THE POLITICS OF RISK AND EU GOVERNANCE OF HUMAN MATERIAL

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ABSTRACT

This paper examines the politics of EU risk governance in relation to human material. It is argued that the political context has informed the way in which risks in relation to various types of human material have come to be defined as policy problems at EU level. In turn, this has influenced the design and/or persistence of institutional arrangements to manage such problems. It is further argued that this political context has resulted in a significant level of disconnection in risk governance in the area. This has happened in two ways. First, there has been a growing level of disconnection between institutional and stakeholder demands for a more expansive approach to risk governance in the area and the narrowly-circumscribed competence under Article 152(4)(a) EC, which permits the adoption of risk regulation regimes that set minimum standards of quality and safety in relation to blood, tissue/cells and organs. Second, it has led to the development of institutional arrangements that promote a bifurcated approach to risk governance, specifically in relation to blood and tissues/cells. Although a hybrid of traditional and new governance mechanisms have been employed to address this problem of disconnection, this has nevertheless added a further layer to already complex institutional arrangements for risk governance in the area. It is suggested that a more integrated approach to EU risk governance in relation to human material is needed. Implementing such an approach would contribute to greater clarity,

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transparency and accountability in decision-making processes, and this could enhance public trust in what is a politically-sensitive area of governance at EU level.

Keywords: risk; risk regulation; European Union; human material; blood; tissue; organs

§1. INTRODUCTION

The management of risk has become an increasingly important feature of EU public health governance. The origins of its growing prominence are to be found in the perceived need to manage emerging risks created by advances in biotechnology, as well as the need to engender public trust and enhance political legitimacy in the wake of failures in governance with respect to managing public health risks at both Member State and EU levels.[1] This has been accompanied by a recognition of the importance of consulting with a broad range of stakeholders and experts, as well as improving governance processes to promote more 'openness, participation, effectiveness and coherence.'[2] Although regulation remains a favoured tool of governance for managing risks to public health at EU level, new governance mechanisms have become more widely used in recent years. New governance has been defined in various ways. Broadly speaking, it is said to permit a more flexible and participatory approach to the formation of policy involving a range of stakeholders through shared learning, benchmarking, development of best practice models, and may include the use of peer pressure to facilitate a shift towards mutually beneficial and agreed upon objectives. This is to be contrasted with traditional command and control models more commonly employed at EU level, for example, through the adoption of regulation in line with treaty-mandated powers.[3]

It is against this background that EU risk governance in relation to human material has emerged, grounded in the competence created under Article 152(4)(a) EC.[4] In line with the parameters of this competence, risk regulation regimes have been established

1 Vos, *Overcoming the Crisis of Confidence: Risk Regulation in an Enlarged European Union* (Working Paper), (University of Maastricht, 2004), 3; Farrell, 'The Emergence of EU Governance in Public Health: The Case of Blood Policy and Regulation', in M. Steffen (ed.), *Health Governance in Europe*, (Routledge, 2005), 135–136.

2 European Commission, *European Governance: A White Paper*, COM (2001) 428 final, (25.7.2001) 8, 19.

3 De Búrca and Scott, 'Introduction: New Governance, Law and Constitutionalism', in G. de Búrca and J. Scott (eds.), *Law and New Governance in the EU and the US*, (Hart, 2006), 2.

4 Article 152(4)(a), Treaty Establishing the European Community (consolidated text) OJ C 325 (24. 12.2002). Article 152(4)(a) EC provides for the adoption of 'measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures.' The adoption of such measures is subject to the caveat set out in Article 152(5) EC which states that 'measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.'

in relation to blood, tissues/cells and organs in circumstances where they have been subjected to political contestation and monitoring. Such regimes operate alongside separate institutional arrangements and other regulation, which are designed primarily to promote innovation in circumstances where the application of industrial processes to human material gives it significant commercial potential or value. Dealing with risk in the context of innovation involving the use of human material has been largely removed to a technocratic environment, to be overseen by those with the relevant scientific expertise. This bifurcated approach to risk governance in the area has been further complicated by the employment of a range of new governance mechanisms in recent years, which has been designed to address a range of ethics- and differential risk-based concerns that have been raised by stakeholders, as well as the European Parliament (Parliament).

This article aims to examine the politics of EU risk governance in relation to human material. It is argued that the political context has informed the way in which risks in relation to various types of human material have come to be defined as policy problems at EU level. In turn, this has influenced the design and/or persistence of institutional arrangements to manage such problems. It is further argued that this political context has contributed to a significant level of disconnection in the area.[5] This has happened in two ways. First, there has been a growing level of disconnection between the narrowly-circumscribed competence under Article 152(4)(a) EC and institutional and stakeholder demands for a more expansive approach to risk governance. Second, it has led to the development of institutional arrangements that promote a bifurcated approach to risk governance, specifically in relation to blood and tissues/cells. Although EU decision-makers have sought to address this problem of disconnection through employing a hybrid of traditional and new governance mechanisms, it has nevertheless added a further layer to already complex institutional arrangements for risk governance in the area.

In the circumstances, it is suggested that a more integrated approach to EU risk governance in relation to human material is needed. This approach would contribute to greater clarity, transparency and accountability in respect of decision-making processes, and has the potential to enhance public trust in what is a politically sensitive area of EU governance. Adopting such an approach would require that institutional reform be implemented in order to bring to an end the current bifurcated approach to risk governance. In terms of facilitating public trust, it would also be important to ensure that ongoing political monitoring takes place with regard to EU risk governance in relation to human material, whether related to innovation or not. In order to examine these arguments, an overview is first provided of the political context in which risk governance in relation to human material has emerged at EU level. Thereafter, an analysis is provided

5 In using the term 'disconnection', I am drawing on and adapting arguments made by Roger Brownsword regarding the problem of maintaining regulatory connection in relation to new technologies, 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*, (Hart, 2008), 26.

of the policy and regulatory initiatives that have been pursued to date in relation to blood, tissues/cells and organs. The final section of the article examines how and why disconnection has occurred in EU risk governance in this area.

§2. MANAGING RISK INVOLVING HUMAN MATERIAL: EXAMINING THE POLITICAL CONTEXT

Over the past thirty years, the emergence of risks brought about by developments in science and technology, as well as those related to globalization, has led to claims that we are now living in a risk society where public uncertainty over the scope and effects of such risks demand an effective political response.[6] This 'popularisation of risk'[7] raises a number of problems in the political context, as successful management of perceived risks to public health may involve taking account of the fact that they are socially-framed and may turn on the particularities of historical and cultural context, as well as being subject to renegotiation in the wake of subsequent scientific and technology developments. While such renegotiation may involve input from scientific and ethics experts, it ultimately becomes a matter for those in political leadership to determine where to draw the line in this negotiation process, in circumstances where public trust, the legitimacy of decisions taken, or the allocation of blame, may be at stake.[8]

This process of renegotiation began in earnest at EU level in the wake of the BSE crisis in the late 1990s and led to risk governance in relation to the protection of human health assuming a prominent place on the political agenda.[9] A number of reforms were instituted, including the reorganization of the provision of scientific, as well as other types of expert, advice;[10] the creation of independent agencies adopting explicit strategies

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6 U. Beck, *Risk Society: Towards a New Modernity*, (Sage, 1992), 19.

7 Wynne, 'Risk and Social Learning: Reification to Engagement', in S. Krimsky and D. Golding (eds.), *Social Theories of Risk*, (Praeger Publishers, 1992), 283; S. Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States*, (Princeton University Press, 2005), 266.

8 Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States*, (Princeton University Press 2005), 266–267.

9 The BSE crisis at EU level arose in the wake of a perceived failure on the part of EU decision-makers and institutions to manage the risk to EU citizens posed by cases of Bovine Spongiform Encephalopathy (BSE) in cattle, an infectious disease which could be transmitted through the food chain to humans, with fatal consequences. The human form of the virus is known as variant Creuzfeldt-Jakob disease (vCJD). One of the consequences of this crisis was a loss of public confidence in the provision and use of scientific advice, as well as risk management generally, at EU level. For an overview of the BSE crisis and its consequences at EU level, see Vos, 'EU Food Safety Regulation in the Aftermath of the BSE Crisis', 23(3) *Journal of Consumer Policy* 227 (2000).

10 I acknowledge that the provision and use of scientific advice in the assessment and management of risk at EU level in matters relating to the protection of human health has produced a wealth of academic literature in the area. It is an issue, however, which is outside the scope of this article. For a recent overview of the key issues, as well as the literature, in the area, see M. Everson and E.Vos (eds.), *Uncertain Risks Regulated,* (Routledge-Cavendish, 2009).

involving risk assessment and communication; a more inclusive approach to policy-making; and the use of a more diversified portfolio of regulatory mechanisms.[11] During this same period, the precautionary principle was also adopted as a guiding principle in EU risk governance.[12] Despite assertions that its adoption provided the central underpinning for the approach subsequently taken to risk regulation at EU level,[13] there has been little evidence of its explicit application in either democratic or technological decision-making processes associated with risk regulation involving human material.[14]

This is so notwithstanding the fact that risk regulation initiatives under Article 152(4)(a) EC coincided with the adoption of the principle, and the fact that it potentially has an important role to play in the area, particularly with regards to dealing with scientific uncertainty, as well as enhancing public trust in risk regulation regimes that have been established to date. This is not to say that precautionary measures have not been adopted in EU risk governance involving human material,[15] but perhaps the lack of an explicit adoption of the precautionary principle in the area could be said to result from the particular political dynamics that structured the creation and parameters of this treaty competence, as will be made clear in the next section of the article. More broadly, it may also reflect an ongoing tension at EU level as to whether the precautionary principle should be regarded as having universal application, or whether a

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11 European Commission, *European Governance: A White Paper*, (2001) 428 final (25.7.2001); De Marchi, 'Public Participation and Risk Governance', 30(3) *Science and Public Policy* 171 (2003), 172.

12 The precautionary principle is not defined in the EC Treaty. It is referred in Article 174(2) EC where it states that 'Community policy on the environment shall aim at a high level of protection … It shall be based on the precautionary principle…'. Notwithstanding the specific reference to the use of the principle in the context of the environment in the EC Treaty, the Commission has stated that its scope and application is much wider at EU level, 'specifically where preliminary objective scientific evaluation, indicates that there are reasonable grounds for concern that the potentially dangerous effects on the *environment*, *human, animal or plant health* may be inconsistent with the high level of protection chosen for the Community', see European Commission, *Communication from the Commission on the Precautionary Principle*, COM (2000) 1 final (2.2.2000), paragraph 3. In addition, it was recognised by the Court of First Instance as being a 'general principle of Community law', applicable in relation to Community action in the areas of public health, safety and the environment, see Joined Cases T-74/99, T-76/00, T-83/00, T- 84/00, T-85/00, T-132/00, T-141/00, *Artegodan GMbH & Ors v Commission* [2002] ECR-II 4945, paragraphs 183–184.

13 De Sadeleer, 'The Precautionary Principle in EC Environmental and Health Law', 12(2) *European Law Journal* 139 (2006), 140.

14 Fisher has observed that while the adoption of the precautionary principle has been 'widely recognised' as central to risk regulation at EU level, 'there has been little examination of the inter-relationship between the two', see E. Fisher, *Risk Regulation and Administrative Constitutionalism*, (Hart, 2007), 210–211.

15 For example, there is a reference in paragraph 2 of the Recital to the Blood Directive (see later in this article) to the need to adopt 'all *precautionary* (emphasis added) measures during the collection, processing, distribution and use' of blood and blood components 'in order to safeguard public health and to prevent the transmission of infectious diseases'. As the substantive part of the Directive makes clear, however, the adoption of such precautionary measures are linked into standard-setting for quality and safety rather than the general adoption of the precautionary principle, in this policy sector.

more nuanced approach is needed to take account of the importance of context, both in its interpretation and its application, across various policy sectors.[16]

While the precautionary principle does not appear to operate as the defining principle in EU risk governance in relation to the use of human material, ethical concerns about whether the use of certain types of human material should be permitted in scientific and technological settings have led to institutional and stakeholder demands that a precautionary approach be applied to decision-making and regulatory processes in the area. While advances in scientific research and biotechnology offer the potential for developing life-saving therapies for chronic and debilitating diseases as a result of the expanded use of human material, it is argued they also raise concerns on both ethical and risk-based grounds as to whether such advances should be supported, particularly where they may affect human genetic heritage, or the creation of life itself.[17] In this context, deontologically-inspired discourse, informed by references to the need to uphold human dignity as well as to avoid the commodification of the human body, has provided important signifying terms at EU level for those advocating a precautionary, if not prohibitory, approach to the use of certain sorts of human material including human embryos, in such settings.[18]

Those with ethics expertise have come to be seen as mediators in political conflict that has arisen at EU level in relation to the use of human material in such circumstances, providing a bridge between citizens and EU decision-makers in advising on the acceptability (or otherwise) of governance initiatives.[19] This has led to the creation of the European Group on Ethics in Science and New Technologies (EGE) which has provided advice on a range of ethical issues pertaining to the use of human material.[20] With

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16 Fisher, *Risk Regulation and Administrative Constitutionalism*, 240–241; for the development of further arguments on the importance of taking account of context in the interpretation and application of the precautionary principle at EU level, see Fisher, 'Opening Pandora's Box: Contextualising the Precautionary Principle in the European Union', in M. Everson and E. Vos (eds.), *Uncertain Risks Regulated*, (Routledge-Cavendish, 2009), 21–45.

17 For a discussion of ethical and other concerns raised by the expanded use of human material, see Brazier, 'Human(s) (as) Medicine(s)', in S. A. M. McLean (ed.), *First Do No Harm: Law Ethics and Healthcare*, (Ashgate, 2006), 187–203.

18 It should be noted that in contrast to this position, there are those who favour a more utilitarian approach to the use of human material, particularly in the context of scientific research (see Harris et al., 'An Ethical Framework for Stem Cell Research in the European Union', 13(3) *Health Care Analysis* 157 (2005). Although a detailed examination of key arguments put forward along the deontological-utilitarian divide regarding the ethics of using human material is outside the scope of this article, for an overview see Farrell, 'The Body Politic: Ethical Concerns, Regulatory Dilemmas and Human Embryonic Stem Cell Research in the European Union', 28(2) *Zeitschrift für Rechtssoziologie* 215 (2007), 219–221.

19 Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States*, (Princeton University Press, 2005), 201.

20 For further details of ethics advice provided by the EGE in relation to the use of different types of human material, see http://ec.europa.eu/european_group_ethics/index_en.htm (accessed 2.1.2009). The extent to which the provision of ethics advice by bodies, such as the EGE, has been effective in mediating political conflict over ethical concerns in this area is not examined further in this article. For

or without formal input from bodies such as the EGE, however, political conflict over ethical issues has remained a feature of inter-institutional negotiations over the adoption of Framework Directives based on Article 152(4)(a) EC. At first glance, this appears surprising given the fact that the competence is narrowly circumscribed to provide for the establishment of risk regulation regimes setting minimum standards of quality and safety in relation to human material such as blood, tissues/cells, and organs. As will become clear when the parameters of the political conflict that erupted during the course of such negotiations are examined in the next section of the article, however, ethical aspects are seen as being inextricably linked to risk governance in the area by those who object to the use of particular types of human material, such as human embryos.

Risk regulation under Article 152(4)(a) EC is linked into institutional arrangements and other regulations which are designed primarily to promote innovation in circumstances where the application of industrial processes to human material gives it significant commercial potential or value. Innovation strategy with a view to creating a highly competitive and dynamic knowledge-based economy has been high on the EU political agenda since the Lisbon Strategy was first initiated in 2000.[21] Within the relevant academic and policy literature dealing with innovation, the focus has traditionally been on examining how systems and institutions interact to produce new knowledge, products and services drawing on a predominantly economic, market-based perspective.[22] Within this context, innovation was seen as a good in itself and the centrality of technology was taken for granted. In recent years, however, there has been a shift towards adopting a more critical approach to examining the inter-relationship between regulatory processes and innovation,[23] as well as how risk governance relates to, and impacts upon, innovation.[24] In a recent Communication on the issue, the Commission underlined that an innovation-friendly market requires consumer trust and safety in products and services, particularly with regard to their safety. Regulation was seen as the bridging mechanism for facilitating risk governance in a way that promoted innovation. Appropriately applied, regulation could create a research and business environment that was predictable, offering the potential to reduce transaction costs in design, implementation and impact on products and services.[25]

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different perspectives on the issue, see Lenoir, 'Biotechnology, Bioethics and Law: Europe's 21st Century Challenge', 69(1) *Modern Law Review* 1 (2006), 3; Plomer, 'The European Group on Ethics: Law, Politics and the Limits of Moral Integration in Europe', 14(6) *E. L. J.* 839 (2008).

21 See http://ec.europa.eu/growthandjobs/index_en.htm, (accessed 2.1.2009).

22 Borrás, 'System of Innovation Theory and the European Union', 31(6) *Science and Public Policy* 425 (2004), 426.

23 European Commission (DG Enterprise), *Innovation Tomorrow: Innovation Policy and the Regulatory Framework: Making Innovation an Integral Part of the Broader Structural Agenda*, (Brussels, 2002).

24 Gonçalves, 'Risk and the Governance of Innovation in Europe: An Introduction', 73(1) *Technological Forecasting and Social Change* 1 (2006), 2.

25 European Commission, Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: *Putting Knowledge into Practice: A Broad-based Innovation Strategy for the EU*, COM (2006) 502 final, 4–6.

What is missing from the Commission's analysis of the inter-relationship between risk, regulation and innovation, however, is an explicit acknowledgement that the management of risk is subject to political context, particularly in sensitive areas of risk governance such as that involving the use of human material. This political context can lead to a degree of unpredictability resulting from stakeholder pressure, adverse public reaction, and the emergence of unforeseen problems arising at national level, which in turn may impact at EU level. This unpredictability has the potential to produce unintended outcomes from regulatory processes which may, or may not, be conducive to innovation. Notwithstanding aspirational rhetoric from the Commission in this area, available evidence points to ongoing conflict and tension at institutional level over how best to manage risk and innovation through regulation with regard to the use of human material.[26] Such unresolved conflict has led to the development of institutional structures and decision-making processes that have resulted in a bifurcated approach to risk governance at EU level in the area.

Reference has previously been made to efforts in recent years to the reform of governance processes at EU level. One of the aims of such reform has been to address problems that have arisen as a result of a perceived lack of public trust in decision-making involving developments in biotechnology.[27] Engendering public trust requires the implementation of mechanisms designed to provide information, enhance transparency and consultation in decision-making, ensure that ethical concerns are taken into account, and to facilitate the accountability of decision-makers within democratic processes and institutions. It is debatable, however, whether the way in which the EU polity is structured allows for the incorporation of such mechanisms in a meaningful way, notwithstanding recent attempts at reform. Operating more like a regulatory state, it requires expertise and the neutrality of regulators to function effectively in what is a multi-level governance environment. It has been argued that decision-making in this type of regulatory state cannot be legitimatized through traditionally-accepted forms of civic participation and parliamentary accountability, as one would expect to find in a majoritarian democracy.[28] If such line of argument is to be accepted, then facilitating public trust in EU risk governance involving human material within this context is likely to be problematic, particularly given the reliance placed on the use of regulation as a legitimation tool. It is an issue to which we shall return once we have examined the emergence and impact of EU risk governance in relation to human material in the next section of the article.

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26 Kent et al., 'Towards Governance of Tissue Engineered Technologies in Europe: Framing the Case for a New Regulatory Regime', 73(1) *Technological Forecasting and Social Change* 41 (2006).

27 European Commission, *European Governance: A White Paper*, 3–7.

28 Magnette, 'European Governance and Civic Participation: Beyond Elitist Citizenship?', 51(1) *Political Studies* 144 (2003); G. Majone (ed.), *Regulating Europe*, (Routledge, 1996).

§3. EU GOVERNANCE OF HUMAN MATERIAL

A. BLOOD

In late 2000, the European Commission (Commission) published a legislative proposal for the adoption of a Framework Blood Directive.[29] Controversy and conflict dominated the passage of the Directive through the legislative process, centring mainly on what method of blood donation – paid or unpaid – should be recognized as the preferred approach for sourcing blood and blood products within the EU.[30] Both ethical and safety arguments were put forward in support of the adoption of voluntary and unpaid blood donation as the preferred method of donation in the EU context. Those who support this method of donation draw on Titmuss's conception of the gift relationship to argue on ethical grounds that it promotes altruism and contributes to greater social solidarity among citizens.[31] In contrast, the buying and selling of blood results in its commodification in the marketplace and devalues its socio-cultural importance in human relationships.[32] It is also argued that this method of donation should be preferred on safety grounds as altruistic donors are less likely to be carrying blood-borne diseases that will harm recipients, given that there are no financial incentives to provide misleading information about any health problems they may have.[33]

Those in favour of paid donation view ethical objections to this method of sourcing blood and blood products as somewhat hypocritical in the EU context, given the significant reliance on importation of such products in the face of national shortfalls in meeting consumer demand.[34] In such circumstances, 'moral misgivings' concerning paid donors are simply 'transferred across national borders', rather than being resolved.[35] It is further argued that blood products sourced from paid donation are now as safe as those sourced from unpaid donation given advances in technology, as well as stricter donor screening

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29 European Commission, Proposal for a Directive of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Council Directive 89/381/EEC, COM (2000) 816 final (13.12.2000).

30 Sauer et al., 'The Regulation of Blood and Tissues in the European Union', 6 *Pharmaceuticals Policy and Law* 47 (2005), 51.

31 R. Titmuss, *The Gift Relationship: From Human Blood to Social Policy*, (George Allen and Unwin, 1970), 224–225.

32 Keown, 'The Gift of Blood in Europe: An Ethical Defence of EC Directive 89/381', 23(2) *Journal of Medical Ethics* 96 (1997), 99.

33 Beal and van Aken, 'Gift or Good? A Contemporary Examination of the Voluntary and Commercial Aspects of Blood Donation', 63(1) *Vox Sanguinis* 1 (1992), 2–3.

34 Lewis, 'Europe: Blood Donation', 339(8799) The Lancet 981 (1992).

35 Del Pozo, 'Paying Donors and the Ethics of Blood Supply', 20(1) *Journal of Medical Ethics* 31 (1994), 33–34; von Schubert, 'Donated Blood: Gift or Commodity? Some Economic and Ethical Considerations on Voluntary vs Commercial Donation of Blood', 39(2) *Social Science and Medicine* 201 (1994), 204.

protocols.[36] In any case, it is suggested that there is a need to be responsive to consumer demand and choice in allowing such products to circulate in the EU blood market, given national shortages in the area. Although this debate has been described as an inadequate frame of reference for taking account of the now complex inter-relationship between ethical, socio-cultural and economic issues affecting blood quality and safety,[37] the fraught negotiations over the Blood Directive made it clear that this debate nevertheless has the potential to generate significant political conflict in circumstances where public support remains strong for the retention of the gift relationship in blood donation.[38] In the circumstances, EU decision-makers were forced to find a way forward which would accommodate the opposing sides in this debate, as well as achieve an acceptable political compromise that would allow for the adoption of the Directive.

The nature of the political compromise reached can be gleaned from the carefully-crafted wording used in the Directive. In the non-binding Recital, it states that 'voluntary and unpaid blood donations are a factor which can contribute to high safety standards for blood... and therefore to the protection of human health.[39] Member States are simply 'encouraged' rather than required to take 'all necessary measures to facilitate voluntary and unpaid blood donations.'[40] It is made clear through the use of aspirational and open-ended terminology that the embedding of voluntary and unpaid donation as the preferred method for sourcing the Community blood supply had little political appeal in terms of its inclusion in a binding risk regulation regime to be established under the terms of the Directive.[41] After protracted institutional negotiations, the Blood Directive was eventually adopted on 27 January 2003, and was required to be transposed into national law by 8 February 2005.[42] Following consultation with relevant scientific experts, a series

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36 Beal, 'Titmuss Revisited', in E.A.E. Robinson (ed.), 'Altruism: Is It Alive and Well?', 9(4) Transfusion Medicine 352 (1999), 355.

37 Farrell, 'Is the Gift Still Good? Examining the Politics and Regulation of Blood Safety in the European Union', 14(2) *Medical Law Review* 155 (2006), 164, 168; C. Waldby and R. Mitchell, *Tissue Economies: Blood, Organs and Cells Lines in Late Capitalism*, (Duke University Press, 2006), 49.

38 INRA (Europe), Eurobarometer 41.0, *Europeans and Blood*, (Report prepared for the European Commission, 1995); European Opinion Research Group, EEIG, *Le don de sang* Eurobaromètre special 1883–4/Vague 58.2, (Report prepared for the European Commission, 2003).

39 Paragraph 23, Recital, Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 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 L 2003 33/30. (hereinafter referred to as the Blood Directive).

40 Article 20(1), Blood Directive.

41 Further evidence of this political reality is to be found in recent Commission reports which reveal the wide diversity of views and approaches taken at Member State level regarding levels of reimbursement or other (financial) incentives associated with blood donation, see European Commission, Report from the Commission to the Council and the European Parliament, Report on the Promotion by Member States of Voluntary Unpaid Blood Donations, COM (2006) 217 final.

42 Article 32(1), Blood Directive.

of Commission Directives were subsequently adopted, which elaborate in more detail on the framework quality and safety standards set out in the primary Directive.[43]

The implementation of the Blood Directive has been subject to ongoing political monitoring, with the Commission being required to submit regular written reports to this effect to a number of EU institutions, including the Parliament.[44] These reports reveal widespread implementation of the Blood Directive at national level, together with the creation of the necessary institutional and personnel reforms which were required in order to facilitate such implementation.[45] Transaction costs for New Accession States have been particularly burdensome, however, given the under-developed organization of their national blood supplies when compared to other more established Member States. In a separate report prepared on the use of voluntary and unpaid blood donation at national level, the Commission found a significant degree of variation in its interpretation, as well as in the priority given, to embedding it as the preferred method of donation, by individual Member States.[46]

EU risk governance in relation to blood also involves taking into account institutional arrangements and other regulation that cover blood products, or what are more formally described in regulatory terms as medicinal products derived from human blood or plasma. The most important of these is Directive 2001/83/EC, which establishes a comprehensive Community code relating to medicinal products for human use.[47] In Article 31 of the Blood Directive, amendments were made to Article 109 of Directive 2001/93/EC, which specifically deals with blood products. This was designed to ensure that standard-setting in relation to technical requirements set out in the Blood Directive also applied to the collection and testing of the human blood and human plasma used

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43 Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, OJ L 2006 38/40; Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells, OJ L 2006 294/32.

44 Commencing 1 July 2004, the Commission is required every three years to provide to the European Parliament, as well as the Economic and Social Committee and the Committee of the Regions, a report on the implementation of requirements under the Blood Directive, in particular those relating to inspection and control. This is in addition to providing reports submitted by Member States on the experience gained in implementing the Blood Directive (see Article 26, Blood Directive).

45 European Commission, Report from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: First Report on the Application of the Blood Directive, COM (2006) 313 final; European Commission, Meeting of the Competent Authorities on Blood and Blood components: Summary Report, 13 September 2006, (Art. 25 Dir.2002/98/EC), Brussels SANCO C/6 TB/gcs D (2006) 360346.

46 European Commission, Report from the Commission to the Council and the European Parliament: Report on the Promotion by Member States of Voluntary Unpaid Blood Donations, COM (2006) 217 final.

47 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 2001 311/67.

in such products.[48] Risk governance in relation to such products at an institutional level takes place under the auspices of the European Medicines Agency. Risk assessment and evaluation of such products is largely overseen by scientific experts in this technocratic environment, far removed from the political sphere in which the Blood Directive was adopted and its implementation continues to be monitored.[49] Given that the vast majority of these blood products are sourced from paid donation, it also provides a useful way of avoiding ongoing political conflict generated by the longstanding debate over the merits of unpaid versus paid donation. In turn, this may account at least in part for institutional arrangements that promote a bifurcated approach to managing risk with respect to blood and its components on the one hand, and blood (plasma-derived) products on the other hand.[50]

B. TISSUES AND CELLS

In June 2002, the Commission published a proposal for a Tissues and Cells Directive. In its explanatory memorandum to the proposal, it acknowledged that there was currently inadequate transnational regulation with regard to quality and safety in this area. This needed to be redressed in the light of rapid scientific and technological developments, as well as significant growth in cross-border trade of tissues and cells.[51] During the course of the legislative passage of the proposal, however, inter-institutional conflict once again erupted over ethical concerns. On this occasion, it centred on the extent to which the use of human embryonic stem cells (hESCs) should be permitted for use, if at all, under the terms of the Directive. Members of Parliament argued that ethical concerns were inextricably linked to standard setting for quality and safety, thereby falling within the scope of the competence under Article 152(4)(a) EC. The Council of Ministers (Council) and the Commission disagreed.[52]

Ethical concerns over the use of hESCs had been the subject of ongoing political conflict at EU level, particularly in relation to whether funding for research in this area

48 Farrell, 'Is the Gift Still Good? Examining the Politics and Regulation of Blood Safety in the European Union', 174.

49 Farrell, 'Governing the Body: Examining EU Regulatory Developments in Relation to Substances of Human Origin', 27(3–4) *Journal of Social Welfare and Family Law* 427 (2005), 431.

50 In examining this debate, I acknowledge that recombinant products (which do not contain plasma) have been recommended as safer than plasma-derived products, and are available for use in certain Member States, such as the United Kingdom and Ireland. The high cost of such products, however, means that plasma-derived products are still in wide use within the EU (see Lira, 'Recombinant Proteins in Therapeutics: Haemophilia Treatment as an Example', 1 *International Archives of Medicine* 4 (2008), (http://www.intarchmed.com/content/pdf/1755–7682–1-4.pdf, accessed 5.12.2008).

51 European Commission, Proposal for a Directive of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells: Explanatory Memorandum, COM (2002) 319 final, 2–14.

52 For an overview of such negotiations, see Farrell, 'Governing the Body: Examining EU Regulatory Developments in Relation to Substances of Human Origin', 433–434.

should be permitted under the Sixth Framework (FP6) programme. There had been a number of attempts to craft a political consensus on the issue, with the EGE publishing an advisory opinion on ethical aspects of hESC research;[53] the Commission publishing a staff working paper which examined the scientific, ethical, social and legal issues affecting hESC research; and an inter-institutional seminar being held to further examine ethical issues in the area.[54] While this enabled a political compromise to be achieved which permitted the funding of hESC research in limited circumstances under FP6, it failed to resolve the deep divisions that continued to exist over the issue.[55] Debates over the funding of hESC research under FP6 took place in parallel with inter-institutional negotiations over the Tissues and Cells Directive, and so provided yet another political opportunity for those with ethical concerns in relation to hESC use to air their views on the matter.

In the end, a muddled political compromise was reached over the issue in the final text of the Directive. Concerns over ethical issues regarding hESC use were noted in the non-binding Recital.[56] In line with the principle of subsidiarity, Member State positions on the matter were respected, although it made for a less than comprehensive EU-wide risk regulation regime with regard to the use of stem cells generally.[57] Interestingly, ethical principles regarding the preferred method of donation, as well as the fact that importation of tissues and cells from third countries took place, were both formally acknowledged in the substantive part of the Directive.[58] Unlike the Blood Directive, the locus of political conflict in relation to this latter Directive focused primarily on ethical aspects of hESC use, rather than on the preferred method of donation for tissues and cells. This may have accounted for greater leeway given to emphasizing voluntary and unpaid donation as the preferred method of donation in the substantive part of the Tissues and Cells Directive.[59] What was becoming increasingly clear in the wake of continuing inter-institutional conflict which arose in relation to both Directives was that, while there may have been a political consensus on the need for EU-wide risk regulation in relation to the

53 European Group on Ethics in Science and Technology, *Ethical Aspects of Human Stem Cell Research and Use*, Opinion No. 15, (http://ec.europa.eu/european_group_ethics/docs/avis15_en.pdf, accessed 2.1.2009).

54 European Commission, *Report on Human Embryonic Stem Cell Research*, SEC (2003) 441.

55 Conflict over ethical aspects of research on human embryos and human embryonic stem cell research arose again in the context of the Seventh Framework funding programme, see Farrell, 'Stem Cell Politics', 12(3) *Eurohealth* 33 (2006), 34.

56 Paragraph 12, Recital, Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 of setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells, OJ L 2004 102/48 (hereinafter referred to as the Tissues and Cells Directive).

57 Farrell, 'The Body Politic: Ethical Concerns, Regulatory Dilemmas and Human Embryonic Stem Cell Research in the European Union', 223–225.

58 Articles 9 and 12, Tissues and Cells Directive.

59 Farrell, 'Governing the Body: Examining EU Regulatory Developments in Relation to Substances of Human Origin', 435.

use of these types of human material based under Article 152(4)(a) EC, such competence was proving to be too narrow to accommodate ongoing political conflict over ethical concerns involving the use of human material.

The Tissues and Cells Directive was eventually adopted on 31 March 2004 and was required to be transposed into national law by 7 April 2006.[60] In the intervening period, a number of Commission Directives were adopted in consultation with relevant scientific experts, which elaborate in more detail on the technical aspects of the standards set out in the Framework Directive.[61] As with the Blood Directive, the Tissues and Cells Directive has all the hallmarks of a traditional risk regulation regime and indeed adopts a similar format in terms of standard-setting for quality and safety. Such similarity has extended to the provision of reports at regular intervals to relevant EU institutions, including the Parliament and Council, regarding implementation of the Directive.[62] Responses provided to the Commission by Member States regarding the implementation of the Directive at national level reveal transaction costs have been substantial for many Member States, in particular the New Accession States, with respect to establishing appropriate accreditation, licensing and inspection procedures given the wide range of activities and establishments that are covered by the Directive. Problems have also been experienced with the interpretation and transposition of the wording of the Directive into national law in some Member States, and the relatively short period of time allowed for transposition of the Directive into national law.[63]

EU risk governance in relation to tissues and cells also involves taking account of institutional arrangements and other regulation that deal with tissue and cell-based products. This includes Directive 2001/83/EC to which reference has previously been made, as well as the new Regulation on Advanced Therapy Medicinal Products (ATMPs).[64] It establishes an EU-wide regulatory framework for the marketing, quality

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60 Article 31(1), Tissues and Cells Directive.

61 Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, OJ L 2006 38/40; Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells, OJ L 2006 294/32.

62 Before 7 April 2008 and every three years thereafter, the Commission is required to provide to the European Parliament, as well as the Council, the European Economic and Social Committee and the Committee of the Regions, a report on the implementation of the requirements of this Directive, in particular with respect to inspection and monitoring. This is in addition to providing reports submitted by the Member States on the experience gained in implementing the Tissues and Cells Directive (see Article 26, Tissues and Cells Directive).

63 European Commission, Summary Table: Responses from Competent Authorities: Questionnaire on the Transposition and Implementation of the European Tissues and Cells Regulatory Framework,SANCO C6 CT/gcs D (2007) 360045.

64 Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC)

and safety of ATMPs derived from gene, cell and tissue engineering therapies that have been prepared industrially or manufactured by a method involving an industrial process, whether the material involved is autologous or allogeneic in origin. It had a relatively long gestation period, and is designed to establish a clear and consistent EU-wide approach to the marketing of such products,[65] in what is acknowledged to be an innovative and potentially commercially lucrative area of biotechnology.[66]

The ATMP Regulation makes clear that it does not derogate from the basic principles set out in the Tissues and Cells Directive, and is specifically subject to quality and safety standards set out therein with regard to donation, procurement and testing of tissues and/or cells to be used in ATMPs.[67] As encountered during the passage of the Directive, ethical concerns also generated political conflict during inter-institutional negotiations that took place over the adoption of the Regulation. In particular, objections were raised by stakeholders in relation to permitting the production of ATMPs that were derived from hESCs, human-animal hybrids or chimeras, or that would otherwise involve germline modification. In order to accommodate such objections, the Regulation makes clear that it does not interfere with decisions made by Member States regarding the use of specific types of human cells, such as hESCs, or animal cells. In addition, it does not affect national laws that restrict or do not permit the sale, supply or use of medicinal products containing these sorts of cells.[68]

The processes associated with EU risk governance in relation to tissue and cell-based products appear to reflect a similar approach taken in relation to the use of blood products: a largely technocratic-driven process conducted under the auspices of the European Medicines Agency, which is mediated by those with scientific expertise. There is a discernible difference from the earlier approach taken in relation to blood products, however, since the ATMP Regulation makes provision for a Committee for Advanced Therapies to be established and its remit will include consideration of ethical issues. The

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No 726/2004, OJ L 2007 324/121 (hereinafter referred to as ATMP Regulation). Articles 2(1)(a) and (b) define an 'Advanced Therapy Medicinal Product' as a gene therapy medicinal product as defined in Part IV of Annex I to Directive 2001/83/EC; a somatic cell therapy medicinal product as defined in Part IV of Annex I to Directive 2001/83/EC; a tissue engineered product that (b) contains or consists of engineered cells or tissues, and is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing or replacing a human tissue. A tissue engineered product may contain cells or tissues of human or animal origin, or both. The cells or tissues may be viable or non-viable. It may also contain additional substances, such as cellular products, bio-molecules, biomaterials, chemical substances, scaffolds or matrices. Excluded from this definition are products containing or consisting exclusively of non-viable human or animal cells and/or tissues, which do not contain any viable cells or tissues and which do not act principally by pharmacological, immunological or metabolic action. This definition is in addition to the definitions set out in Article 1, Directive 2001/83/EC and Article 3(a)-(l); (o)-(q) of Directive 2004/23/EC.

65 Paragraph 5, Recital, ATMP Regulation.

66 Sanzenbacher et al., 'European Regulation Tackles Tissue Engineering', 25(10) *Nature Biotechnology* 1089 (2007), 1089.

67 Paragraph 14, ATMP Regulation.

68 Paragraph 7, Recital, ATMP Regulation.

aim is for the composition of the Committee to be broadly inclusive of those with relevant scientific expertise, as well as clinicians and representatives of patient associations.[69] It remains to be seen, however, whether this will be more process-oriented than substantive in practice, particularly with regard to the Committee having real influence in the governance of ATMPs.[70] Notwithstanding this development, institutional arrangements persist which promote a bifurcated approach to EU risk governance involving the use of tissues and cells.

C. ORGANS

There has been a growing level of activity at EU level in recent years with respect to issues affecting organ donation and transplantation. This has included the funding of a number of projects which have been aimed at gathering information and promoting greater coordination between Member States in the area.[71] In 2007, the Commission published its first Communication in the area, which examined policy options and set out a preliminary action plan which was designed to promote greater coordination, as well as to develop strengthened cooperation, between Member States. This was done with a view to increasing the number of organs available for transplantation, as well as the efficiency of organ procurement, in addition to taking measures to combat organ tourism.[72]

While acknowledging that the issue of organ shortage makes the risk-benefit ratio in the case of organ donation and transplantation fundamentally different to that involving other human material such as blood and tissues/cells,[73] the Commission nevertheless underlined in the Communication that quality and safety issues were also important elements that needed to be taken into account in the area. This was particularly so given the risk of transmission of infectious diseases and cancers through the transplantation

69 Article 11, ATMP Regulation.

70 By way of comparison, a study which examined the implementation of a more inclusive approach to participation and decision-making in the case of EU risk governance involving genetically modified organisms (GMOs) found little evidence of an improvement in 'participatory co-production of knowledge nor of public deliberation', see Borrás, 'Legitimate Governance of Risk at the EU Level? The Case of Genetically Modified Organisms', 73(1) *Technological Forecasting and Social Change* 61 (2006), 71.

71 European Commission, Commission Staff Working Document Accompanying Document to the Communication from the Commission to the European Parliament and Council: Organ Donation and Transplantation: Policy Actions at EU Level: Impact Assessment, COM (2007) 275 final, SEC (2007) 705.

72 European Commission, Communication from the Commission to the European Parliament and Council: Organ Donation and Transplantation: Policy Actions at EU Level, COM (2007) 275 final. On an EU-wide basis, there are over 50,000 people on waiting lists for organ transplantation. Many of those on such lists die before an appropriate organ becomes available (see European Commission, SEC (2007) 705, 50).

73 European Commission, COM (2007) 275 final, 10.

process, the growing rate of cross-border exchange of organs between Member States, and the emergence of organ tourism.[74] In light of such issues, the Commission argued that there was a need to ensure a high level of health protection for EU citizens with respect to organ donation and transplantation, which could best be achieved through the adoption of a Framework Directive in line with treaty-mandated powers under Article 152(4)(a) EC.

The Commission also indicated in this Communication that it planned to make use of the Open Method of Coordination (OMC) to implement the action plan.[75] OMC has become a popular new governance mechanism in recent years at EU level and it has been used in an increasing number of social policy sectors, including health care. It is said to permit a more flexible and participatory approach to the formation of policy involving a range of stakeholders through shared learning, benchmarking, best practices and, if necessary, peer pressure to move national policies towards mutually beneficial and agreed upon objectives.[76] In making clear that it intended to make use of OMC in its action plan, the Commission signalled a shift away from using more traditional command and control mechanisms that were more readily apparent in the case of earlier governance initiatives in relation to blood and – to a lesser extent – in the case of tissues and cells.

Following the publication of its first Communication, the Commission embarked upon a series of consultation meetings with both experts and stakeholders in the area with a view to receiving feedback on its proposed action plan, as well as input on the drafting of the proposal for a Directive in the area. The Commission's adoption of OMC raised concerns amongst some stakeholders who viewed it as adding an unwanted layer of bureaucracy to EU-wide action in the area. They argued that this had the potential to divert limited national personnel and administrative resources away from focusing on strategies to address the major challenges in the area.[77] Calls were also made for a great degree of flexibility to be built-in to any EU-wide risk regulation regime, given the markedly different risk-benefit ratio that applies in the case of organ donation and transplantation. This meant that both clinicians and patients needed to be allowed sufficient freedom to make decisions about the relative risks associated with the use of particular organs for transplantation, given factors such as organ shortage, long waiting

74 Ibid., 3.

75 Minutes of the meetings held with stakeholders and experts in the field of organ donation and transplantation regarding the Commission's action plan can be obtained from the following website: http://ec.europa.eu/health/ph_threats/human_substance/events_organs_en.htm, accessed 2.1.2009.

76 Borrás and Jacobsson, 'The Open Method of Coordination and New Governance Patterns in the EU', 11(2) *Journal of European Public Policy* 185 (2004), 188–189; Hervey, 'The European Union's Governance of Health Care and the Welfare Modernization Agenda', 2(1) *Regulation & Governance* 103 (2008), 103.

77 European Commission, 2nd National Expert Meeting on Organ Donation and Transplantation at Community Level: Summary Report, Meeting held in Brussels on 20 November 2007, SANCO C6 (2008) D/ 360020/EFZ/ci.

lists and the fact that organ transplantation was often the only life-saving option for those with end stage organ failure.[78]

In December 2008, the Commission published a second Communication in the area in which it set out an amended action plan which listed five objectives, as well as ten priority actions.[79] Drawing on OMC methodology, the Commission emphasised that these actions aimed to reinforce cooperation between Member States through the 'identification and development of common objectives and guidelines, jointly-agreed indicators and benchmarks, and identification and sharing of best practices'.[80] In pursuit of these actions, the Commission also indicated that it would support and promote EU-wide agreements between Member States on various aspects of transplant medicine, in particular those dealing with patient mobility, extra-Community patients and the creation of a European transplant research network.[81] At the same time as the Commission published this second Communication, it also issued its proposal for a Framework Directive in the area.[82]

The overarching aim of the proposed Directive is to lay down 'rules to ensure high standards of quality and safety for organs of human origin intended for transplantation to the human body'.[83] In terms of standard-setting for quality and safety, it adopts a similar format to the earlier Directives adopted under Article 152(4)(a) EC, with some variation to take account of the specific issues that arise in the case of organ donation and transplantation. In the preamble to the proposal, it is acknowledged that the risk-benefit ratio in organ transplantation is such that the overall benefits are high and therefore more risks are acceptable than would be the case with blood and most tissue or cell-based treatments. Despite the fact that the proposal contains many of the hallmarks of a traditional risk regulation regime based on standard-setting for quality and safety, the Commission has taken on board feedback received in consultations with experts and

78 House of Lords European Union Committee, *Increasing the Supply of Donor Organs within the European Union,* Volume 1: 17th Report of Session 2007–08, (HL Paper 123–1), (The Stationery Office, 2008). Because of the problems created by chronic organ shortage, there has been increasing resort to the use of what are described as 'marginal' or 'expanded donors'. On the basis of traditional clinical criteria, organs donated by such donors would not ordinarily be an optimal match for a potential recipient, but transplantation has nevertheless gone ahead because this may have represented the only life-saving option in the circumstances, (see Audard et al., 'Renal Transplantation from Extended Criteria Cadaveric Donors: Problems and Perspectives Overview', 21(1) *Transplant International* 11 (2007), 11–17).

79 European Commission, Communication from the Commission: *Action Plan on Organ Donation and Transplantation (2009–2015): Strengthened Cooperation between Member States*, COM (2008) 819/3 final, 2–8.

80 Ibid., 2.

81 Ibid., 6.

82 European Commission, *Proposal for a Directive of the European Parliament and of the Council on standards and quality of human organs intended for transplantation*, COM (2008) 818 final (hereinafter referred to as a Proposal for a Directive on Organ Transplantation).

83 Article 1, Chapter 1, Proposal for a Directive on Organ Transplantation, 11.

stakeholders and sought to provide for a significant degree of flexibility in a number of specific areas.

Of particular note in the proposal is the reference to the use of standard operating procedures defined as 'written instructions describing the steps in a specific process...',[84] which appears to allow for flexibility in designing national quality programmes, traceability, adverse event reporting, procurement, transport and characterisation of organs. In addition, the importance of adopting an appropriate organizational model for procuring organs has been underlined in the proposal. This is linked into the design requirements for national quality programmes that aim to cover all stages of the chain from donation to transplantation or disposal of organs. In reality, it appears likely that the Commission will advocate that national quality programmes should include a significant component of the Spanish model in relation to organ procurement, given its spectacular success in increasing the rate of deceased organ donation. Key aspects of the model include the establishment of a transplant co-ordination network at national, regional and hospital levels. In addition, specially-trained physicians act as transplant co-ordinators and are based in every hospital, where they operate independently of the transplant team.[85] At the time of writing this article, the proposal has not yet been the subject of institutional scrutiny and negotiations under the co-decision procedure, therefore, the outcome of such process is awaited with interest.

§4. THE PROBLEM OF DISCONNECTION

An examination of policy and regulatory initiatives involving human material has revealed a significant level of disconnection in EU risk governance in the area. This has occurred in a number of ways. In the case of initiatives based on the competence in Article 152(4)(a) EC, disconnection has occurred because the design of regulatory regimes has been unable to fully accommodate the ethical and differential risk-based concerns affecting blood, tissues/cells and organs. The origins of this growing disconnection in the regulatory process are to be found in the political dynamics then current at the time that Article 152(4)(a) EC was first created through the Treaty of Amsterdam in 1999. At the time, the political objective was primarily focused on achieving a number of ends at national level. These included the need to regain political credibility on the part of national governments in the aftermath of blood contamination scandals; enhancing public trust in national blood and regulatory institutions dealing with public health risks; and finally, ensuring that the sharing of competence to act in a health-related

84 Article 3(o), Chapter 1, Proposal for a Directive on Organ Transplantation, 12.

85 For further details regarding the Spanish model for organ procurement, see Matesanz, 'Factors Influencing the Adaptation of the Spanish Model of Organ Donation', 16(10) *Transplant International* 736 (2003).

area at EU level remained limited.[86] As a result, it led to a bottom-up approach to EU risk governance that was narrow rather than expansive, and largely confined to the establishment of traditional risk regulation regimes in which standard-setting for quality and safety predominated.

In the case of blood, there was widespread agreement that EU action could add value through the establishment of an EU-wide regulatory regime for blood quality and safety despite disagreement between stakeholders concerning the preferred method of donation. Setting standards of quality and safety was vital to limiting the potential spread of infectious agents in the blood supply in circumstances where such agents knew no national borders. Against this background, the scope of the competence under Article 152(4)(a) EC made sense. The underlying rationale for adopting a traditional risk regulation regime based on standard setting for quality and safety became less clear in the case of tissues and cells. In this regard, the management of risk was viewed differently, with institutions such as the European Parliament, as well as stakeholders, wanting to make a more explicit link between ethical concerns and risk governance in the area. Various strategies were pursued by the Commission in an attempt to forge a political compromise from conflict which arose over ethical concerns regarding hESC use during the course of inter-institutional negotiations. Such strategies included drawing on ethics expertise through advisory opinions provided by the EGE; the production of a Commission staff working paper; and the holding of an inter-institutional bioethics seminar on the issue.

Whether or not these strategies could be characterised as new governance mechanisms, the fact that the Commission was forced to resort to them highlighted a more general strategic problem in terms of EU risk governance in the area: the fact that the link was increasingly being made in the political arena between risk regulation and ethical concerns in relation to the use of (certain types of) human material. The narrowly-circumscribed competence under Article 152(4)(a) EC was proving to be a rather rigid tool of governance for managing such concerns in the context of diverse socio-cultural views about the use of human material, such as hESCs. It resulted in EU risk regulation relating to hESCs being less than comprehensive.[87] Given that a recent Eurobarometer survey found that public support for the use of hESCs is largely contingent on the fact that it is 'tightly regulated',[88] the problems experienced with accommodating ethical concerns over such use in the Tissues and Cells Directive is not a situation that is likely to enhance public trust in EU action in the area.

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86 Farrell, 'Is the Gift Still Good? Examining the Politics and Regulation of Blood Safety in the European Union', 176–177.

87 Farrell, 'Governing the Body: Examining EU Regulatory Developments in Relation to Substances of Human Origin', 435.

88 Gaskell et al., *Europeans and Biotechnology in 2005: Patterns and Trends*. Eurobarometer 64.3, (A Report to the European Commission's Directorate-General for Research, 2006), 31.

Taking a more cynical view of inter-institutional negotiations leading up to the adoption of the Tissues and Cells Directive, the narrow scope of Article 152(4)(a) EC also offered a convenient political scapegoat to justify the position of the Council and Commission that ethical concerns raised by the Parliament and stakeholders concerning the use of hESCs were outside Community competence,[89] and therefore a matter for individual Member States. In this way, the continuing failure to obtain a political consensus on hESC use, which could have stalled the regulatory agenda in the area, was neatly side-stepped through due deference to 'ethical subsidiarity'.[90] While this may have represented a neat political compromise in the absence of such consensus, it is debatable whether it was one which was likely to enhance the legitimacy of regulation in this area.

For those involved in parliamentary deliberations leading up to the adoption of the Tissues and Cells Directive, ethical concerns in relation to the use of certain sorts of human material, such as hESCs, were seen as intrinsically linked to risk governance. Political conflict over ethical issues in the context of such deliberations raised wider questions about whether the use of this sort of human material should be permitted, if at all. The need to achieve a compromise over the final text of the Directive appeared to override such concerns. While this was eventually achieved, the failure to engage in a deeper political examination of the reasons for stakeholder conflation of ethics- and risk-based concerns was also not a situation that was likely to facilitate public trust in EU governance initiatives in this area.[91] A more positive development has been ongoing political monitoring of the implementation of risk regulation regimes in blood and tissues/cells through reports provided on a regular basis to relevant EU institutions. This has been useful on a number of grounds: they identify problems experienced in ensuring compliance with the regulatory regime;[92] they ensure that information about how the regime operates is in the public domain; and they create an opportunity for ongoing monitoring at EU level by democratically-accountable institutions, such as the Parliament.

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89 Farrell, 'Governing the Body: Examining EU Regulatory Developments in Relation to Substances of Human Origin', 433–434.

90 Faulkner et al., 'Purity and the Dangers of Regenerative Medicine: Regulatory Innovation of Human Tissue-Engineered Technology', 63(9) *Social Science & Medicine* 2277 (2006), 2284.

91 Similar arguments have been made in the context of examining the relationship between ethics and risk-based concerns in the GMO debate in the UK, (see Wynne, 'Creating Public Alienation: Expert Cultures of Risks and Ethics on GMOs', 10(4) *Science as Culture* 445 (2001), 466).

92 Problems with ensuring compliance has long been acknowledged as a problem in relation to the implementation of risk regulation regimes, see C. Hood et al., *The Government of Risk: Understanding Risk Regulation Regimes*, (Oxford University Press, 2001). Indeed, problems with compliance have also been identified by relevant stakeholders who have highlighted the role of the Commission in contributing to difficulties in this regard. This led one UK-based blood expert to question whether meaningful EU-wide action would be possible in the event of emerging risks to the blood supply in the future, (see Robinson, 'The European Union Blood Safety Directive and its Implications for Blood Services', 93(2) *Vox Sanguinis* 122 (2007), 129).

In the case of EU governance in organ donation and transplantation, it has become apparent that risk-based concerns are at the heart of institutional and stakeholder concerns over a proposed Directive to establish an EU-wide risk regulation regime in the area. Such concerns centre upon the need for such a regime to remain sufficiently flexible to allow for discretion in the exercise of clinical judgement and patient choice with regard to determining the acceptability of risks relating to organs which become available for transplantation. In the context of the chronic shortage of organs in the vast majority of Member States, a more differentiated approach to managing risk is needed in this context than arguably is permitted under Article 152(4)(a) EC. This has resulted in the use of new governance mechanisms, such as OMC, in order to ensure that this is taken into account in policy-making processes. In any case, the use of OMC is an implicit acknowledgement that the range of policy challenges in organ donation and transplantation that would benefit from EU-wide action cannot be easily accommodated within the parameters of the competence as it stands.

An examination of the proposed Directive on organ transplantation reveals that the Commission has sought to incorporate a greater degree of flexibility into the traditional risk regulation regime format, than has been seen to date in relation to earlier initiatives in blood and tissues/cells. The underlying rationale for doing so is the necessity of taking into account the need for a differential approach to assessing risk which operates in the context of organ donation and transplantation. The proposal also appears to engage in a degree of competence stretching in attempting to create a link between standard setting for quality and the establishment of preferred organizational models for enhancing organ procurement. Although the final text of the Directive is yet to be agreed upon, what is apparent is that in seeking to accommodate institutional and stakeholder demands regarding a range of ethics and differential risk-based concerns, a hybrid form of governance is now emerging in relation to risk regulation in relation to human material under Article 152(4)(a) EC.

Disconnection in EU risk governance in relation to human material has also taken place as a result of existing institutional arrangements that promote a bifurcated approach to managing risk in relation to the use of human material, such as blood and tissues/cells. This approach appears to have been justified in policy terms on the basis that separate risk assessment and regulatory arrangements are deemed necessary at an institutional level where human material is used in processes and/or products that are likely to promote innovation or otherwise have commercial potential. Once classified in this way, risk governance has been managed within a largely technocratic environment overseen by those with relevant scientific expertise, with little evidence of ongoing political monitoring of the type embedded within risk regulation regimes established under Article 152(4)(a) EC. In practice, it appears as if the political dimension to the management of risk involving human material is seen in institutional terms as a hindrance to innovation because of its capacity to generate unpredictability for the research and business environment.

As became clear during the legislative passage of the ATMP Regulation, many of the concerns raised by stakeholders regarding the use of particular types of human material, such as hESCs, were also raised during the course of inter-institutional negotiations over the adoption of the Tissues and Cells Directive.[93] The use of different regulatory and institutional environments in which to manage such generic concerns is not conducive to promoting clarity, transparency or accountability in decision-making with regard to managing risk in the area – hardly a situation that is likely to inspire public confidence and therefore trust in EU decision-making processes in this area. The solution proposed in terms of addressing such stakeholder concerns has been to establish an advisory structure which aims to promote a more inclusive approach to addressing ethical and other concerns in relation to the implementation of the ATMP Regulation. Questions remain, however, over the extent to which this structure is likely to be more process-oriented than substantive in practice, offering little in the way of opportunities to exert real influence with respect to ethics and risk governance in this area.

§5. CONCLUSION

This article examined the politics of risk governance in relation to human material at EU level. Such examination revealed that the political context was important in informing not only how risks in relation to various types of human material came to be defined as policy problems, but also in influencing the design and/or persistence of institutional arrangements to manage such problems. The political dynamics which originally structured the creation of Article 152(4)(a) EC determined the nature and scope of the competence to establish traditional risk regulation regimes setting standards for quality and safety involving blood, tissues/cells and now organs. They also influenced the extent to which such regimes remain within the sphere of political contestation and monitoring. Where risks related to innovation in the use of human material were at issue, however, the problem was defined as one which was to be managed in a largely technocratic environment, overseen by those with relevant scientific expertise.

It is also apparent that there is a significant level of disconnection in EU risk governance involving human material. As successive policy and regulatory initiatives were brought forward pursuant to Article 152(4)(a) EC, it became clear that the competence was too narrowly-circumscribed to accommodate emerging ethics and differential risk-based concerns associated with various types of human material within its remit. The proposed solution to the problem of disconnection in this area by EU decision-makers was to employ a range of traditional and new governance mechanisms, as well as to adopt a more inclusive approach to consultation and the provision of (ethics and/or policy) advice. While the adoption of this hybrid approach may have been considered necessary

93 Sanzenbacher et al., 'European Regulation Tackles Tissue Engineering', 1089.

to address such concerns, it nevertheless added a further layer of complexity to existing institutional arrangements and occurred in circumstances where the problems created by the current bifurcated approach to risk governance in the area were not addressed. At the very least, it would be beneficial in terms of facilitating public trust if risk in relation to innovation involving the use of human material were subject to ongoing political monitoring of the type seen in relation to risk regulation regimes that have been established under Article 152(4)(a) EC. Such reform needs to be underpinned, however, by a commitment on the part of EU decision-makers to bringing about a more integrated approach to risk governance in relation to human material. Implementing this approach would contribute to greater clarity, transparency and accountability in decision-making processes and this could enhance public trust in what is a politically-sensitive area of governance at EU level.