1. Introduction

Biotechnology astonishes in its ingenuity and its potential. It confers the ability to change the characteristics of living organisms potentially without limit, transferring genetic information and traits across species. It grants the capacity to increase control over our surroundings, benefiting the environment, farmers and consumers, as well as the very poor in developing countries. The transformative potential of agricultural biotechnology, however, cuts both ways, raising profound questions about the type of world we are creating. Resistance is neither surprising nor unreasonable. As Sheila Jasanoff puts it, ‘these far-reaching alterations in the nature and distribution of resources, and in the roles of science, industry and the state, could hardly occur without wrenching political upheavals’.1 The regulation of genetically modified organisms (GMOs) reflects a real tension that pervades the management of all new technologies, between a desire to reap economic and social benefits and concern about unintended consequences.2

The history of technological change might suggest that, although resistance to change is common, it can be overcome, with change eventually normalised. History also reminds us, however, that there can be a dark side to progress, not least the closing down of other possible responses to needs or wants. To take an apposite example, even if we cannot readily identify alternative paths to social benefits, regret for the (perhaps unthought-of) path never taken has to be possible in the face of the huge environmental damage that goes along with the benefits brought by current farming practices.

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2 Andrew Barry, Political Machines: Governing a Technological Society (The Athlone Press, 2001), observes ‘a political preoccupation with the problems technology poses, with the potential benefits it promises, and with the models of social and political order it seems to make available’, p. 2; also Monroe E. Price, ‘The Newness of New Technologies’ (2001) Cardozo Law Review 1886.
THE EU’S MORATORIUM ON AUTHORISATION OF GMOs

GMOs properly hit EU politics in the late 1990s, receiving a huge amount of media attention. The regulatory framework for GMOs, in place since 1990, was perceived to be profoundly inadequate and was targeted by a range of groups including environmental interest groups and those representing small farmers. The late 1990s saw high-profile and popular campaigns against GM food around the EU. So, for example, in both the UK and France protestors destroyed GM crops. Not only were their actions widely reported, but the protestors took advantage of subsequent criminal trials to highlight their concerns about GMOs. Dolly the sheep, the first cloned mammal, was introduced to the international media in Scotland in 1996, stimulating enormous interest in the safety and ethical implications, as well as the potential, of biotechnology. In 1997, the European Commission went ahead with the authorisation of a variety of GM maize in spite of angry objections from a number of Member States, a European Parliament resolution against authorisation, and the positive approval of only one Member State in Council. This notorious case highlighted not only possible overreaching on the part of the Commission, but also the real disagreement on the content and appropriateness of risk assessment under the 1990 legislation. And then in 1998 Dr Arpad Pusztai announced on a television documentary that rats fed on GM potatoes suffered from stunted growth, suppressed immune systems and reduced body weight. There was a very public battle about the validity of his data, culminating in his suspension from employment. Although his claims never really

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3 Other than in quotations, I will for simplicity refer to the EU/European Union rather than the EC/European Community even when discussing what is strictly still ‘EC law’. Note that, following the 2007 Lisbon Treaty, the Union will in any event take over the Community’s legal capacity.

4 See the discussion at the beginning of Chapter 2. This continues around the EU. Crops have more recently been destroyed in at least France, the Netherlands and Germany; see European Commission, Second Report on the Experience of Member States with GMOs placed on the Market under Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms COM (2007) 81 final.


recovered, this case created prominent media coverage of scientific uncertainty about the effects of GMOs.\(^7\)

The legal response to this enormous interest in GMOs was spectacular and unplanned. The legislation that had required the authorisation of GMOs since 1990 fell apart. Between 1998 and 2004 no applications for authorisation of GMOs reached the end of the decision-making process, and a number of Member States introduced measures barring national market access to GMOs that had already been authorised. This was the famous *de facto* moratorium on the authorisation of GMOs,\(^8\) a remarkable, probably unprecedented, breakdown in the EU legal framework. The moratorium was ‘implemented’ by the Commission’s decision to stop pushing GMOs through the authorisation process. And this was most immediately prompted by declarations from 12 (of the then 15) Member States that they were opposed to further authorisations of GMOs.\(^9\) It is too soon to go into detail on EU decision-making procedures (on which see especially Chapter 3) but, in short, these Member States had the majority they needed in Council to reject Commission proposals for the authorisation of specific GMOs.\(^10\) Although the legality of the Council’s position would have been at least questionable under the terms of the legislation, the Commission chose not to attempt to challenge, or indeed regularise, the moratorium. Instead, the Commission worked with the Member States and others to renegotiate the regulation that applied to GMOs, completely replacing and strengthening the EU’s legislative framework. Only after the deadline for

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\(^7\) Dr Pusztai gave evidence for the purposes of House of Commons Select Committee on Science and Technology, Session 1998–99, 1st Report, *Scientific Advisory System: Genetically Modified Foods*.


\(^9\) Two declarations were made by different groups of Member States in the 2194th Council Meeting, 24/25 June 1999: *Declaration by the Danish, Greek, French, Italian and Luxembourg Delegations Concerning the Suspension of New GMO Authorisations*; *Declaration by the Austrian, Belgian, Finnish, German, Netherlands, Spanish and Swedish Delegations*. With slightly different emphases, both declarations state the intention of the Member States to block the authorisation of GMOs in Council pending amendment of the legislation. Ireland, Portugal and the UK did not join either declaration.

implementation of the new regulation did the Commission begin to step up its formal pressure on Member States.\footnote{By the time of the mid-term review of the \textit{Life Sciences Strategy} (European Commission, Staff Working Document, \textit{Communication on the Mid-term Review of the Strategy on Life Sciences and Biotechnology SEC (2007) 441}, two cases were pending, p. 44. The Commission had earlier brought a partially successful action against France in respect of failure to implement the legislation, C-296/01 \textit{Commission v France} [2003] ECR I-13909.}

Whilst cause and effect between moratorium and pressures on the Commission is not straightforward, the Commission was at this time making a determined effort to bolster its own legitimacy in other areas. It was in no position to face down the Member States on such a politically sensitive topic. Most obviously, a European Parliament Committee Report, detailing numerous allegations of nepotism and financial fraud and mismanagement, led to the resignation of the entire Santer Commission in March 1999.\footnote{Committee of Independent Experts, \textit{Allegations Regarding Fraud, Mismanagement and Nepotism in the European Commission} (1999). See Paul Craig, ‘The Fall and Renewal of the Commission: Accountability, Contract and Administrative Organisation’ (2000) 6 \textit{European Law Journal} 98.} Not surprisingly, this received massive media attention around the EU, and amplified scepticism about the Commission, the EU institutions and even the ideals of EU integration. The new Prodi Commission was not formally appointed until September 1999. So the immediate response to the declarations leading to the moratorium came at a time when the EU was being administered by what was effectively a ‘caretaker’ Commission.\footnote{The interim Marin Commission.}

And this came on top of the credibility crisis provoked by BSE. In March 1996 the British Government had announced a link between ‘mad cow disease’ (that is bovine spongiform encephalopathy (BSE)), eating beef and a new form of a fatal and distressing human brain disease, Creutzfeldt-Jakob disease (v-CJD).\footnote{The full story can be found in the Phillips Report, \textit{Inquiry into the emergence and identification of Bovine Spongiform Encephalopathy (BSE) and variant Creutzfeldt-Jakob Disease (vCJD) and the action taken in response to it up to 20 March 1996} (House of Commons, 2000), available at http://www.bseinquiry.gov.uk/ (accessed December 2007). See Elizabeth Fisher, \textit{Risk: Regulation and Administrative Constitutionalism} (Hart Publishing, 2007), Chapter 2, for a concise and interesting examination of the many complexities.} The possibility of such a link had always been vehemently denied by the UK Government and the Commission. The relevant British scientific working party into BSE had in 1988 concluded that it was ‘most unlikely’ that there would be any human health implications. It had emphasised uncertainty, and also the serious implications of being wrong, but this was nevertheless for a number of years interpreted by the British Government...
as a basis for a ‘campaign of reassurance’ on the safety of beef.\textsuperscript{15} BSE affected many thousands of animals in the UK, and the mass slaughter that followed provided dramatic and widely distributed images of pyres of burning cattle. Beef sales plummeted, along with public confidence in regulators. The disease was most prevalent in the UK, but quickly became a European problem as other Member States sought to limit its effects on their own industry, restricting British beef imports, either independently or through EU action. In 1997 the European Parliament criticised in great detail the Commission’s handling of BSE, accusing the Commission amongst other things of a ‘policy of disinformation’ in respect of both public opinion and relations between Community institutions.\textsuperscript{16} BSE also threatened the fundamental assumptions of the internal market as Member States refused to comply with EC law.\textsuperscript{17} This was the context in which the first significant imports of GM products (soya) began in 1996. So, at a time of significant public interest in the import of GMOs, the basic competence of the EU institutions in matters of risk was an issue of popular politics.\textsuperscript{18}

The BSE debacle stimulated a massive rethink of risk regulation around the EU and in the EU itself. The politics of risk, especially around food, has been stirred up afresh by more localised scandals from time to time, for example dioxin in Belgian poultry (arguably partially responsible for the subsequent fall of the Belgian Government), salmonella in eggs, foot and mouth disease and avian flu. Food risks are highly sensitive, with cultural and historical aspects that exacerbate the potential for disagreement around the EU. We should expect GM food to be no different, compounding the anxiety about the technology more generally, and spilling over into non-food GMOs such as cotton and flowers. The period of the moratorium saw a major upheaval in the

\textsuperscript{15} Phillips Report, above n. 14.


\textsuperscript{18} The BSE crisis is explicitly linked to the moratorium on GMOs by Gregory Shaffer and Mark Pollack, ‘Regulating Between National Fears and Global Disciplines: Agricultural Biotechnology in the EU’ (2004) \textit{Jean Monnet Working Paper} 10/04.
approach of the EU to food safety. A new General Food Regulation was introduced in 2002.\textsuperscript{19} It sets out general principles of food law, and establishes the European Food Safety Authority (EFSA). Whilst agencies at national level usually ‘borrow’ the political legitimacy of the national political institutions, here the Commission seems to be hoping to gain some legitimacy from the exercise of expertise by the EFSA. According to the General Food Regulation, EFSA is ‘an independent scientific point of reference in risk assessment’.\textsuperscript{20} The Regulation uses EFSA to provide scientific excellence, and to separate this science from political (including national in this EU context) and industry influence. These are direct responses to some of the identified failures in the management of BSE.\textsuperscript{21} The rethink of food risks, and its considerable centralisation through EFSA, is directly relevant to the perceived need to renegotiate the regulatory framework applying to GMOs. The Commission would probably be wrong to see public rejection of GMOs as being solely about food, although this is the primary focus at the moment.\textsuperscript{22} The concerns, especially about uncertainty and the purposes or distribution of benefits of the technology, apply more broadly. But, nevertheless, food does end up in a very particular institutional framework that is especially sensitive to both the political risks and the internal market risks of getting things wrong. By asserting its role in the response to risk, the EU makes clear the potentially profound implications of the internal market. Different national approaches to risk pose major challenges to the internal market, as exemplified by the experience with BSE, and indeed again with GMOs. In addition, however, regulating risk is seen as a way to respond visibly to the needs of the European peoples, to re-engage with citizens. The institutions have become self-aware in their search for legitimacy, seeing risk regulation as, perhaps paradoxically, both a way to ‘reconnect’ with the European publics and a way to reduce threats to the internal market.

In the period of the moratorium, the EU’s legitimacy problems were extensive and high profile, ranging from the ‘democratic deficit’ (which can imply concern about the very existence of the EU as well as its decision-making mechanisms) to questions about basic competence and questions of honesty and trustworthiness. One of the central responses to the EU’s legitimacy

\textsuperscript{19} Regulation 178/2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety [2002] OJ L 31/1.

\textsuperscript{20} Regulation 178/2002, above n. 19, Recital 34.

\textsuperscript{21} The scientific committees dealing with BSE had been dominated by British experts, and heavily influenced by the British political agenda (in turn too closely involved with promotion rather than regulation of the industry). See above n. 16.

\textsuperscript{22} See for example European Commission, above n. 11.
dilemmas has been an effort to move towards improved openness and public involvement in the ‘life’ of the EU.\textsuperscript{23} There are many possible meanings for ‘public participation’, and many possible purposes, from improving democracy to encouraging regulatory compliance. In this book, public participation in decision making is not particularly examined in its own right. Instead, it is linked with the vast range of issues raised by GMOs, and with the need to explore values that go beyond those covered by risk assessment.

A turn to participation is now almost an instinctive response to concerns about legitimacy, concerns that, as we have seen, arise frequently and with no little drama in the EU. The Commission’s ‘European governance’ project typifies the turn to participation.\textsuperscript{24} The governance project was instigated in 2000, a self-conscious response to, bluntly put, the unpopularity both of the EU and of the Commission more specifically. The five ‘principles of good governance’ established in this process were ‘openness, participation, accountability, effectiveness and coherence’.\textsuperscript{25} An important and explicit part of Commission reflection at this period was a reassessment of the position of scientific and technical expertise in decision making.\textsuperscript{26} A self-consciousness about ‘scientific governance’ permeates policy, and commitment to openness, especially with regard to uncertainty and disagreement, is a conventional element of the governance of expertise in the EU. The regulatory bodies seem to understand the importance of public participation, the importance of values as well as safety, to decision making. But there is real ambiguity on this, generally and in the regulation of GMOs, given the continued commitment to scientific decision making.


\textsuperscript{25} Commission (2001), above n. 24, p. 10.

Efforts to persuade rather than enforce were obviously attractive when the Member States declared their opposition to further authorisations of GMOs in 1999. Moreover, given the rethinking of risk and governance at this time, the adequacy of the legislation was suspect even to a techno-enthusiastic Europhile. Public anger about GMOs seemed to take everyone, not just the Commission, by surprise, as indeed does the continued persistence of concern. There was a sense that formal action would be counterproductive. Even the affected commercial entities hesitated,\(^{27}\) and in any event food retailers and processors began to respond to consumer rejection of GM technology, in some cases undertaking that their products did not contain GM material. Most strikingly perhaps, whilst the Commission was under considerable pressure from its trade partners (especially the US) even before the moratorium, formal World Trade Organization (WTO) dispute resolution was not sought until 2003. This is not an enormous delay relative to other claims, although dissatisfaction with EU regulation predated the moratorium, but the delay did mean that the new regulatory structure was in place before litigation. We might assume that the hesitation was in part down to fear of further consumer backlash against the technology, and a hope that consumers would learn to accept GMOs. But, in addition, it was perhaps recognised that such a high profile and difficult dispute had the potential to disrupt already controversial WTO bodies.

There had been massive protests during the WTO’s ministerial conference in Seattle in November 1999 (not long after the Member State declarations on GMOs). These protests were so intense that the conference’s opening ceremony was cancelled, a state of emergency declared and a curfew imposed.\(^{28}\) The protests included a wide range of groups and interests, and were the most dramatic demonstration that the trade elite should henceforth expect public scrutiny of the impact of trade on other social objectives. Seattle became the pivotal moment in a much broader ‘anti-globalisation’ movement, which included environmental, development and consumer protection perspectives. GMOs had vast potential as a symbol for a particular negative perception of globalisation. The vulnerability of the international trading system’s popular legitimacy and authority in the longer term emphasised for the EU at least the need to address the public concerns that had provoked the moratorium.

\(^{27}\) Although in 2001 Monsanto challenged Italy’s safeguard measures (Case C-236/01 Monsanto Agricoltura Italia SpA v Presidenza del Consiglio dei Ministri [2003] ECR I-8105). In May 2007 (Case T-139/07 Pioneer Hi-Bred v Commission [2007] OJ C 155/28) Pioneer Hi-Bred challenged the Commission’s failure to submit its application in respect of insect-resistant GM maize 1507 to committee. The industry also brought civil actions against the protestors digging up trial planting.

But if all of this makes caution about GMOs seem the only possible response, we need to remember the very significant pressures that urge speedy commercialisation. ‘Knowledge’ is thought generally to be a key source of wealth in post-industrial society, and that must have enormous implications for government (EU or national) policy towards science and technological development. The *Life Sciences Strategy*, drafted by the Commission and ‘welcomed’ by the Council,29 presents biotechnology as ‘the next wave of the knowledge-based economy’,30 and a key objective of the EU is, famously, to be ‘the most competitive and dynamic, knowledge-based economy in the world.’31 The *Life Sciences Strategy* addresses ‘white’, ‘red’ and ‘green’ (industrial, medical and agricultural32) biotechnology policy together, which emphasises the size of the potential economic benefits associated with biotechnology.33 A wide range of industrial sectors is identified as ‘based on’ biotechnology, which in turn is deemed essential for economic prosperity.34 Indeed, the economic potential of biotechnology pervades the *Life Sciences Strategy*, and is if anything increasingly emphasised in the ongoing annual reviews of the Strategy: the overriding objective seems to be ‘to improve the situation for European biotechnology’.35

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29 *Council Conclusions and Roadmap of 26 November 2002 for a Strategy on Life Sciences and Biotechnology* [2003] OJ C 39/9. The Communication was considered by industry and competitiveness councils, whilst the environment council considers applications for authorisation of individual GMOs.


32 ‘Blue’ biotechnology, the marine and aquatic applications of biotechnology, is occasionally discussed.


The whole meaning and transformative nature of the ‘knowledge economy’ is contested, especially here because the role of agricultural biotechnology in this brand new economy is as much about potential as current performance. Whilst the contribution of biotechnology to economic development tends to be presented in the official policy as objective fact, a necessity to which we must adapt, these conclusions are of course profoundly value laden, closing out alternative development paths. But when biotechnology is presented as an economic revolution (and by 2007 the Commission is talking of the ‘bio-economy’36) the consequences of being left behind start to look disastrous. This economic focus means that corporate and government priorities increasingly coalesce around questions of ‘wealth creation’.37

There are other possible social benefits to agricultural biotechnology, beyond the economic, as hinted in the first paragraph of this chapter, and as explored a little further in Chapter 2. But whilst feeding the poor and (especially) sustainability are increasingly referred to in EU policy, it is the sense that an economic opportunity is passing us by that dominates. Like the transformative potential of GMOs, the economic potential cuts both ways. It is a huge promise, but the profit motive also creates mistrust and provides no reason to tolerate uncertainty.

2001 saw the introduction of the first major plank of the new structure of regulation, with the Deliberate Release Directive,38 applying to all GMOs for release into the environment or placing on the market. By 2003 the other major pieces of legislation were also in place – the Food and Feed Regulation,39 applying special rules to GM food and feed, and the Traceability and Labelling Regulation,40 filling out the rules on labelling and traceability for all GMOs.

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36 European Commission, above n. 11. Indeed the Commission has even set up a network on the knowledge-based bio-economy – KBBE-NET, ibid.
37 Joseph Murphy and Les Levidow, Governing the Transatlantic Conflict Over Agricultural Biotechnology: Contending Coalitions, Trade and Standard Setting (Routledge, 2006). The ‘Competitiveness in Biotechnology Advisory Group’, consisting of representatives ‘from all the various industry segments and from companies at every stage of company development together with entrepreneurial academics’ made recommendations to the Commission, above n. 30, p. 7. Industry (and ‘entrepreneurial academics’) have a great deal to contribute on enhancing competitiveness and wealth creation, but there is an obvious risk that they (and these particular elements of policy) could dominate.
40 Regulation 1830/2003 concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products
In theory the ‘moratorium’ on authorisations was brought to an end by the authorisation of Bt11 sweetcorn in May 2004.\textsuperscript{41} It is not at all obvious that the decisions taken so far really demonstrate the existence of an effective and predictable regulatory system. Under the new legislation, Member States can either accept or reject the Commission’s proposal on an application for authorisation of a GMO by qualified majority voting. In every case until the end of 2007, the Member States have been deadlocked, unable to find a qualified majority in either direction.\textsuperscript{42} That means that the Commission takes the final decision on authorisation. This way of ending the moratorium is no less acrimonious or ambiguous than its inception.

THE NEW TECHNOLOGY

Technology powerfully affects our relationships with each other, and with our environment, redistributing risks and benefits and potentially changing the ways we think about the world. One of the serious difficulties in the regulation of GMOs is in the extreme polarisation of views on what is at stake with this technology. Some think that this is an unprecedented change in human relationships with our environment, others that it is a simple next step in our constant efforts to control the environment around us. Even the ‘newness’ of GMOs is contentious.

Manipulation of plant and animal genes for human ends has been going on for millennia, albeit until recently in ignorance of the existence of the gene. Traditional breeding involves ‘crossing’ plants or animals in the search for a preferred trait, such as increased productivity. Similarly, ancient applications of technology to food production include the use of enzymes in the preparation of food and drink, most obviously the micro-organisms in yeast in brewing beer and baking bread. Indeed the phrase ‘agricultural biotechnology’ sometimes implies a continuum with modern applications of technology. In this book, ‘agricultural biotechnology’ is used in a more popular sense, specifically to refer to modern biotechnological techniques. In any event, I start from the position that we should simply be thinking much harder about modern applications of biotechnology than we have to about, for example, the use of


\textsuperscript{42} The Decisions can be found at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm (accessed December 2007).
yeast. This book is not about all agricultural biotechnology applications, but specifically about the regulation of GMOs. The manipulation of living organisms at the level of the gene rests on the 19th century discovery of the inheritability of the characteristics of living organisms by Mendel. Watson and Crick described the double helix in 1953, and from that point the gradual discovery of the properties of ‘genes’ led to the 1973 turning point of insertion of toad DNA into a bacterial cell. In modern biotechnology, barriers of sexual compatibility, which had always meant, for example, that a bacterium could not be ‘crossed’ with corn, no longer apply. Modern biotechnology can isolate the DNA fragments responsible for a preferred trait, manipulate that gene in the laboratory, and insert it into potentially any other organism.

Social and political tensions around new technological development are not unique to genetic modification. One of the questions about the experience of GMOs is whether more general lessons can be learned for the future. Lessons are, and should be, sought in past experience, even if one of those lessons is that it is not sensible to extrapolate directly from one technology to another, for example, from nuclear power or chemicals policy to agricultural biotechnology. Differences between technologies rest not only on the hazards and benefits of a new technology, but also on the social processes that they engage. The acceptability of a technology depends on a number of factors, including the familiarity and personal usefulness of the technology (for example, information and communications technologies as opposed to biotechnology), the distribution of knowledge (so whether we can get decent technical advice from our neighbour or only from more distant experts) as well as risks and benefits, and the open or monopolistic structure of the industry controlling the technology. It should not be assumed that a new technology can be assessed using the tools that proved effective for the last technology. Familiar and elaborate

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43 See Eleni Zika et al., *Consequences, Opportunities and Challenges of Modern Biotechnology for Europe* (JRC, European Commission, 2007) for a review of the many different technologies available.

44 James Watson and Francis Crick, ‘A Structure for Deoxyribose Nucleic Acid’ (1953) 171 *Nature* 737. DNA (deoxyribonucleic acid) is a molecule that contains the information that controls the synthesis of enzymes and other proteins, and they then provide the basic metabolic processes of all cells. A gene is a DNA sequence, and the total set of genes of an organism is the genome. This is organised into chromosomes in the nucleus of the cell.


tools of risk assessment failed to capture the issues relating to genetic modification. And the approach taken (or missed) in respect of biotechnology will not necessarily capture what is distinctive next time. But, nevertheless, there seems to be a particularly self-conscious reflection on the experience of biotechnology in discussion of nanotechnology, perceived as the ‘next big thing’, both in its positive potential and, apparently, in its potential to provoke public concern.47 Anticipation of widespread public concern in this case contrasts sharply with what seems to have been a complete failure of regulators and the industry to anticipate the intensity of the public response to the new technology of genetic modification.

In the case of nanotechnology, there may still be opportunities for engagement before institutional and economic commitments are entrenched. This is one big lesson from the agricultural biotechnology experience – the conditions that might make the technology socially acceptable were considered far too late. Engagement on GMOs was through protest, ‘objection’ rather than a positive consideration of the development of social life. The UK Government’s approach to nanotechnology seems to accept the fundamental point that early engagement is needed. Government agrees it should initiate ‘adequately funded public dialogue around the development of nanotechnologies’, and that ‘properly targeted and sufficiently resourced public dialogue will be crucial in securing a future for nanotechnologies’:

The Government’s aim for public dialogue around nanotechnologies is to elicit and understand people’s aspirations and concerns around the development of these technologies. Through the dialogue process, scientists and the public can jointly explore existing and potential opportunities, and policy-makers will want to hear about, and then respond to, public concerns related to ethical, social, health, safety and environmental issues.48

This is potentially very positive. We will see throughout this book that there is a basic mainstream acceptance of decades of work and mountains of evidence from the social sciences on public responses to new technologies and risk.

47 See for example Royal Society and Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (2004). See also some of the documents on the EU’s nanotechnology website (http://cordis.europa.eu/nanotechnology/home.html, accessed December 2007), where the use of biotechnology experience is more implicit, although sometimes raised directly, for example *The Future of Nanotechnology: We Need to Talk* (2006). More generally, the Council sees research in biotechnology as ‘a model for integrating activities addressing ethical and social aspects from the earliest possible stage’, above n. 29, para. 6.

Different approaches by experts and the public are not necessarily about ignorance or irrationality, but might include judgments on the broader context of the developments. But as we will also see throughout this book, there are significant hangovers from the deeply embedded understanding of expert approaches as real and rational and public approaches as emotional and irrational. And, even at a purely practical level, putting the new understanding into action is enormously difficult. So for nanotech we need to think about how we might realistically perform this upstream engagement, when research is in the private sector, and its objectives and trajectories are unclear. Public involvement generally is more difficult to achieve when decisions are distant. The perceived relevance to one’s own life increases as the decision gets closer in time and in space. Regardless of the amount of debate on nanotechnology ‘upstream’, there may well be a new constituency when a decision is made on using nanotechnology in the hospital, factory or field down the road.

And even in the report quoted above, the UK Government takes a somewhat instrumental view towards public participation, such that public involvement makes an already determined trajectory for a technology more acceptable. Government also, even at this early stage, whilst acknowledging social and ethical concerns, concentrates on more tractable (although still difficult) questions of risk to the environment and human health. Whilst the relevance of a broad range of values is accepted, the familiar questions of safety and risk return to the centre of things. We will see this throughout our discussion of GMOs. In part this might be government paying cynical lip service to the importance of democracy. In part, it might just be that this really is very difficult. Brian Wynne argues that whilst the ‘political fact’ of public opinion is accepted as real and indeed legitimate, the reality, the ‘intellectual substance’ of what lies behind it, is not. Public views are not ‘recognized to be what they are, which is public judgments of the quality of existing knowledge, and of the exaggerated claims made for it by scientists and the policy bodies they advise’. Official emphasis on science silences these concerns about uncertainty, and by presenting the ‘objectivity’ of decisions leaves unspoken the economic and scientific values behind decisions. It is not possible to simply tack the correct understanding of public views onto existing ways of doing things.

50 Wynne, above n. 49, p. 457.
Although the potentially disruptive effects of new technologies can be exaggerated, genetic modification does pose new and difficult problems for lawyers. This book addresses legal responses to the dilemma of agricultural biotechnology, ranging from the authorisation process, through intellectual property to international trade law. The law in this area addresses modes of decision making as much as substantive standards, and modes of decision making are forced to grapple with the promise and threats of GM. Whilst this book examines the legal framework of decision making, however, it should be clear that the social acceptability, the meaning, of new technologies cannot be reduced to a series of discrete and relatively simple decisions.

THE STRUCTURE OF THE BOOK

A range of legal disciplines are inevitably involved in the regulation of GMOs. There is a danger that each legal discipline will pass the buck, claiming that the most difficult legal questions are simply not relevant in that area. One of the central, if often implicit, concerns of this book is the need for dialogue between different legal specialisms. So, for example, it is increasingly accepted that GMOs will have distributional effects, and that the way in which a technology distributes costs and benefits will affect its acceptability. But the full magnitude of the dislocation faced by non-GM farmers, and its almost complete neglect by the framework for authorisation, is brought sharply into focus by the potential scope of patent infringement. Neither patent law nor the set of rules on authorisation obviously has the tools to consider this dislocation comfortably. This might turn attention to the role of civil liability in redistributing the costs and responsibilities of GMOs, but here we find an opaque set of rules no better suited to addressing these questions. Only a more holistic approach to the regulatory framework can begin to identify and examine legal responses to GMOs. In particular, the aim of this book is to examine the capacity of these different legal disciplines to hear and address the range of issues raised by these new technologies. Laws and regulations a-plenty are in place, and institutions are adapting and shifting to deal with the newness of GMOs. But GMOs provoke a very broad range of concerns, and it is debatable to what extent law is able to hear, let alone answer, the full range of social questions.

This book attempts to examine what is at stake in the regulation of GMOs. Chapter 2 outlines the main pressures faced in the regulation of agricultural biotechnology, the range of hopes and concerns raised by the technology. The safety of GMOs is not straightforward, but poses relatively familiar and manageable problems for regulators. Safety questions also imply, however, real issues of ignorance and uncertainty, which are less tractable. This chapter
also explores a related and less precise category of political, ethical and socioeconomic concerns about GMOs. These include distributional issues, food security, and biocentric questions about the integrity of nature. The range of concerns and the underlying uncertainty about the impacts of the technology demand that we engage with the role and purpose of GMOs. We will see as we move through the chapters that there is a constant struggle to find space in the regulatory process for the full expression of the substantive questions legitimately raised in respect of GMOs. But the jurisdictions examined here have at least recognised in principle the value-based nature of debate on new technologies. A far-reaching and innovative ‘GM dialogue’ in the UK provides a case study in Chapter 2 of a government trying to come to terms with the breadth of issues raised by agricultural biotechnology, through a combination of expert and public deliberation.\textsuperscript{52} This GM dialogue also shows another thread running through this book. Even if the breadth of the debate is recognised in principle, risk or at least expertise always seems to be the most comfortable basis for the decision. The hegemony of risk, discussed also in this chapter, is very difficult to shake off.

Chapter 3 discusses in detail the authorisation process for GMOs in the EU. EU legislation requires the industry to seek authorisation of each GMO on a case-by-case basis, and this chapter traces the efforts of legislators to respond to diverse and conflicting pressures in this area. As discussed above, the legislation on GMOs fell apart quite spectacularly in the late 1990s, with the introduction of a moratorium on the authorisation of GMOs. The new set of legislation attempts to respond to the inadequacies of the earlier framework. As suggested in the discussion of Chapter 2 above, one of the lines running through this book is the difficulty of addressing in the regulatory framework the full breadth of questions provoked by GMOs. This is reflected in a tension between the role of science (and sometimes also other forms of expertise) and the role of politics or public opinion in decision making on GMOs, and compounded in the EU authorisation regime by the sensitivity of the allocation of authority between national and central decision makers. This question of the battle for authority in a system of multi-level governance is another of this book’s themes. Chapter 3 explores the detail of the legislation along these lines of debate, and in short argues for greater national autonomy on GMOs, allowing national decision making on the basis not just of risk to the environment or health, but also on the basis of ‘other legitimate factors’.

The ‘regulation’ of agricultural biotechnology does not begin and end with the procedure for the authorisation of a product or process, and Chapters 4 and

\textsuperscript{52} Generally in this book, whilst of course other jurisdictions are of great interest, the UK is used when a national example is required.
move into the broader scope of regulation, looking at the legal environment that applies when authorised GMOs are cultivated or marketed in the EU. The regulation of GMOs in the EU is underpinned by a rhetoric of consumer choice, given legal substance by obligations to label GMOs. It seems to be assumed that any public concerns about GMOs not addressed in the authorisation process can be picked up in the market place. And, because we have mandatory labelling, the market does provide a space for some expression of the full range of objections to GMOs. It is, however, unfortunate that the pattern of the legislation concentrates so much on the largely individualised and shallow forum of the market. The role of consumers in GMO regulation crucially assumes the availability of meaningful choice, and so some distinctiveness between GM, conventional and organic farming. But the pervasiveness of genetic material means that, once cultivation of GM crops is widespread in the EU, GM material is likely to be present in non-GM crops.

Rules to ensure the ‘coexistence’ of different forms of agriculture are in principle a matter for the Member States, but Chapter 4 explores the very tight (and, it is argued, largely misconceived) constraints within which the national authorities are operating. The potentially serious impact of GM farming on other forms of agriculture, for example if the presence of GM material affects the status (organic or ‘GM-free’) or performance of non-GM food or crops, raises questions of civil liability for adverse effects of GM farming. It is currently far from certain in what circumstances GM farmers or the biotechnology industry will face liability for the adverse effects of their industry. Nor is liability for other possible negative impacts (on human health or the environment) either entirely clear or likely to be extensive. The allocation of costs and responsibilities if things go wrong should have been a central part of the very hard fought, slow and complex regulatory settlement on GMOs. Liability rules are always politically difficult, but they are especially fraught in respect of GMOs for two main reasons. First, like other regulation, liability prefers to deal with calculable risk. But uncertainty about effects pervades the regulation of GMOs. And, secondly, much of the detail of liability schemes provides an implicit protection for innovative or regulated products on the assumption that they can be deemed to be in the public interest. In fact, consensus around the public interest in this particular technological development is precisely what has broken down.

Intellectual property in agricultural biotechnology is explored in Chapter 5, as a further final element of the legal environment in which GMOs are grown and sold. The proprietary nature of the technology and the dominance of large corporate ownership highlight questions about the distributional impact of GMOs, globally and locally. The assertion of control over its products by the biotechnology industry in this context contrasts very sharply with its complete denial of responsibility for untoward effects. It is also interesting to note that
the patenting system is so far the most fruitful area of regulation for consideration of the ethical implications of agricultural biotechnology. But again, whilst the language is in place, it is extraordinarily difficult to follow through.

In short, the current framework for ‘living with GMOs’ leaves some issues entirely unaddressed, and responds poorly to others. Much of the policy discussion seems to assume that widespread GM agriculture is an objective and unavoidable fact to which other forms of agriculture must adapt, rather than a choice.

The EU regime on GMOs was developed and is applied in the shadow of WTO rules on trade liberalisation. This has led to an acrimonious, longstanding and ongoing disagreement over the propriety of EU regulation of GMOs. North American and other farmers who had adopted GM crops widely in the 1990s found themselves unable to sell their products in the EU, and the biotechnology industry found an enormous market drifting out of reach. There is also a sense that there was much to play for, with the US and EU each trying to influence the choice of regulatory regime elsewhere in the world. Chapter 6 analyses some of the main challenges for the EU in justifying its GMO regulation before the WTO, including discussion of the 2006 Panel decision on the moratorium. The WTO rules do provide considerable space for the justification of otherwise doubtful measures by reference to a broad range of public values, and space for most of the concerns expressed about GMOs could be found somewhere. But some issues are heard more clearly than others. There are many incentives on WTO members to frame the reasons for their legislation modestly, primarily on the basis of risk to human health and environmental protection. So, as before, notwithstanding an openness in principle, the actual basis for a decision is in fact rather narrow. Even these social objectives must be pursued by WTO members within very tight constraints. As at other levels of decision making, the degree of autonomy for the members of the WTO to respond to the demands of their citizens is a challenging question. The development of a reasonably predictable and testable approach to decision making, without discounting democratic pressures, is an important task and suggests, as at EU level, the need to work through greater flexibility for members.

The regulation of GMOs is about far more than science, risk and safety. GMOs provoke a wide range of substantive concerns which merit serious consideration. This implies in turn that the public as well as experts have a role in regulation. But an overwhelmingly scientific (or technical, or even legalistic) focus can silence other voices. The danger of impoverishing debate is real.