013), OJ 2006 L 391/1.

¹⁵⁰ Arts 41–42, *ibid.*

¹⁵¹ Art. 43, *ibid.*

¹⁵² Arts 46–49, *ibid.*

¹⁵³ Art. 44(3), *ibid.*

¹⁵⁴ Directive 2004/10/EC on the Harmonization of Laws, Regulations and Administrative Provisions Relating to the Application of the Principles of Good Laboratory Practice and the Verification of their Applications for Tests on Chemical Substances, OJ 2004 L 50/44.

¹⁵⁵ Art. 1(1), *ibid.*, provides that Member States ‘shall take all measures necessary to ensure that laboratories carrying out tests on chemical products . . . comply with the principles of [GLP] . . . as laid down in Annex I to this Directive’. See also Rec. 8, *ibid.* Also see Directive 2004/9/EC on the Inspection and Verification of Good Laboratory Practice, OJ 2004 L 50/28.

¹⁵⁶ See *Good Laboratory Practice*, available at <http://www.oecd.org/countries/argentina/good-laboratorypracticeglp.htm> (last visited 22 December 2016).

¹⁵⁷ E.g. ISO/IEC 17000:2004, *Conformity Assessment—Vocabulary and General Principles*, available at http://www.iso.org/iso/catalogue_detail?csnumber=29316; ISO 9000: 2005, *Quality Management System—Fundamentals and Vocabulary*, available at <http://www.iso.org/iso/>

soft law guidance¹⁵⁸ and includes preclinical safety evaluation of biotechnology-derived pharmaceuticals, or ICH S6 (produced in collaboration between the EU, US, and Japan),¹⁵⁹ and further guidance applicable to clinical safety.¹⁶⁰ Although compliance with these standards is not mandatory it is normally required for the studies that are used to support applications for clinical trial authorization or market authorization. In either case (and in the former case because clinical trials are also required for the latter), the focus is on regulating harms or hazards pertaining to safety in order to get (safe) new products to market.

All laboratories carrying out tests on chemical products must comply with the OECD's principles of GLP.¹⁶¹ The European Medicine Agency's (EMA's) instantiation of the latter principles¹⁶² focus on ensuring product safety by seeking to 'define a set of rules and criteria for a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, reported and archived'.¹⁶³ Member States are permitted to 'provisionally prohibit or make subject to special conditions the marketing of that substance on its territory' where application of the GLP principles demonstrates a chemical substance examined under the Directive nevertheless 'presents a danger to man and the environment',¹⁶⁴ which again underlines the importance of only certain harms or hazards as the subject of technological risk regulation. Exceptions from GLP are permitted for studies employing specialized test systems. These are often needed

catalogue/catalogue_ics/catalogue_detail_ics.htm?csnumber=42180); ISO 15189: 2007, *Medical Laboratories—Particular Requirements for Quality and Competence*, available at http://www.iso.org/iso/iso_catalogue/catalogue_ics/catalogue_detail_ics.htm?csnumber=42641 (all last visited 22 December 2016).

¹⁵⁸ Produced by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (the guidance in the immediately previous footnote is likewise produced by this international body). Guidance includes: *Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals*, (ICH M3[R2]) CPMP/ICH/286/95; *Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals*, (ICH M3[R2]) CPMP/ICH/286/95; *Safety Pharmacology Studies for Human Pharmaceuticals*, (ICH S7A) CPMP/ICH/539/00; *Duration of Chronic Toxicity Testing in Animals (Rodent and Non-Rodent Toxicity Testing)*, (ICH S4A) CPMP/ICH/300/95; *Carcinogenicity: Testing for Carcinogenicity of Pharmaceuticals*, (ICH S1B) CPMP/ICH/299/95.

¹⁵⁹ See further *Clinical Efficacy and Safety Guidelines*, available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000085.jsp&mid=WC0b01ac0580027549 (last visited 22 December 2016).

¹⁶⁰ *Guidance on Quality, Pre-Clinical and Clinical Aspects of Gene Transfer Medicinal Products*, CHMP/GTWP/234523/09; *Non-Clinical Studies Required before First Clinical Use of Gene Therapy Medicinal Products*, EMEA/CHMP/GTWP/125459/2006; *Biological Active Substances Produced by Stable Transgene Expression in Higher Plants*, EMEA/CHMP/BWP/48316/2006; *Guidance on Human Cell-Based Medicinal Products*, EMEA/CHMP/410869/2006; EMA, *Reflection Paper on Stem Cell-Based Medicinal Products*, CAT/571134/09; EMA, *Reflection Paper on In-Vitro Cultured Chondrocyte Containing Products for Cartilage Repair of the Knee*, CAT/CPWP/568181/2009.

¹⁶¹ These are appended to Directive 2004/10/EC, *supra* note 154, in Annex 1.

¹⁶² Defined in *ibid.*, 2.1 of Annex 1.

¹⁶³ *Good Laboratory Practice*, available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000158.jsp (last visited 22 December 2016).

¹⁶⁴ Art. 5(2) Directive 2004/10/EC, *supra* note 154.

for biopharmaceuticals and the exception from GLP facilitates speedier progress to marketing authorization. Even then the justification can be made that safety is not jeopardized and that, overall, preclinical trials place safety centre stage.

Prompted by disasters like the TGN1412 incident in which six first-in-human (Phase I) trial participants had to be placed in intensive care after suffering multiple organ failure,¹⁶⁵ a precautionary approach to risk is likely to be adopted before moving to clinical research and seeking permission for trials from research ethics committees.¹⁶⁶ As such, although the guidance works to steer preclinical research, it has ‘hard’ (and pre-emptive) effects in practice. Compliance with GLP (and the costs incurred) is justified by the need to ensure quality, efficacy, and safety of products—that is, technological risk is regulated (prior to and) in order to permit market circulation.

Clinical research, like GLP, is closely aligned to market authorization, discussed further later, in relation to which the relevant legislation mentions clinical trials data as the basis for the market authorization of pharmaceutical treatments on the grounds of their quality, safety, and efficacy.¹⁶⁷ In other words, through these criteria technological risk pertains to a narrow range of harms or hazards and this provides the focus of the legislation rather than ‘comparative therapeutic efficacy’ of the medicine and a genuine need for it. Clinical trials are subject to specific regulation, with the Clinical Trials Directive¹⁶⁸ (CTD) dating from 2001 being replaced by the new Clinical Trials Regulation¹⁶⁹ (CTR), which entered into force on 16 June 2014 but could not apply at the earliest before 28 May 2016, and is due to come into operation in 2018.¹⁷⁰ The CTR (like the CTD before it) requires Member States to set standards for the planning, performance, reporting, and archiving of research. The very definition of clinical trials in the CTR (and the CTD) highlights their alignment to the requirements for market authorization and the importance of its focus on the specific instantiation of technological risk (focusing on product safety) for the creation of biomedical knowledge and the technoscientific development it enables. Under the CTR, clinical trials are clarified as being a type of clinical study¹⁷¹ that is an investigation:

¹⁶⁵ Kmietowicz, ‘Rules for Drug Trials Should Be Tightened, Say Experts’, 333 *British Medical Journal* (2006) 276.

¹⁶⁶ This is apparent from the long time it has taken Geron to progress to clinical development, even though it has substantial preclinical data for its human embryonic stem cell derived products; see <http://www.geron.com/> (last visited 22 December 2016).

¹⁶⁷ Directive 2001/83/EC, *supra* note 18.

¹⁶⁸ Directive 2001/20/EC on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use, OJ 2001 L 121/34. This requires the Commission to establish principles relating to GCP and detailed rules in line with those principles.

¹⁶⁹ Regulation (EU) 536/2014 on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/20/EC, OJ 2014 L 158/1.

¹⁷⁰ Art. 99, *ibid.* Directive 2001/20/EC, *supra* note 168, continues to apply in a transitional period, see Art. 98, *ibid.*

¹⁷¹ Art. 2(2)(2), *ibid.* provides ‘clinical study’ ‘means any investigation in relation to humans intended: (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; (b) to identify any adverse reactions to one or more medicinal

in relation to humans intended: (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; (b) to identify any adverse reactions to one or more medicinal products; or (c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products; *with the objective of ascertaining the safety and/or efficacy of those medicinal products*.¹⁷²

The reasons for the adoption of the CTR underline the salience and centrality of safety as the focus of technological risk regulation, as well as the marginalization of other kinds of harms or hazards within the development pipeline. Experience under the CTD gave rise to concerns that differences in its application in the EU's (now) 28 Member States (up from 15 in 2001) would undermine scientific research.¹⁷³ These differences were exacerbated by the 'cumbersome procedures for multi-centre clinical trials in different Member States' leading to an 'impact on academic as well as non-academic research'.¹⁷⁴ In particular, 'Scientific development . . . suggests that future clinical trials will target more specific patient populations, such as subgroups identified through genomic information. In order to include a sufficient number of patients for such clinical trials it may be necessary to involve many, or all, Member States'.¹⁷⁵ Attention here is on generating more specific safety data as the basis for the production and marketing of pharmaceuticals that are aimed at specific populations. Consequently, it became necessary to revise the applicable law, such as through the introduction by the EMA of an EU portal¹⁷⁶ that serves as a single entry point for the submission of an application for the authorization of clinical trials to the reporting Member State¹⁷⁷ and an EU database for the storage of the application and related data.¹⁷⁸ The EU portal also provides the means for communication of, inter alia, the result of the application.¹⁷⁹

products; or (c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products; with the objective of ascertaining the safety and/or efficacy of those medicinal products'.

¹⁷² Art. 2(2)(1) Regulation (EU) 536/2014, *supra* note 169 (emphasis added). This definition is very similar to that under Art. 2(a) Directive 2001/20/EC, *supra* note 168, particularly the objective: a 'clinical trial' means 'any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) *with the object of ascertaining its (their) safety and/or efficacy*' (emphasis added).

¹⁷³ Since around the mid-1980s the preference was to opt for the adoption of directives rather than regulations, and yet the increase in the number of Member States and diversity in their legal cultures (including in implementation and compliance with EU law) has led to a more general growing preference for regulations.

¹⁷⁴ European Commission, Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector, COM(2008) 666 final, 8. Reflected in Rec. 4 Regulation (EU) 536/2014, *supra* note 169.

¹⁷⁵ Rec. 4 Regulation (EU) 536/2014, *supra* note 169.

¹⁷⁶ Arts 5, 16, and 80, *ibid*.

¹⁷⁷ In the first instance the trial sponsor shall propose the reporting Member State. In the event that this proposal is declined, more detailed rules determine which Member State shall report: see Art. 5, *ibid*.

¹⁷⁸ Art. 81, *ibid*.

¹⁷⁹ Art. 8, *ibid*.

In order to introduce these changes and reinforce their utility so as to make it easier to generate safety data it was also necessary to reconsider the legal form or instrument in respect of clinical trials.¹⁸⁰ As summarized in the CTR, the adoption of a regulation ‘would present advantages for sponsors and investigators, for example in the context of clinical trials taking place in more than one Member State, *since they will be able to rely on its provisions directly [before national courts]*’.¹⁸¹ By contrast, the CTD (as a directive) could only be relied upon directly in very specific circumstances;¹⁸² which meant that in most cases domestic implementing legislation was applicable. In the case of the UK, for example, the CTD was adopted into domestic law by its transposition through the Medicines for Human Use (Clinical Trials) Regulations 2004.¹⁸³ In short, the adoption of an EU regulation (the CTR) more uniformly harmonizes and enhances the efficacy and uniformity of EU law. Further, under the CTR the link between clinical trials and product marketing, and the continuing focus on product safety as the specific instantiation of technological risk, is specified and tightened through its foundation on the dual legal basis of Article 114 TFEU and Article 168(4)(c) TFEU. These provisions provide objectives that are ‘pursued simultaneously’ and ‘one is not secondary to another’.¹⁸⁴ As regards Article 114 TFEU, the CTR:

harmonizes the rules for the conduct of clinical trials in the Union, *therefore ensuring the functioning of the internal market in view of the conduct of a clinical trial in several Member States*, the acceptability throughout the Union of data generated in a clinical trial and submitted in the application for the authorisation of another clinical trial or of the placing on the market of a medicinal product, *and the free movement of medicinal products used in the context of a clinical trial*.¹⁸⁵

In a derogation from the limits on EU competence for the protection and improvement of health, Article 168(4)(c) TFEU builds on the shared competence in respect of common safety concerns relating to public health matters.¹⁸⁶ With this provision as a legal basis, the CTR is used to set ‘*high standards of quality and*

¹⁸⁰ Consistent with the legal basis for internal market legislation under Art. 114 TFEU.

¹⁸¹ Rec. 5 Regulation (EU) 536/2014, *supra* note 169 (emphasis added). Art. 288 TFEU defines directives and regulations. A directive is ‘binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods’. By contrast a regulation has ‘general application. It shall be binding in its entirety and directly applicable in all Member States.’

¹⁸² Under the doctrine of direct effect. The CJEU has found that provided they are sufficiently clear, precise, and unconditional the provisions of directives can be relied upon before Member State courts as against the Member State only (that is, not individuals), but only where their deadline for implementation has passed and the Member State has not properly implemented them (Case 71/74, *Van Duyn v. Home Office*, [1974] ECR 1337 (ECLI:EU:C:1974:133); Case 148/78, *Pubblico Ministero v. Tullio Ratti*, [1979] ECR 1629 (ECLI:EU:C:1979:110)). By contrast the CJEU has found that regulations are capable of being relied upon before Member State courts as against the Member State and individuals, as appropriate, from the date they enter into force and become applicable (as specified in the specific instrument) (Case 39/72, *Commission v. Italy*, [1973] ECR 101 (ECLI:EU:C:1973:13)).

¹⁸³ Statutory Instrument No. 1031/2004.

¹⁸⁴ Rec. 82 Regulation (EU) 536/2014, *supra* note 169.

¹⁸⁵ Rec. 82, *ibid.* (emphasis added). ¹⁸⁶ Art. 4(2)(k) TFEU.

safety for medicinal products by ensuring that data generated in clinical trials are reliable and robust.¹⁸⁷ Overall, founded upon this dual legal basis, the CTR is focused on regulating technological risk instantiated as product safety.

All clinical trials falling within the scope of the CTR (and CTD before it) must be designed, conducted, and reported in accordance with GCP, with Member States being required to establish systems of monitoring and inspection. Many of the GCP rules are further concretized in other legislation,¹⁸⁸ which will be replaced in line with the application of the CTR.¹⁸⁹ Detailed guidance established by the EMA, in accordance with the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), supplements EU legislation on GCP.¹⁹⁰ GCP is:

*a set of detailed ethical and scientific quality requirements for designing, conducting, performing, monitoring, auditing, recording, analysing and reporting clinical trials ensuring that the rights, safety and well-being of subjects are protected, and that the data generated in the clinical trial are reliable and robust.*¹⁹¹

GCP frames the rights of individual trial subjects as concerning their protection from the risk of whatever is being trialled. In particular, at the heart of GCP is the requirement that ‘the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests.’¹⁹² The relationship between risk and markets reappears here: the CTR (and the CTD) (and thus the detailed guidance based thereon) refers to the marketing of medicinal products as its underlying basis and highlights how risk articulates to markets, which is of course a consequence of the legal basis for the regulation (Art. 114 TFEU).¹⁹³

The CTR (like the CTD) makes reference to the ‘protection of trial subjects’.¹⁹⁴ Protection of the research subject is safeguarded through risk assessment based on the results of toxicological experiments prior to any clinical trial, screening by research ethics committees and Member States’ competent authorities, and rules on the protection of personal data.¹⁹⁵ References to consent occur through the CTR,¹⁹⁶ and it is connected with the protection of clinical research subjects ‘such as the 2008 version of the World Medical Association’s Declaration of Helsinki’.¹⁹⁷ Further protections are provided in the CTR, including for those who are incapable of giving legal consent to clinical trials.¹⁹⁸ The EU database

¹⁸⁷ Rec. 82 Regulation (EU) 536/2014, *supra* note 169 (emphasis added).

¹⁸⁸ Directive 2005/28/EC Laying down Principles and Detailed Guidelines for Good Clinical Practice as regards Investigational Medicinal Products for Human Use, as well as the Requirements for Authorization of the Manufacturing or Importation of Such Products, OJ 2005 L 91/13.

¹⁸⁹ For the state of play at time of publication, see *Implementation Measures by the Commission in the Context of Regulation (EU) No 536/2014—Overview and State of Play*, available at http://ec.europa.eu/health/files/clinicaltrials/overview_clinical_trials.pdf (last visited 22 December 2016).

¹⁹⁰ EMA, *E6: Guideline for Good Clinical Practice*, CPMP/ICH/135/95.

¹⁹¹ Art. 2(2)(30) Regulation (EU) 536/2014, *supra* note 169 (emphasis added).

¹⁹² Art. 3(a), *ibid.* ¹⁹³ Rec. 8, *ibid.* ¹⁹⁴ Ch. V, *ibid.* ¹⁹⁵ Rec. 67, *ibid.*

¹⁹⁶ Embedded throughout and including: Recs 15, 17, 27, 44, 76, and 80, Art. 3, and Ch. V (on protection of subjects and informed consent) *ibid.*

¹⁹⁷ Rec. 80, *ibid.* ¹⁹⁸ Especially Art. 31 and Art. 32, *ibid.*

noted earlier brings together information on the content, commencement, and termination of clinical trials, which is subject to protections for confidentiality and invokes the right to privacy. Cross-references to the Data Protection Directive (that will have to be revised upon the adoption of the new EU data protection legislation)¹⁹⁹ are also embedded throughout EU clinical trials regulation—but this protection of individual privacy essentially serves to legitimate the focus on regulating for product safety. The CTR maintains additional risk-related requirements in order to ensure product safety is central to the manufacture and import of investigational medicinal products,²⁰⁰ labelling,²⁰¹ the verification of compliance of investigational medicinal products with good clinical and manufacturing practice through inspections,²⁰² and finally notification of adverse reactions.²⁰³ Where the latter are fatal or life-threatening they must be notified to the competent authorities in the Member States. Overall, therefore, the CTR (like the CTD before it) and the detailed guidance upon which it is based are concerned with the regulation of technological risk in order to ensure the safety and marketability of products.

Special provision is made for research into paediatric and orphan products so as to facilitate their development, which is undermined by, *inter alia*, the generally more difficult research process, a potentially higher cost-to-benefit ratio than for other medicines, and the resulting reduced incentive to invest in them in the first place, all of which can relate to the often smaller numbers of people who can be research subjects and who might benefit from the availability of more specialist products in individual Member States. As in relation to intellectual property safeguards, therefore, specific regulation on paediatric and orphan products seeks to mitigate the risks (especially financial) to developers. Paediatric clinical research is supported by the EU's legislation on medicinal products for paediatric use.²⁰⁴

¹⁹⁹ EU legislation currently comprises Directive 95/46/EC on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, OJ 1995 L 281/31 (Data Protection Directive). This includes data in healthcare settings, such as that in research and development of pharmaceuticals and medical technologies more broadly. Regulation (EU) 2016/679 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation), OJ 2016 L 119/1 entered into force on 24 May 2016, but will not apply until 25 May 2018. Like the CTR and the proposed new medical devices legislation, the replacement of the Data Protection Directive with the General Data Protection Regulation is notable for adoption of the latter legislation in the form of a regulation. The General Data Protection Regulation will (by its nature) better ensure the uniformity of EU law in relation to the protection of personal data (in addition there will be a new directive on the protection and free movement of data in relation to criminal offences and penalties—this is less important for present purposes). See further: European Commission, Proposal for a Regulation of the European Parliament and of the Council on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data (General Data Protection Regulation), COM(2012) 11 final; European Commission, Agreement on Commission's EU Data Protection Reform Will Boost Digital Single Market, IP/15/6321. On the revision of EU data protection law, see Hustinx, *supra* note 9.

²⁰⁰ Ch. IX Regulation (EU) 536/2014, *supra* note 169.

²⁰¹ Ch. X, *ibid.*

²⁰² Ch. XIII, *ibid.*

²⁰³ Ch. VII, *ibid.*

²⁰⁴ Regulation (EC) 1901/2006 on Medicinal Products for Paediatric Use and Amending Regulation (EEC) 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) 726/2004, OJ 2006 L 378/1.

This provides for, inter alia, EU-wide data collection of paediatric studies,²⁰⁵ an EU 'network of excellence',²⁰⁶ and a Paediatric Committee, operating within the general EU and ICH framework.²⁰⁷ The network 'should contribute to the work of strengthening the foundations of the European Research Area in the context of Community Framework Programmes for Research, Technological Development and Demonstration Activities, benefit the paediatric population and provide a source of information and expertise for industry'.²⁰⁸ The network, as well as other incentives, such as the assessment by the EMA of paediatric investigation plans, fee waivers for scientific advice, information and transparency measures, and research funding under the FP and now Horizon 2020,²⁰⁹ are supported by EU funds.²¹⁰ The focus of these efforts is on facilitating the market authorization of products for paediatric use. In other words, nevertheless the focus remains on regulating risk instantiated as being about product safety.

The same can be said about legislation on paediatric clinical research. The latter is carried out in relation to so-called 'orphan' medicines, that is, those intended for a rare disease or if the product's development would not be commercially viable without incentives.²¹¹ As with other internal market legislation, a key justification for specific legislation for orphan products is the avoidance of distortions of competition and barriers to cross-border trade within the EU.²¹² EU-level action was also justified 'in order to take advantage of the widest possible market and to avoid the dispersion of limited resources',²¹³ as well as the need to foster the development of EU-based companies that can compete with companies based in the US and Japan; places that already had in place systems that incentivized the development of orphan drugs.²¹⁴

In addition to GLP and GCP, and legislation on clinical trials and research into paediatric and orphan products, EU law also regulates the use of animals in the context of scientific research²¹⁵ which includes research into NHTs.²¹⁶ This is subject to licensing, inspection, and oversight by a competent authority of the Member State,²¹⁷ which is responsible for ensuring that all breeders, suppliers, and users of animals in scientific research are authorized and registered and that they comply with the Directive.²¹⁸ In order to facilitate compliance,

²⁰⁵ Rec. 31 and Art. 41, *ibid.*, provide that the database on clinical trials established by Directive 2001/20/EC 'should include a European register of clinical trials of medicinal products for paediatric use comprising all ongoing, prematurely terminated, and completed paediatric studies conducted both in the Community and in third countries'.

²⁰⁶ Rec. 31 and Art. 44, *ibid.*

²⁰⁷ Directive 2001/20/EC, *supra* note 168, and ICH guideline E11 on the Development of Medicinal Products for the Paediatric Population, are noted as important reference points for the Committee's work. See Rec. 8 Regulation (EC) 1901/2006, *supra* note 204.

²⁰⁸ See Rec. 31 and Art. 44, *ibid.* ²⁰⁹ Rec. 30 and Art. 40, *ibid.*

²¹⁰ Rec. 35, *ibid.*

²¹¹ Art. 3 Regulation (EC) 141/2000 on Orphan Medicinal Products, OJ 2000 L 18/1.

²¹² Rec. 3, *ibid.* ²¹³ Rec. 3, *ibid.*, also see Rec. 4. ²¹⁴ Rec. 2 and Rec. 8, *ibid.*

²¹⁵ Directive 2010/63/EU on the Protection of Animals Used for Scientific Purposes, OJ 2010 L 276/33. Art 62 provides that the Directive repeals Directive 86/609/EEC from 2013 and Art. 63 provides that the Directive replaces point (a)(iv) of Art. 8 Regulation (EC) 1069/2009.

²¹⁶ Rec. 42, *ibid.*

²¹⁷ Art. 59, *ibid.*

²¹⁸ Art. 20(1), *ibid.*

regular inspections are also required.²¹⁹ Member States are required to recognize test data that complies with EU legislation on testing methods—without such a requirement Member States might create barriers to trade in the products that were tested.²²⁰ Moreover, although concern for animal welfare is reflected in the legislation, the rationale is similar to that for concern over human research subjects: protection in order to satisfy ethics and rights-based concerns, but so as to support consumption of products that are deemed safe since they meet the criteria for market authorization.

EU law on genetically modified micro-organisms (GMMOs)²²¹ and the harmful release into the environment of genetically modified organisms (GMOs)²²² is the final example of the regulation of technological risk. Like the other examples considered here, product safety provides a key rationale for the applicable legislation. For instance, GMO legislation is founded on the idea that it is ‘necessary to approximate the laws of the [Member States] . . . concerning the deliberate release into the environment of GMOs and to ensure the safe development of industrial products utilising GMOs’.²²³ Underpinning this legislation is the assumption that the harms or hazards that may arise from GMMOs or GMOs can be controlled. This is, of course, a matter of heated debate.²²⁴ In this way the legislation makes an implicit assumption about the nature and level of risk (in short, its focus) that are not necessarily shared by all—and far from being technical and neutral acts, they are actually intensely political. To give another example, Member States must ensure that a risk assessment is carried out by anyone using GMMOs.²²⁵ Competent authorities in the Member States are required to monitor, *inter alia*, the suitability of containment and other protective measures, waste management, and emergency response measures. In short, legislation on GMOs and GMMOs is intended to prevent the harmful release of such organisms.

Although particularly applicable to food, the legislation is also relevant to medicines that use GMMOs and GMOs which are developed and marketed within the EU. NHTs that are, or consist of, GMMOs or GMOs as defined in these directives have yet to be developed, but as mentioned earlier they are likely to become a reality. Such products would be covered by medicinal products

²¹⁹ Art. 34(1), *ibid.*

²²⁰ Rec. 42, Art. 2(2) and Art. 46, *ibid.* (with an exception for data that needs further testing for the protection of public health, safety, or the environment).

²²¹ Directive 2009/41/EC on the Contained Use of Genetically Modified Micro-Organisms, OJ 2009 L 125/75.

²²² Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Directive 90/220/EEC, OJ 2001 L 106/1.

²²³ Rec. 7, *ibid.*

²²⁴ For discussion see Lee, *supra* note 8.

²²⁵ Defined in Art. 2(b), Directive 2009/41/EC, *supra* note 221, as ‘a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination; within the terms of this definition’. Further specification is provided in Annex I. They do not include, e.g., *in vitro* fertilization.

legislation (which is considered next) rather than GMMO or GMO legislation, subject to the requirement for an equivalent environmental risk assessment.²²⁶ Relatedly, one EU-funded project, TERPMED, hopes to ‘pharm’, that is, derive new bioactive molecules from genetically modified plants. ATryn, a product which was authorized for marketing in 2007, is expressed in the milk of transgenic goats. According to the EGE such animals are, therefore, potentially important ‘[i]n fundamental bio-medical research to improve our genetic and physiological knowledge; [t]o make models of human diseases; [and] [a]s an alternative source of tissues and organs for “xenotransplantation”’.²²⁷

D. Marketing and Product Safety

As already pointed out, technological risk is a central concern of EU marketing legislation and related guidance, and like the other techniques deployed through the development pipeline the focus is on regulating the harms or hazards that pertain to product safety of pharmaceuticals and medical devices. Just as in relation to other types of regulatory activity, this focus marginalizes and obscures other kinds of harms or hazards to which risk might pertain as well as alternative understandings of risk and framings of regulation. In this way marketing legislation is the culmination of the EU’s various efforts to shape technoscientific trajectories, in that it ensures market availability and a return on the investment of time and money in development. As such, this type of regulatory activity is vital to market optimization and through it the production and legitimation of the EU’s identity and project of integration. This legislation is concerned with ensuring pharmaceuticals and medical devices can be put onto the market, i.e. granted market authorization, but only when they are safe, efficacious, and of the correct quality, and it is to this extent that the legislation pre-empts Member State measures. EU legislation on medicinal products dates from the 1960s and is the oldest on product safety. The legislation has been significantly revised²²⁸ and is now assembled into the 2001 Community code.²²⁹

Under the Community code, medicinal products are defined by ‘presentation’²³⁰ and by ‘function’²³¹ and that includes most pharmaceuticals except those that are ATMPs.²³² There are several types of procedure for the marketing of pharmaceuticals,²³³ but it is the centralized procedure involving the EMA that

²²⁶ Art. 5 Directive 2001/18/EC, *supra* note 222. Also see EMA, *Guideline on Environmental Risk Assessments for Medical Products Consisting of, or Containing, Genetically Modified Organisms (GMOs)*, EMEA/CHMP/BWP/473191/2006—Corr.

²²⁷ Group of Advisors on the Ethical Implications of Biotechnology (now EGE), *Ethical Aspects of Genetic Modification of Animals (Opinion No. 7)*.

²²⁸ E.g. Directive 65/65/EEC on the Approximation of Provisions Laid Down by Law, Regulation or Administrative Action Relating to Proprietary Medicinal Products, OJ 1965 L 22/369.

²²⁹ Directive 2001/83/EC, *supra* note 18.

²³⁰ For more detail see *supra* note 18.

²³¹ Likewise, see *supra* note 18.

²³² Regulation (EC) 1394/2007, *supra* note 21.

²³³ For an overview see *Authorization Procedures for Medicinal Products*, available at http://ec.europa.eu/health/authorisation-procedures_en.htm (last visited 22 December 2016). Mutual recognition applies to most conventional products and means that a manufacturer can obtain market authorization in one Member State after which it is recognized in all others—producing competition between Member State regulators. There is also the less well-used decentralized procedure,

is most applicable to NHTs. This is the case since this procedure is compulsory for products derived from biotechnology (which obviously includes ATMPs) and includes vaccines produced by specially engineered plants noted earlier, orphan medicinal products, and products for human use containing an active substance authorized and intended for the treatment of HIV/AIDS, cancer, neurodegenerative disorders, or diabetes.²³⁴ Products that represent a significant scientific, therapeutic, or technical innovation or that benefit public health can also make use of this route to the market. Consistent with Article 114 TFEU the Community code and the legislation on the centralized procedure include safeguard clauses that permit temporary measures by Member States, but these focus on public health grounds.²³⁵ Public policy and public morality grounds are available to prohibit medicinal products including ATMPs, but they can be used only exceptionally.²³⁶ The latter is therefore available to prohibit ATMPs that make use of, for example, embryonic stem cells. The narrow scope of these grounds for temporary national measures underscores the narrowing of regulatory attention to ensuring product safety, and the marginalization of other harms or hazards to which risk regulation might pertain.

EU legislation on medical devices currently takes the form of three directives, but these will (likely) be replaced by two new regulations.²³⁷ The reason for the replacement (like the replacement of the CTD by the CTR noted earlier) further

which allows for simultaneous approval in several Member States and is applicable to the majority of conventional medicinal products.

²³⁴ Regulation (EC) 726/2004, *supra* note 20.

²³⁵ Specifically, Art. 35(1) Directive 2001/83/EC, *supra* note 18, states: 'Where a Member State considers that the variation of a marketing authorization which has been granted in accordance with the provisions of this Chapter or its suspension or withdrawal is *necessary for the protection of public health*, the Member State concerned shall forthwith refer the matter to the Agency' (emphasis added). Art. 35(2) continues in a similar vein: '*in exceptional cases, where urgent action is essential to protect public health*, until a definitive decision is adopted a Member State may suspend the marketing and the use of the medicinal product concerned on its territory. It shall inform the Commission and the other Member States no later than the following working day of the reasons for its action' (emphasis added). Art. 20(4) Regulation (EC) 726/2004, *supra* note 20, on the centralized procedure states: 'Where urgent action is *essential to protect human health or the environment*, a Member State may, on its own initiative or at the Commission's request, suspend the use in its territory of a medicinal product for human use which has been authorised in accordance with this Regulation' (emphasis added) and there are similar reporting procedures as under the Community code.

²³⁶ Rec. 13 Regulation (EC) 726/2004, *supra* note 20 states: '*Member States should be able exceptionally to prohibit the use in their territory of medicinal products for human use which infringe objectively defined concepts of public policy and public morality*' (emphasis added). More specifically, Rec. 7 Regulation (EC) 1394/2007, *supra* note 21, states: 'The regulation of advanced therapy medicinal products at Community level *should not interfere with decisions made by Member States on whether to allow the use of any specific type of human cells*, such as embryonic stem cells, or animal cells. *It should also not affect the application of national legislation prohibiting or restricting the sale, supply or use of medicinal products containing, consisting of or derived from these cells*' (emphasis added).

²³⁷ At the time of writing, and by contrast to the regulation of clinical trials, the new medical devices legislation has yet to be adopted and so further consideration of the possible changes to EU regulation in this area will not be considered. See further *Revision of the Medical Device Directives*, available at http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/revision/index_en.htm (last visited 22 December 2016).

underscores the salience and centrality of product safety as the focus of technological risk regulation. Indeed, it is noted that against:

constant technological and scientific progress, *substantial divergences in the interpretation and application of the rules have emerged, thus undermining the main objectives of the Directives, i.e. the safety of medical devices and their free movement within the internal market*. Moreover, regulatory gaps or uncertainties exist with regard to certain products (e.g. products manufactured utilising non-viable human tissues or cells; implantable or other invasive products for cosmetic purposes).²³⁸

The (proposed) new regulatory framework ‘aims to overcome these flaws and gaps and to further strengthen *patient safety*’.²³⁹ Significantly, safety is explicitly tied to the achievement of programmatic priorities, in that it is noted that the framework ‘*should be supportive of innovation and the competitiveness of the medical device industry* and should allow rapid and cost-efficient market access for innovative medical devices, to the benefit of patients and healthcare professionals’.²⁴⁰

The current legislation on medical devices (at the time of writing) is (unusually) explicitly presented as ‘Based on the New Approach’²⁴¹ to harmonization and is applicable to the cluster of examples referred to above, i.e. apps that monitor health and lifestyle, self-diagnosis kits like 23andme, and medical devices using DEHP. In addition to the Medical Devices Directive that in all likelihood applies to these examples, since it is applicable to devices that are used in the diagnosis, prevention, monitoring, treatment, or alleviation of disease that do not achieve their intended purpose by pharmacological, immunological, or metabolic means (the definition of medical devices), there is also the Active Implantable Medical Devices Directive.²⁴² There is a separate *In Vitro* Diagnostic Medical Devices Directive.²⁴³ Medical devices legislation is important for marketing in that it requires and leads to ‘CE’ product safety certification, which is otherwise regulated in the EU by the Directive on General Product Safety.²⁴⁴ This system contrasts with that applicable to medicines, in that the CE system is more industry-based.²⁴⁵ These marketing

²³⁸ European Commission, Proposal for a Regulation on Medical Devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, COM(2012) 542 final, at 2 (emphasis added).

²³⁹ *Ibid.* (emphasis added). ²⁴⁰ *Ibid.* (emphasis added).

²⁴¹ *Medical Devices*, available at http://ec.europa.eu/health/medical-devices/regulatory-framework/index_en.htm (last visited 22 December 2016). Original capitalization.

²⁴² See Directive 93/42/EEC, *supra* note 19 on Medical Devices and Art. 1(2)(a) Directive 90/385/EEC on the Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices, OJ 1990 L 189/17. The latter Directive also covers devices used in ‘diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process’ and to ‘control conception’. Under Art. 1(2)(c) an ‘active implantable medical device’ is defined as ‘any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure’.

²⁴³ Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices, OJ 1998 L 331/1.

²⁴⁴ Directive 2001/95/EC on General Product Safety, OJ 2002 L 11/4.

²⁴⁵ Dorbeck-Jung and Chowdhury, ‘Is the European Medical Products Authorization Regulation Equipped to Cope with the Challenges of Nanomedicines?’, 33 *Law and Policy* (2011) 276, at 282.

rules are also pertinent to the law and regulation of research processes discussed earlier in that marketing authorizations cannot be granted without compliance with principles of good laboratory and clinical practice.²⁴⁶

Similar to the pharmaceuticals legislation, medical devices legislation includes safeguard clauses that permit Member States to introduce temporary measures derogating from the free movement of goods, typically expressed in these or similar terms: ‘in order to ensure *protection of health and safety and/or to ensure that public health requirements are observed*’.²⁴⁷ A little wider than the temporary derogation on (essentially) public health grounds in relation to pharmaceutical products under the Community code, these temporary derogations again underline the narrow focus on product safety as the central concern of risk regulation through internal market law. The French ban on the use of tubes containing DEHP from paediatric, neonatal, and maternity units on public health grounds (again, which was noted in relation to negative integration) might therefore be permitted on a temporary basis.²⁴⁸ Further, this ban has in fact prompted attempts to ensure that future revisions of the applicable legislation contain a similar ban (which would of course be an EU-wide ban). This move underscores the interactive relationship between justifications for restrictions on free movement (here found in harmonization measures and to some extent duplicating those found in Article 36 TFEU) and legislative revision in an effort to maintain a connection with and

²⁴⁶ E.g. Rec. 4 Directive 2004/10/EC, *supra* note 154 provides that the EU’s marketing legislation lays down ‘that non-clinical tests on pharmaceutical products are to be carried out in accordance with the principles of . . . [GLP] in force in the Community for chemical substances, compliance with which is also required by other Community legislation’. Also see Rec. 3 Directive 2005/28/EC, *supra* note 188.

²⁴⁷ Art. 10(c) Directive 90/385/EEC, *supra* note 242: ‘Where a Member State considers in relation to a given product or group of products that, *in order to ensure protection of health and safety and/or to ensure that public health requirements are observed*, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited, restricted or subjected to particular requirements, it may take any necessary and justified transitional measures’ (emphasis added) and ‘The Member State shall then inform the Commission and all the other Member States of the transitional measures, giving the reasons for its decision’. Elsewhere Art. 8 Directive 93/42/EEC, *supra* note 19 on Medical Devices states:

Where a Member State ascertains that the devices . . . when correctly installed, maintained and used for their intended purpose, may compromise the *health and/or safety of patients, users or, where applicable, other persons*, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance with this Directive. (Emphasis added)

Finally, Art. 13 Directive 98/79/EC, *supra* note 243, ‘Where a Member State considers . . . that, *in order to ensure protection of health and safety and/or to ensure that public health requirements are observed pursuant to Art. 36 of the Treaty*, the availability of such products should be prohibited, restricted or made subject to particular requirements, it may take any necessary and justified transitional measures. It shall then inform the Commission and all the other Member States, giving the reasons for its decision’ (emphasis added). Once any of these safeguard clauses has been triggered the Commission goes on to consult the other Member States and decide on new or amended legislation in order to address the regulatory challenge.

²⁴⁸ Most likely under Art. 8 Directive 93/42/EEC, *supra* note 19.

shape technoscientific trajectories (but in ways that continue to centralize product safety concerns over other possible matters as the focus of technological risk regulation). However, further underlining the implications of the focus on product safety, a ban on 23andme for reasons beyond a failure to meet essential health and safety requirements would not seem to be permitted under this legislation—and since those requirements have been met the Medicines and Healthcare products Regulatory Agency has authorized this product's marketing in the UK.²⁴⁹

There is additional product safety legislation relating to human tissue,²⁵⁰ blood,²⁵¹ and organs.²⁵² However, this legislation is not based on Article 114 TFEU; instead it is based on (what is now) Article 168 TFEU (which as noted earlier is the legal basis for EU action in the field of public health), since these things are not commonly recognized as 'products' in European cultures.²⁵³ The focus of this legislation is still on the regulation of risk, including in the case of NHTs. Yet, the fact that the basis of this legislation is Article 168 TFEU suggests that the market frame must sometimes recede from view or be supported by others—such as bioethics, as exemplified in references to EGE opinions in the recitals introducing and justifying legislation,²⁵⁴ or elsewhere through assurances of compliance with human rights protections, for instance in relation to clinical trials.

Overall, product safety legislation focuses on a narrow set of harms or hazards and it is these that form the focus of technological risk regulation understood as being about product safety and quality.²⁵⁵ The underpinning rationale of this focus is the internal market and the generation of economic optimization. As stated in the Community code: 'Trade in medicinal products within the [EU] is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products . . . , and such disparities directly affect

²⁴⁹ Again, in this case the legislation that is likely to apply is Directive 93/42/EEC, *supra* note 19. For authorization of '23andme' see *supra* note 73.

²⁵⁰ Directive 2004/23/EC on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells, OJ 2004 L 102/48.

²⁵¹ Directive 2002/98/EC on Setting Standards of Quality and Safety for the Collection, Testing, Processing, Storage and Distribution of Human Blood and Blood Components and Amending Directive 2001/83/EC, OJ 2002 L 33/30.

²⁵² Directive 2010/53/EU on Standards of Quality and Safety of Human Organs Intended for Transplantation, OJ 2010 L 207/14.

²⁵³ A.-M. Farrell, *The Politics of Blood: Ethics Innovation and the Regulation of Risk* (2012); Farrell, 'The Politics of Risk and EU Governance of Human Material', 16(1) *Maastricht Journal of European and Comparative Law* (2009) 41.

²⁵⁴ E.g. Directive 2004/23/EC, *supra* note 250 and Regulation (EC) 1394/2007, *supra* note 21.

²⁵⁵ See, e.g., Recs 1–5, 8, 11, 13, 15, 19, 28, 31, and 32 and Arts 1, 8, 9, 11, and 16–24, and of course the title of Directive 2004/23/EC, *supra* note 250; Recs 3, 4, 7, and 11 Directive 2011/62/EU amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, as regards the Prevention of the Entry into the Legal Supply Chain of Falsified Medicinal Products, OJ 2011 L 174/74. This Directive aims to prevent falsified medicines, which can include NHTs, such as the monoclonal antibody, Avastin, see the report to the effect that some samples of Avastin had salt, starch, and various chemicals, but none of the life-saving active ingredients, see <http://www.reuters.com/article/2012/02/27/us-avastin-idUSTRE81Q29X20120227> (last visited 22 December 2016).

the functioning of the internal market'.²⁵⁶ So, for example, the need to 'safeguard public health' articulated as a patient or consumer safety matter is mentioned (and is the central ground for a temporary derogation from the legislation and the free movement of goods), but the rationale is protecting and promoting the market in those products.²⁵⁷ The Community code is exemplary of this: '[w]hile the fundamental objective of the regulation of medicinal products is to safeguard public health, this aim should nevertheless be achieved by means that *do not impede the free movement of safe medicinal products within the Union*'.²⁵⁸

An important consequence of the focus on safety and quality is that new products do not have to constitute improvements over and above what is already available. For example, as the EMA explains in its 'soft law' guidance on 'medicinal products', 'it is *not necessary for the benefit-risk profile of an experimental medicine [in clinical trials] to [be] at least as favourable as the benefit-risk profile of any or all established medicines in order to receive marketing authorisation*'.²⁵⁹ For example, producing a new pharmaceutical that has fewer side effects can be useful, as can having multiple equally effective medicines available as a way of tackling resistance to medication. However, consistent with the criteria for market authorization under the Community code, clinical trials need only at the bare minimum ensure that pharmaceuticals are as good as or at least no worse than existing products. In short, the focus is on bringing goods to market rather than improvements in health outcomes.

Regulating technological risk instantiated as product safety is of continuing importance in that it extends beyond market authorization into post-marketing monitoring and surveillance. In relation to medicinal products or pharmaceuticals, for example, this occurs through so-called pharmacovigilance,²⁶⁰ a system that requires those who hold the authorizations and medical professionals to be watchful for and report adverse reactions (a similar system operates under the medical devices legislation). The *efficacy* of ATMP products must also be

²⁵⁶ Rec. 4 Directive 2001/83/EC, *supra* note 18.

²⁵⁷ The EU is not alone in focusing on markets, see R. C. Eccleston, *A Model Regulatory Program for Medical Devices: An International Guide* (2001), at 3–4.

²⁵⁸ Rec. 4 Directive 2010/84/EU Amending, as Regards Pharmacovigilance, Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, OJ 2010 L 348/74 (emphasis added).

²⁵⁹ EMA, *Reflection Paper on the Need for Active Control in Therapeutic Areas Where Use of Placebo is Deemed Ethical and One or More Established Medicines are Available*, EMA/759784/2010, at 3–4 (emphasis added). Art. 82 Regulation (EU) 536/2014, *supra* note 169 states that on the basis of Art. 168(4)(c) TFEU the new regulation helps to ensure 'that treatments and medicines which are *intended to be an improvement of a treatment of patients* build on reliable and robust data' (emphasis added). This basis implies that clinical trials data is also intended to demonstrate that a new pharmaceutical is an improvement over what is already available. However, the criteria for market authorization ensure that this is not necessarily the case.

²⁶⁰ Regulation (EU) 1235/2010 Amending, as Regards Pharmacovigilance of Medicinal Products for Human Use, Regulation (EC) 726/2004, OJ 2010 L 348/1; Directive 2010/84/EU Amending, as Regards Pharmacovigilance, Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, OJ 2010 L 348/74; Arts 101–108b Directive 2001/83/EC, *supra* note 18.

followed up²⁶¹ and there is a requirement to ensure the traceability of ATMPs.²⁶² Member States share pharmacovigilance information through the EMA and its Pharmacovigilance Risk Assessment Committee, using the 'Eudravigilance' database.²⁶³ In addition, the Product Liability Directive²⁶⁴ provides that producers are liable for damage caused by a defect in products, except where it is possible to show that the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered.²⁶⁵ In these main ways EU post-marketing legislation extends the preemptive effects of EU internal market law (in relation to Member State measures).

Although there is no harmonization of a 'basket of healthcare goods' across the EU's internal market, there are additional post-marketing techniques aimed at facilitating take-up and consumption by healthcare systems. For example, there are efforts to develop common EU-level health technology methodologies for assessing NHTs.²⁶⁶ This occurs through the sharing of national health technology assessments.²⁶⁷ These efforts are risk-based: they are concerned with assessing, inter alia, the product safety risks posed by NHTs and putting that knowledge forward for consideration in funding decisions.

5. Conclusions

It should be apparent by now that the EU's internal market law remains of ongoing relevance to the regulation of new and innovative technologies. Internal market law plays a leading role by engaging with and seeking to regulate technological risk through the complementary modes of negative integration and positive integration that have been traced in Sections 3 and 4 of this chapter. In terms of negative integration, regulation principally occurs through the engagement of internal market provisions and principles with national measures that seek to regulate new technologies. In this mode EU law disapplies national laws that are deemed unjustifiably restrictive to free movement. This does not go so far as to narrow the range of national regulation to product safety, but there is a narrowing of the scope of permissible risk regulation. The interpenetration of trade through the facilitation

²⁶¹ Art. 14(1) Regulation (EC) 1394/2007, *supra* note 21. For other medicinal products, generally only safety studies are requested.

²⁶² Art. 15, *ibid.* ²⁶³ Regulation (EU) 1235/2010, *supra* note 260.

²⁶⁴ Directive 85/374/EEC on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, OJ 1985 L 210/29.

²⁶⁵ Knowledge of the possibility of a defect is likely to make the defence inapplicable: *A v. National Blood Authority*, *The Times*, 4 April 2001 (QB).

²⁶⁶ This is a 'toolkit' that assists in making specific technology appraisal decisions (such as made by NICE in England).

²⁶⁷ Art. 15(2)(b) Directive 2011/24/EU, *supra* note 17 provides that one of the objectives of the health technology assessment network shall be to support Member States in the provision of objective, reliable, timely, transparent, comparable, and transferable information on the relative efficacy as well as on the short- and long-term effectiveness, when applicable, of health technologies and to enable an effective exchange of this information between the national authorities or bodies.

of free movement is in turn tied to the production and legitimation of the EU's identity, socio-technical order, and the project of integration.

Through the complementary and necessary mode of positive integration the EU becomes even more clearly involved in the regulation of technological risk. This occurs through the use of various techniques, foremost among them internal market legislation, but also encompassing a range of supporting measures. These positive integration techniques are all directed at regulating technological risk instantiated narrowly as product safety, occasionally with references to guarantees of compliance with ethical standards and protections (and human rights usually through those). The central aim of these techniques is to prevent fragmentation of the internal market and the conditions of competition by steering, limiting, and, in the case of legislative measures, pre-empting diverse national approaches and responses to technological risk—and this actually underscores the complexity of risk and the scope for contestation.

In these ways the EU engages with technological risk, and that engagement becomes central to more than the continued application, efficacy, and legitimation of its internal market law. Through its engagement the EU comes to present, produce, and legitimate itself—and its identity—in quite specific ways. The regulation of risk provides the EU with a key opportunity to delineate the boundaries of its responsibility and accountability (i.e. for new technologies that are determined to be 'safe' within the narrow framing of risk), while sidelining notions of risk that pertain to alternative harms and hazards (besides product safety) and key normative questions about technoscientific trajectories, including what is being done, why, how, who benefits, and who is hurt. These matters are decided at the overarching level of governance, but through the subsequent framing of EU regulation as being about regulating a particular kind of risk they are effectively removed as topics of democratic debate. This is despite those dimensions being key biopolitical issues for the EU's citizenry, as well as those who are enfolded in the regime or consume its products,²⁶⁸ but who are thereby reduced to and governed as a very particular kind of European 'risk society'.²⁶⁹

This analysis points to the role of technological risk regulation in extending existing power relations, technoscientific, and ultimately sociopolitical trajectories. Far from simply following technoscientific development and struggling to keep up, internal market law is of central importance to attempts at steering its path and direction, engaging as it does through tightening relations with research and knowledge creation, manufacturing processes, and marketing.²⁷⁰ In these ways the analysis in this chapter also alludes to the ways in which internal market

²⁶⁸ M. Foucault, *Security, Territory, Population: Lectures at the Collège de France, 1977–1978* (2007).

²⁶⁹ U. Beck, *Risk Society: Towards a New Modernity* (1986); U. Beck, *World at Risk* (2009); Giddens, 'Risk Society: The Context of British Politics', in J. Franklin (ed.), *The Politics of Risk Society* (1998).

²⁷⁰ Resonant with work in Science and Technology Studies: Jasanoff, 'The Idiom of Co-Production', in S. Jasanoff (ed.), *States of Knowledge* (2004); S. Jasanoff, *Designs on Nature* (2005).

law is itself representative of (re)configurations between power and responsibility (through the extension of EU power through its market orientation and beyond the formal Treaty-based boundaries), governance and the governed (with the latter extending beyond EU citizens to encompass consumers of internal market law-compliant products and those enrolled as biomedical labour in regulatory processes), knowledge and power (seen in tightening and co-productive relations), and sovereignty and territoriality (through the EU's regulation of free movement across the territory of its Member States), in order to ensure market circulation of products and generate economic optimization.²⁷¹

Overall, the chapter underlines a concern that has been largely overlooked in legal scholarship on new technologies: the alignment, (re)configuration, and (re)orientation of law to and within market-oriented norms, values, and rationalities, as part of political projects of rule (here, the EU's) that seek to shape technoscientific innovation and trajectories in order to serve their particular priorities and aims. In other words, through engagement with technological risk, internal market law is itself being (re)articulated, (re)imagined, (re)oriented, and harnessed as part of a broader strategy of building and (re)legitimizing the EU's identity as a supranational entity.²⁷² In this strategy the EU's socio-technical order and ultimately the project of European integration are to be established upon and legitimated through the achievement of a competitive, innovative, and optimized economy. The focus of the strategy, in short, is on increasing the market availability of goods rather than ensuring that they are comparatively better than existing options, meet genuine health needs, and improve health outcomes.

Despite the masking of these normative dimensions, and the marginalization of other kinds of harms or hazards to which risk might pertain, the EU's dominant market-based identity, order, and model of integration can be challenged. The downplaying of other possible responses to technological risk occurs through constraints on the type, scope, and nature of risks that can feasibly be regulated at Member State level by negative integration and the further limiting of national diversity in technoscientific development by various complementary positive integration techniques that in the case of legislation have pre-emptive effects. The downplaying of other responses marks an attempt to influence technoscientific trajectories by limiting contestation. However, crucially, that same attempt also points to the existence of, and potential for the recognition of, wider understandings of risk and alternative framings of regulation.

In particular, although currently inflected in places and seeming to operate more as legitimating devices, it is possible to use human rights and bioethics in order to contest and (re)frame regulation, especially harmonization legislation and supporting measures. For example, there could be an increased stress on the

²⁷¹ Foucault, *supra* note 4; A. Ong, *Neoliberalism as Exception: Mutations in Citizenship and Sovereignty* (2006). Cf. W. Walters and J. H. Haahr, *Governing Europe: Discourse, Governmentality and European Integration* (2006).

²⁷² B. Anderson, *Imagined Communities* (1983); Y. Ezrahi, *The Descent of Icarus* (1990); J. C. Scott, *Seeing Like a State* (1998).

EU's responsibility to ensure a high level of human health protection in order to ensure the development of products that are safe, genuinely needed in order to meet pressing health needs, and comparatively better than existing options. These (and other possible) framings can bring into view and regulate for a more diverse set of aims and concerns, recognize contestation about the focus and direction of scientific and technological development, and facilitate democratic debate.²⁷³ Far from lagging behind technoscientific development, the way in which the EU keeps up—via internal market law and supplementary techniques that are steered by the aims and priorities set at the overarching level of governance—leads to a particular economic and market identity and orientation and the downplaying of other possible responses.

²⁷³ For discussion see Flear, *Governing Public Health*, *supra* note 10.