1 Introduction

Throughout human history, blood has been imbued with many social and cultural meanings. It has also been used to identify and classify human beings, as well as structure social relationships.[1] The twentieth century saw a revolution in the use of blood, with scientific discoveries transforming its role in modern medicine. The sourcing and supply of blood became organised on a national basis in developed countries, underpinned by the notion of the gift relationship which promoted altruistic, non-remunerated blood donation in the context of an anonymous relationship between donors and recipients.[2] Scientific and technological developments led to the industrial production of plasma-derived medicinal products (plasma products),[3] which were predominantly sourced from individuals who received financial compensation for providing their blood (paid donors).[4] In turn, this facilitated the development of a global blood market in such products.[5]

[1] D. Nelkin, 'Cultural perspectives on blood', in E. A. Feldman and R. Bayer (eds.), *Blood Feuds: AIDS, Blood, and the Politics of Medical Disaster* (New York: Oxford University Press, 1999), pp. 274–92.

[2] R. M. Titmuss, *The Gift Relationship: From Human Blood to Social Policy* (London: George Allen & Unwin, 1970).

[3] Plasma is the straw-coloured fluid in which blood cells are suspended. It contains a high concentration of various proteins. Through a treatment process known as fractionation, plasma proteins are separated into fractions of more or less purified proteins with different properties. Plasma products often require thousands of donations in order to manufacture a single batch. For further details, see P. Hagen, *Blood Transfusion in Europe: A 'White Paper'* (Strasbourg: Council of Europe, 1993), pp. 188–90.

[4] For the purposes of this book, the term 'paid donor' is used, although I acknowledge that the for-profit plasma products industry prefers the term 'compensated donor' on the grounds that the individual is being compensated for their time and effort in undertaking plasma donation. See Plasma Protein Therapeutics Association (PPTA), *The Facts about Plasma Collection* (www.pptaglobal.org).

[5] For an overview of the early development of the plasma products industry, see P. Hagen, *Blood: Gift or Merchandise? Towards an International Blood Policy* (New York: Alan R. Liss Inc., 1982).

In the 1980s, the acquired immune deficiency syndrome (AIDS) emerged as an epidemic in the developed world. The infectious agent responsible for the disease, which later became known as the human immunodeficiency virus (HIV), was found to be transmissible by blood.[6] Once HIV testing became available, large numbers of individuals were also found to have been infected with the virus through the use of blood. In the 1990s, revelations about the circumstances that had led to HIV blood contamination episodes caused political scandals in a number of developed countries, where it became clear that the response by those with responsibility for the blood system had been inadequate. These scandals were characterised by adverse media reaction, protracted litigation in the courts, state-sponsored tribunals of inquiry, as well as institutional and regulatory reform of national blood systems.[7] For those deemed responsible for the contamination episodes, the consequences included public excoriation and on occasion the imposition of criminal sanctions. For those individuals who were infected with HIV through blood, it was a deeply personal tragedy, resulting in serious disability and/or loss of life.[8]

Risk, public health and human biological materials

Risk governance in public health is not new, but we now live in an era of globalisation where such risks may have a rapid and wide-ranging impact with deleterious social, economic and political consequences. This is particularly true in relation to risks to public health posed by infectious diseases. In recent years, it has been recognised that there is

[6] The human immunodeficiency virus (HIV) is the virus that causes the acquired immune deficiency syndrome (AIDS). A person may be infected with the virus, but will only be considered to have AIDS once there is severe immune deficiency, or s/he is diagnosed with illnesses associated with such deficiency.

[7] For the purposes of this book, the use of the term 'blood system' is intended to refer to the collection and supply of blood components; the manufacture and supply of plasma products; and policy and regulatory processes involved in these activities. When reference is made to the term 'blood supply', it is confined to collection and supply issues involving blood and plasma products, primarily at national level.

[8] For an overview, see L. Leveton, H. C. Sox and M. A. Stoto (eds.), *HIV and the Blood Supply: An Analysis of Crisis Decisionmaking* (Committee to Study HIV Transmission through Blood and Blood Products, Division of Health Promotion and Disease Prevention) (Washington, DC: National Academy Press, 1995); The Honourable Mr Justice H. Krever, *Commission of Inquiry on the Blood System in Canada*, 3 vols (Ottawa: Canadian Government Publishing, 1997); E. A. Feldman and R. Bayer (eds.), *Blood Feuds: AIDS, Blood, and the Politics of Medical Disaster* (New York: Oxford University Press, 1999); The Right Honourable Lord Archer of Sandwell QC, N. Jones and J. Willetts, *Independent Public Inquiry Report on NHS Supplied Contaminated Blood and Blood Products* (2009).

a need for more effective global governance in this area.[9] In turn, this has fed into new initiatives in risk governance at national and regional levels to address the issue.[10] Risks to public health may often require governing entities to balance competing considerations in seeking to protect citizens' health. These may include the need to balance individual rights or entitlements to freedom of choice and liberty of the person against the need to protect the collective well-being of the population. At state level, the recognition of public health risks within national boundaries, such as those posed by infectious diseases, may result in the need to implement restrictive measures with regard to the movement of persons and goods, in order to prevent the spread of the disease. While this may have an adverse economic impact on trade and the daily lives of citizens, it is also likely to have significant political repercussions at global level.[11]

The need to engage in a similar balancing act has emerged in recent years in the context of risk governance involving the use of human biological materials, where the need to protect public health may be at stake. As a result of scientific research and technological innovation, their use in medico-scientific settings has expanded rapidly in recent years. While there has been significant political support for promoting innovation and the commercial potential of new health technologies that may result from these developments, there has also been a need in political terms to manage ethical tensions that have arisen in the public domain over their use. The aim of this book is to explore these issues in detail through examining the inter-relationship between politics, ethics and law in risk governance involving human biological materials, drawing on an in-depth qualitative study of the sourcing and supply of blood.

There are a number of reasons for choosing this case study. First, blood has socio-cultural, scientific and commercial value, and it is this multi-valuing that is likely to present challenges in terms of facilitating effective risk governance. Blood has long been recognised as

[9] L. O. Gostin, 'Meeting the survival needs of the world's least healthy people: a proposed model for global health governance', *Journal of the American Medical Association*, 298 (2007), 225–8.

[10] For example, the European Union (EU) created a legal competence in the field of public health in 1999 (see Article 152(4)(a) of the European Community (EC) Treaty, now Article 168(4)(a) of the Consolidated Version of the Treaty on the Functioning of the European Union, OJ C 83, 30.3.2010 (TFEU)). Since such time, the EU has adopted a number of policy initiatives, as well as regulatory regimes, in the field. For further details, see http://ec.europa.eu/health/index_en.htm.

[11] D. P. Fidler and L. O. Gostin, 'The new International Health Regulations: an historic development for international law and public health', *Journal of Law, Medicine and Ethics*, 34 (2006), 85–94 at 91–3.

having significant socio-cultural and religious value.[12] Family and kinship were traditionally structured by blood ties, which were in turn intertwined with both individual and national identity.[13] Scientific and technological developments in the twentieth century, however, led to both the medicalisation and the industrialisation of blood and its components.[14] Blood transfusion, as well as the infusion of plasma products, became widely used therapies in clinical settings, with significant patient benefit.[15] When combined with the legacy of socio-cultural value ascribed to blood, this altered characterisation brought about by scientific research and technological developments has led to ethical complexity, policy conundrums and regulatory tensions in risk governance, as was evidenced by HIV blood contamination episodes and their aftermath. Findings from an examination of how risk was managed in this context are therefore likely to have broader implications for risk governance involving multi-valued human biological materials, particularly given their use in a range of new health technologies including cellular therapies and tissue-engineered products.[16]

Second, two of the main legacies of HIV blood contamination episodes in developed countries are the increased use of the precautionary principle to manage risk, as well as a much stronger patient-centred approach to promoting safety and achieving good clinical outcomes.[17]

[12] P. Camporesi, *The Juice of Life: The Symbolic and Magical Significance of Blood*, trans. R. R. Barr (New York: Continuum Publications, 1996), pp. 14–32.

[13] D. M. Schneider, 'What is kinship all about?', in R. Parkin and L. Stone (eds.), *Kinship and Family: An Anthropological Reader* (Oxford: Blackwell Publishing, 2003), pp. 257–74; Nelkin, 'Cultural perspectives on blood', pp. 285–6.

[14] For an historical overview of such developments, see D. Starr, *Blood: An Epic History of Medicine and Commerce* (New York: Alfred A. Knopf, 1998).

[15] C. D. Hillyer, N. Blumberg, S. A. Glynn *et al.*, 'Transfusion recipient epidemiology and outcomes research: possibilities for the future', *Transfusion*, 48 (2008), 1530–7 at 1531.

[16] *Cellular therapies* involve the transplantation of human cells to replace or replenish damaged tissue and/or cells. Bone marrow, umbilical cord blood and peripheral blood stem cell transplants are examples of this type of therapy. The cells used in transplantation include haematopoietic progenitor cells (HPCs) (see www.aabb.org/resources/bct/therapyfacts/pages/default.aspx). *Tissue-engineered products* contain or consist of engineered cells or tissues which can be administered to human beings with a view to regenerating, repairing or replacing human tissue. Such products may contain cells or tissues of human or animal origin, or both, and cells or tissues may be viable or non-viable: see, for example, Article 1(b), 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) No. 726/2004.

[17] Hillyer *et al.*, 'Transfusion recipient epidemiology and outcomes research', p. 1531; R. E. Davis, C. A. Vincent and M. F. Murphy, 'Blood transfusion safety: the potential role of the patient', *Transfusion Medicine Reviews*, 25 (2011), 12–23; J. L. Callum, Y. Lon, A. Lima *et al.*, 'Transitioning from "blood" safety to "transfusion" safety: addressing the single biggest risk of transfusion', *ISBT Science Series*, 6 (2011), 96–104.

While there has been a significant level of policy and academic debate about the use and limits of the precautionary principle,[18] as well as its application in the public health context,[19] a detailed examination of the aftermath of the HIV blood contamination episodes provides a concrete example of how, and to what extent, the precautionary principle may be said to work in practice, taking account of institutional and resource implications involving the blood system.[20] In addition, it also offers an opportunity to reflect more broadly on the effectiveness (or otherwise) of precautionary strategies in the management of risks to public health.

Finally, the focus on examining risk governance involving the blood system has been an under-researched aspect of the existing socio-legal academic literature on blood-related issues.[21] An early seminal work in the field was Richard Titmuss's *The Gift Relationship*, which was first published in 1970. He conceptualised the gift relationship as involving altruistic, non-remunerated blood donation to anonymous

[18] Various perspectives have been offered on the usefulness (or otherwise) of a precautionary approach to risk governance in relation to the environment, as well as more recently in the area of public health. For example, it has been suggested that we are witnessing a convergence of an approach to precaution between the USA and Europe: see D. Vogel, 'The hare and the tortoise revisited: the new politics of consumer and environmental regulation in Europe', *British Journal of Political Science*, 33 (2003), 557–80. Conversely, it has been suggested that no general statement of convergence can be made between the USA and Europe because it is dependent on the policy sector at issue: see J. B. Wiener and M. Rogers, 'Comparing precaution in the United States and Europe', *Journal of Risk Research*, 5 (2002), 317–49. Sunstein views the application of the precautionary principle as being incoherent and argues for the adoption of an alternative approach to managing risk in the context of uncertainty; see C. Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge University Press, 2005). For a detailed examination of the issue, see Chapter 7.

[19] Much of what has been written about the use of the precautionary principle has been in relation to managing environmental risks. In recent years, there has been a more explicit focus in policy terms on its application in the public health context: see C. Raffensperger and J. Tickner (eds.), *Protecting Public Health and the Environment: Implementing the Precautionary Principle* (Washington, DC: Island Press, 1999). Under EU law, the precautionary principle is now viewed as an autonomous legal principle applicable to the environment and public health: see N. de Sadeleer, 'The precautionary principle in EC environmental and health law', *European Law Journal*, 12 (2006), 139–72.

[20] The advantages and disadvantages of the application of the precautionary principle to transfusion safety have been examined by various commentators within the transfusion medicine literature. See, for example, K. Wilson and M. N. Ricketts, 'The success of precaution? Managing the risk of transfusion transmission of variant Creuzfeldt-Jakob disease', *Transfusion*, 44 (2004), 1475–8; K. Wilson, 'A framework for applying the precautionary principle to transfusion safety', *Transfusion Medicine Reviews*, 25 (2011), 177–83.

[21] For historical, journalistic-style overviews of blood, including sourcing, supply and contamination issues, see the following: Hagen, *Blood: Gift or Merchandise?*; Starr, *Blood*.

patient-recipients. He justified its importance on ethical, economic and safety grounds and argued more broadly for its importance in promoting social solidarity in industrial societies.[22] Titmuss's arguments provoked a lively debate across a range of academic disciplines.[23] Over the last ten years, academic interest by social scientists in blood-related issues has focused on examining the political dynamics which structured HIV blood contamination scandals.[24] There has also been renewed interest in examining the continuing relevance of the gift relationship in genetics research;[25] the expanding economy in human tissue;[26] and the organisational procurement of blood and organs.[27] The role of the law in risk governance involving the blood system has also been an under-researched issue within this literature. What examination of the law that has taken place has most often focused on issues of liability in the wake of blood contamination episodes.[28] While my own research has sought to make a contribution in this regard,[29] this book addresses the

[22] Titmuss, *The Gift Relationship*.

[23] For example, see K. Arrow, 'Gifts and exchanges', *Philosophy and Public Affairs*, 4 (1972), 343–62; P. Singer, 'Altruism and commerce: a defence of Titmuss against Arrow', *Philosophy and Public Affairs*, 2 (1973), 312–20; H. M. Sapolsky and S. N. Finkelstein, 'Blood policy revisited: a new look at "the gift relationship"', *Public Interest*, 46 (1977), 15–27; R. Plant, 'Gifts, exchanges and the political economy of health care. Part 1: Should blood be bought and sold?', *Journal of Medical Ethics*, 3 (1977), 166–73; A. W. Drake, S. N. Finkelstein and H. M. Sapolsky, *The American Blood Supply* (Cambridge, MA: MIT Press, 1982).

[24] For an examination of the social, legal and political aspects of HIV blood contamination episodes and scandals in a range of developed countries, see Feldman and Bayer (eds.), *Blood Feuds*. For a specific examination of the dynamics of policy-making in relation to HIV blood contamination episodes/scandals in a number of countries, see M. Bovens, P. Hart and B. G. Peters (eds.), *Success and Failure in public Governance: A Comparative Analysis* (Cheltenham: Edward Elgar, 2001).

[25] R. Tutton, 'Gift relationships in genetics research', *Science as Culture*, 11 (2002), 524–42; D. Dickenson, 'Consent, commodification and benefit-sharing in genetic research', *Developing World Bioethics*, 4 (2004), 109–24; H. Busby, 'Biobanks, bioethics and concepts of donated blood in the UK', *Sociology of Health and Illness*, 28 (2006), 850–65.

[26] C. Waldby and R. Mitchell, *Tissue Economies: Blood, Organs, and Cell Lines in Late Capitalism* (Durham, NC: Duke University Press, 2006).

[27] K. Healy, *Last Best Gifts: Altruism and the Market for Human Blood and Organs* (Chicago University Press, 2006), pp. 15–22.

[28] E. A. Feldman, 'Blood justice: courts, conflict and compensation in Japan, France and the United States', *Law and Society Review*, 34 (2000), 651–701; A. Rueda, 'Rethinking blood shield statutes in view of the hepatitis C pandemic and other emerging threats to the blood supply', *Journal of Health Law*, 34 (2001), 419–58; R. Goldberg, 'Paying for bad blood: strict product liability after the Hepatitis C litigation', *Medical Law Review*, 10 (2002), 165–200.

[29] A. M. Farrell, 'Is the gift still good? Examining the politics and regulation of blood safety in the European Union', *Medical Law Review*, 14 (2006), 155–79; A. M. Farrell, 'The politics of risk and EU governance of human material', *Maastricht Journal of European and Comparative Law*, 16 (2009), 41–64.

need for a more detailed examination of the role of law and its contextual relationship with ethics and politics in risk governance involving human biological materials.

I acknowledge that there are a range of different subject areas, institutions, techno-scientific developments and sub-systems of governance that could be covered in relation to the chosen case study.[30] A number of deliberate choices have been made, however, with respect to limiting the parameters of examination involving the sourcing and supply of blood, with a view to developing a focused narrative in line with the key arguments made in the book. While such narrative has a broad focus on the management of risk relating to transfusion-transmitted infections (TTIs) through the blood supply,[31] it draws specifically on an in-depth analysis of HIV blood contamination episodes and their aftermath in selected developed countries. Such analysis is limited to an examination of risk governance relating to the sourcing and supply of blood and its components by national blood services, as well as plasma products which are manufactured and supplied by the global for-profit

[30] These issues have been the subject of examination in published literature and include (but are not limited to) the following: non-infectious risks (e.g. H. G. Klein, D. R. Spahn and J. L. Carson, 'Red blood cell transfusion in clinical practice', *Lancet*, 370 (2007), 415–26); donor selection and protection (e.g. A. Eder, M. Goldman, S. Rossmann *et al.*, 'Selection criteria to protect the blood donor in North America and Europe: past (dogma), present (evidence) and future (hemovigilance)', *Transfusion Medicine Reviews*, 23 (2009), 205–20); haemovigilance (e.g. D. Stainsby, H. Jones, D. Asher *et al.*, 'Serious hazards of transfusion: a decade of haemovigilance in the UK', *Transfusion Medicine Reviews*, 20 (2006), 273–82); the optimal use of blood components (e.g. K. Berger, H. G. Klein, R. Seitz *et al.*, 'The Wilbad Kreuth initiative: European current practices and recommendations for optimal use of blood components', *Biologicals*, 39 (2011), 189–93); the role of patients in transfusion safety (e.g. Davis *et al.*, 'Blood transfusion safety: the potential role of the patient'); the use of blood in less developed countries (e.g. D. J. Roberts, J.-P. Allain, A. D. Kitchen *et al.*, 'Blood transfusion in a global context', in M. F. Murphy and D. H. Pamphilon (eds.), *Practical Transfusion Medicine*, 3rd edn (Oxford: Wiley-Blackwell, 2009), pp. 251–65); and the expanded use of cellular therapies (e.g. M. Strong, A. Farrugia and P. Rebulla, 'Stem cell and cellular therapy developments', *Biologicals*, 27 (2009), 103–7; K. Devine, 'Risky business? The risks and benefits of umbilical cord blood collection', *Medical Law Review*, 18 (2010), 330–62; H. Busby, 'The meanings of consent to the donation of cord blood stem cells: perspectives from an interview-based study of a public cord blood bank in England', *Clinical Ethics*, 5 (2010), 22–7).

[31] Although there has been an increased focus on non-infectious risks involved in blood transfusion in recent years (see fn. 30 above), TTIs have certainly garnered most of the attention in political, regulatory, scientific and technological terms over the past twenty-five years. HIV blood contamination episodes in developed countries have provided the focus for much of this attention and, to a lesser extent, hepatitis C (HCV) blood contamination episodes.

plasma products industry, in particular factor concentrates used in the treatment of haemophilia.[32]

National HIV blood contamination episodes and their aftermath provide an opportunity to examine and learn from how a serious public health risk was assessed and managed within and across national boundaries, as well as the ethical, legal and political consequences that flowed from the perceived failure to manage such risk. In addition, risk governance involving the blood system in developed countries such as the United States (USA), France and England will be drawn on by way of example. The reason for choosing these three countries is that while they are similar in the sense that they are all liberal democratic and resource-rich states with long-established national blood services, there were significant differences between them with respect to the sourcing, manufacture and supply of blood components and plasma products, as well as in their political responses to managing the consequences of the risk posed by HIV. Such differences will inform the key arguments presented in this book.

Risk governance of human biological materials: politics, ethics and law

The key objective of this book is to develop an understanding of what constitutes effective risk governance involving multi-valued human biological materials, such as blood. Governance is used here as an overarching term to describe how governing entities engage in policy-making and regulation to meet new and challenging circumstances in situations of complexity and uncertainty, where there is a need to develop new ways of collaboration and decision-making.[33] This

[32] Haemophilia is a genetic disorder that is carried by females, but affects – with rare exceptions – male offspring. The disorder results in a (severe, moderate or mild) deficiency of clotting factors VIII or IX. Factor concentrates are plasma products that have been sourced from thousands of donors in order to extract a concentrated form of the clotting factors which are lacking in those with haemophilia. Factor concentrates can be administered at home to stop internal bleeding episodes (depending on their severity), thus avoiding the need for regular hospital attendance (see Krever, *Commission of Inquiry on the Blood System*, pp. 26–7).

[33] G. Stoker, 'Designing institutions for governance in complex environments: normative, rational choice and cultural institutional theories explored and contrasted', *ESRC Fellowship Paper No. 1* (University of Manchester, 2004). For further details on theories of governance, see J. Pierre (ed.), *Debating Governance: Authority, Steering and Democracy* (Oxford University Press, 2000); J. Pierre and B. G. Peters, *Governance, Politics and the State* (Basingstoke: Palgrave Macmillan, 2000); B. Kohler-Koch and B. Rittberger, 'The governance turn in EU studies', *Journal of Common Market Studies*, 44 (2006), 27–49; V. Chotray and G. Stoker, *Governance Theory: A Cross-Disciplinary Approach* (Basingstoke: Palgrave Macmillan, 2008).

description aptly captures both the opportunities and the difficulties confronting those with responsibility for managing risks to public health at both national and supranational levels. It is also important to be clear about how risk is conceptualised, given that risk governance involving the blood system will be the subject of particular examination in this book.

Within the relevant socio-legal literature, risk has been defined in varying ways and there has been extensive academic debate on its interpretation and application. Risk is often used as a term to describe situations where behaviour is known and where a probabilistic value or calculation can be assigned to outcomes. This needs to be distinguished from uncertainty, where important parameters of circumstances are known, but not the probability of outcomes.[34] Risk analysis to assess the probability of outcomes has traditionally been structured around a tripartite approach comprising risk assessment, risk management and risk communication. While risk assessment has been viewed as the domain of scientific experts who interpret the available empirical data and provide advice on likely outcomes, risk management is seen as ultimately a matter for those in political leadership.[35]

The role of science and politics in risk governance has also attracted significant academic debate. Those with scientific expertise demand that the science–politics divide be maintained in the interests of maintaining integrity and objectivity in the process of risk assessment. Conversely, claims to scientific objectivity and exclusive expertise in risk assessment have been called into question, particularly where sensitive ethical and social issues are at stake.[36] In simple terms, there are those who view risk as an objective and knowable phenomenon which can be measured, whereas for others it is socially constructed and influenced by cultural, institutional and political contexts. From this latter viewpoint, risk is a subjective and reflexive phenomenon, indicative of broader social changes in line with the emergence of what has been described as the

[34] B. Wynne, 'Uncertainty and environmental learning: reconceiving science and policy in the preventative paradigm', *Global Environmental Change*, 2 (1992), 111–27 at 114.

[35] For an overview, see O. Renn, 'Three decades of risk research: accomplishments and new challenges', *Journal of Risk Research*, 1 (1998), 49–71.

[36] For an overview and sociological critique of arguments made regarding the interrelationship between science, society and politics in risk assessment, see R. E. Kasperson, O.Renn, P. Slovic *et al.*, 'The social amplification of risk', *Risk Analysis*, 8 (1988), 177–87; S. Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Cambridge, MA: Cambridge University Press, 1990); U. Beck, *Risk Society: Towards a New Modernity* (London: Sage, 1992); S. Krimsky and D. Golding (eds.), *Social Theories of Risk* (Westport, CT: Praeger Publishers, 1992); B. Wynne, 'Creating public alienation: expert cultures of risk and ethics on GMOs', *Science as Culture*, 10 (2001), 445–81.

'risk society' in advanced post-industrial democracies.[37] There has been criticism of such 'grand narratives' on risk, however, particularly by those who are interested in examining how risk is assessed and managed in institutional and regulatory environments on a day-to-day basis. It is argued that such narratives are not sufficiently nuanced to deal with variability of interpretation and implementation in different policy sectors, as well as across particular national legal and cultural settings.[38]

The politicisation of risk

For the purposes of this book, risk is conceptualised as a socio-cultural construct that is influenced by public perception and necessitates a political response where the protection of public health is at stake. In adopting this perspective, I draw on sociological interpretations of risk with an emphasis being placed on how the political context structures risk governance. In particular, I focus on what happens when a risk to public health becomes politicised, drawing on an examination of the circumstances that led to HIV blood contamination episodes, as well as their aftermath. What such examination reveals is that one of the main features of this politicisation of risk is heightened sensitivity on the part of governing entities to the potential for adverse public reaction resulting from any perceived failure to manage risks to public health. This heightened sensitivity leads to responses by governing entities to emerging risks that are focused on enhancing political credibility and justifying the legitimacy of their preferred course of action.[39] This may result in the subordination of traditional scientific risk assessment and

[37] M. Douglas, *Risk Acceptability According to the Social Sciences* (London: Routledge, 1985); A. Giddens, *The Consequences of Modernity* (Stanford University Press, 1990); U. Beck, *Risk Society*; M. Douglas, *Risk and Blame* (London: Routledge, 1992); P. Slovic, 'Perceived risk, trust, and democracy', *Risk Analysis*, 13 (1993), 675–82; S. Jasanoff, 'Citizens at risk: cultures of modernity in the US and EU', *Science as Culture*, 11 (2002), 363–80.

[38] C. Hood, H. Rothstein and R. Baldwin, *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford University Press, 2001); Wiener and Rogers, 'Comparing precaution in the United States and Europe'; M. J. Smith, 'Mad cows and mad money: problems of risk in the marking and understanding of policy', *British Journal of Politics and International Relations*, 6 (2004), 312–32, at 312, 315–16. For an examination of the impact of national legal cultures and institutions on risk regulation, see E. Fisher, *Risk Regulation and Administrative Constitutionalism* (Oxford: Hart Publishing, 2007); S. Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press, 2005).

[39] There are varying interpretations that can be offered as to what constitutes legitimacy of action, as opposed to legitimating actions, particularly in terms of regulatory governance. My preferred view is that in order to realise legitimacy in the political context, there is a need to achieve a sufficient degree of consensus among relevant stakeholders, as well as in the public domain. This may involve making use