Resistance to New Technology: Nuclear Power Information Technology and Biotechnology

Edited by Martin Bauer
Cambridge: Cambridge University Press, 1995

Product, process, or programme: three cultures and the regulation of biotechnology

SHEILA JASANOFF

Introduction

The development of a multinational regulatory framework for biotechnology during the past twenty years provides an unparalleled opportunity to study the processes by which technological advances overcome public resistance and are incorporated into a receptive social context. Through the vehicle of regulation, states provide assurance that the risks of new technologies can be contained within manageable bounds. Procedures are devised to limit uncertainty, channel the flow of future public resistance, and define the permissible modalities of dissent. Regulation, in these respects, becomes integral to the shaping of technology. A regulated technology encompasses more than simply the 'knowledge of how to fulfill certain human purposes in a specifiable and reproducible way.'[1] Regulation transmutes such instrumental knowledge into a cultural resource; it is a kind of social contract that specifies the terms under which state and society agree to accept the costs, risks and benefits of a given technological enterprise.

The passage of biotechnology from moratorium[2] to market in just twenty years exemplifies this process of social accommodation. During this period, biotechnology moved from a research programme that aroused misgivings even among its most ardent advocates to a flourishing industry promising revolutionary benefits in return for negligible and easily controlled risks. The transformation occurred almost simultaneously and with remarkable speed throughout Europe and North America. To facilitate the commercialization of biotechnology, the United States, and the European Community and several of its member states, adopted laws and regulations to control not only laboratory research with genetically engineered organisms but also their purposeful release into the environment.[3] Risks that once were considered speculative and wholly

unmanageable[4] came to be regarded as amenable to rational assessment in accordance with sound scientific principles. Apocalyptic visions and the rhetoric of science fiction yielded to the weightier discourse of expert advice and bureaucratic practice. The research community coalesced to persuade the public that the risks of biotechnology could be assessed in a reasonable way and that earlier fears of ecological disaster were mostly unfounded.

These changes in the status of biotechnology were all the more noteworthy because, as of the early 1990s, the risks of genetic manipulation remained largely hypothetical. Scientists and industrialists confidently proclaimed that no serious harm would befall ecosystems or human health if our daily bread were baked with genetically engineered, quick-rising yeast, if economically significant crop plants were fitted out with herbicide resistance genes, or if fruit farmers sprayed their orchards with gene-deleted bacteria designed to prevent frost formation. Unlike toxic chemicals, however, the products of the new biotechnology have not been around long enough to display their whole range of beneficial and adverse effects. Despite repeated allusions to Bhopal and Chernobyl by opponents of biotechnology, there is no reservoir of precedents into which one can readily dip for historical parallels to the production and use of laboratory-crafted living organisms – products not of nature but of human invention.

Nonetheless, as regulators in different countries approve new uses of biotechnology and reassure their publics that the risks are manageable, they are obliged to place believable outer limits on the technology's potentially harmful impacts. An important question for students of technology to ask is whether the resulting accounts of risk have diverged cross-nationally, conditioned by varying socio-political influences, as predicted by the social studies of science and as previously documented in studies of environmental regulation and risk management.[5] Were there observable differences in national regulatory responses to biotechnology and, if so, could they be traced to differences in national traditions of legal and administrative decision making? How, in turn, did the process of constructing the risks of biotechnology for regulatory purposes affect the opportunities for public participation and protest?

This chapter is based on a focused comparison of the way governmental authorities in Britain, Germany, and the United States conceptualized biotechnology as a regulatory problem in the specific context of releasing genetically modified organisms (GMOs) into the environment. Looking primarily at events in the decade from 1980 to 1990, I describe how public resistance and state response initially led to quite different understandings about risk in each national context, and hence to divergent characterizations of biotechnology as a policy issue. In all three countries, however, the dominant conception enabled regulators to devise strategies for managing uncertainty and neutralizing the most common

forms of organized opposition. Although their techniques varied – legislation, bureaucratic reorganization and expert advice were differentially employed – regulators in each nation succeeded in rearranging a potentially limitless expanse of scientific unknowns into familiar paradigms of assessment and control. I conclude with some observations about what this analysis implies for mobilization against risk in advanced industrial societies.

Paradigms of control

In order to approve the deliberate environmental release of GMOs, regulators in the United States, Britain and Germany had to persuade their respective political constituencies that the risks of biotechnology, although novel, lay sufficiently close to their prior experience of technological risks to permit effective public control. Although the ultimate goal was the same everywhere, the strategy of public reassurance adopted in the three countries varied, especially in the willingness to admit that biotechnology poses novel or special risks to human well-being. 'Specialness' as it relates to the adverse impacts of biotechnology had been understood on at least three different levels since the 1970s. First, opponents of the technology argued that human intervention through genetic engineering would produce *physical risks* to health and the environment that were different in kind and magnitude from risks created by 'natural' processes of genetic combination and recombination. Secondly, some observers were persuaded that the widespread application of biotechnology in agriculture would create a variety of *social risks*, ranging from the commodification of nature to the elimination of family farms in the West and to severe economic dislocations in developing countries. Thirdly, the esoteric technical content of biotechnology was considered likely to increase the distance between expert decision makers and the lay public, thereby exacerbating the *political risk* – increasingly troubling in modern industrial societies – of excluding citizens from meaningful control over technologies that could transform their lives. As we shall see below, these three dimensions of risk, each entailing its own discourses of protest and legitimation, were emphasized to different degrees in the regulatory politics of the United States, Britain and Germany.

United States – a product-based approach

The first applications for conducting deliberate release experiments caught regulatory agencies in the United States without appropriate institutional

mechanisms in place for conducting persuasive safety evaluations. The only supervisory body that researchers could turn to at the outset was the National Institutes of Health (NIH), which had been regulating laboratory experiments involving recombinant DNA (rDNA) molecules since the mid-1970s. Pursuant to guidelines first adopted in 1976 and substantially relaxed in 1978, all federally funded rDNA experiments had to be approved by NIH's Recombinant DNA Advisory Committee (RAC). Governmental control, in other words, was tied to the sponsorship of research, a scheme that proved increasingly vulnerable as biotechnology headed out of the laboratory toward commercial application.

The insufficiency of the NIH review process was dramatically exposed when two University of California scientists, Steven Lindow and Nickolas Panopoulos, sought permission to carry out a field test using the 'Ice-Minus' bacterium, a member of the *Pseudomonas* family that had been genetically engineered to increase the frost resistance of plants. The scientists advising the NIH reviewed the application, requested some modifications, and decided unanimously on the second round of review that the experiment was safe. Their conclusion, however, was set aside by a federal court of appeals, which blocked the experiment on the ground that NIH had not carried out a proper environmental impact assessment, as required by the US National Environmental Policy Act (NEPA). In *Foundation on Economic Trends v. Heckler*,[6] the court especially deplored NIH's failure to explain why a type of experiment that had been considered too risky to undertake under the 1976 guidelines could now be permitted to go forward with so little explicit consideration of its risks. The scientific community predictably saw this call for greater public accountability as an insupportable intrusion into safety evaluation by a 'technically illiterate' judiciary. All the same, *Heckler* threw into relief the fact that NIH's research-funding mission did not sit well with creating an appropriate institutional forum for airing lay concerns about the risks of commercial biotechnology.

The Ice-Minus episode among others forced the US government to regularize its procedures for controlling the commercial applications of biotechnology. In 1986 the president's Office of Science and Technology Policy (OSTP) published a *Coordinated Framework for the Regulation of Biotechnology*, identifying the responsibilities of the three agencies with most extensive jurisdiction over the new technology – the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the US Department of Agriculture (USDA). A Biotechnology Science Coordinating Committee (BSCC) was established to develop a common inter-agency approach to issues governed by the Coordinated Framework. In addition, each of the lead regulatory agencies developed new institutional capabilities for dealing with biotechnology. For example, EPA

established a Biotechnology Science Advisory Committee (BSAC) to give advice on the scientific aspects of regulation.

These institutional arrangements reflected in the first instance a consensus across the US government that the authority contained in existing laws, aimed largely at controlling physical risks, was sufficient to regulate any novel problems associated with biotechnology. OSTP and the agencies participating in the Coordinated Framework persuaded Congress that regulations issued under the old laws would adequately clarify concepts and eliminate possible jurisdictional overlaps. This approach was consistent with the views of many scientists in research and industry that the risks of biotechnology were not in any sense special or unique, and that biotechnological products – pesticides, drugs, foods, and food additives – should not be treated any differently from similar products created by traditional biological or chemical processes.

While denying the need for new legal authority, the Coordinated Framework happily accepted the institutionalization of new scientific authority. The creation of an expert advisory committee, BSAC, at the individual agency level and a coordinating committee, BSCC, at the inter-agency level indicated that federal regulators viewed the task ahead primarily in scientific terms and were prepared to strengthen their institutional capabilities accordingly. OSTP's central role in developing the Coordinated Framework reinforced the view that regulating biotechnology was not a matter for broad participatory politics but for expert policy making at the highest levels of the executive branch. The object at every turn seemed to be to demonstrate that the mainstream forces of science – not activists like Jeremy Rifkin nor the assorted nay-sayers of the environmental movement – were in the driver's seat with respect to managing the emergent technology.

An influential report published by the National Research Council (NRC) in 1989 lent support to the US government's evolving position that commercial biotechnology should not be regarded as a specially risky enterprise in relation to human health and the environment.[7] On each of three issues where splits had developed among federal regulatory agencies,[8] the NRC report sided with the agencies that took the more benign view of biotechnology's hazards. Specifically, the NRC report concluded that

> (i) the *product* of genetic modification and selection constitutes the primary basis for decisions ... and not the *process* by which the product was obtained; (ii) although knowledge about the process used to produce a genetically modified organism is important ... the nature of the process is not useful for determining the amount of oversight; and (iii) organisms modified by modern molecular and cellular methods are governed by the same physical and biological laws as are organisms produced by classical methods.[9]

The message was obvious: mere use of biotechnological techniques did not make a harmless product dangerous; nor, conversely, were organisms produced by 'classical methods' safe simply because they were not genetically engineered. The report as a whole helped crystallize the conclusion that, for policy purposes, biotechnology was to be regarded as a supplier of familiar classes of products – not as a novel technological process threatening mysterious and incalculable harm to social well-being.

Elaborating on the theme of 'no special hazards', the NRC report on the whole belittled the possibility that GMOs would introduce uncontrollable risks into the environment. With respect to genetically modified plants, for example, the NRC committee concluded, first, that the potential for enhanced weediness was the most significant environmental threat. The committee then determined that this risk was likely to be low for a variety of reasons – for example, that the analogy between genetically modified crop plants and 'exotics' was 'tenuous' and that 'genetically modified crops are not known to have become weedy through the addition of traits such as herbicide and pest resistance.'[10]

As the last sentence suggests, the committee's emphasis throughout the report was on what was already known about genetic engineering and environmental release rather than what still remained unknown. For example, the report took pains to point out that molecular methods, whether used on plants or microorganisms, are highly precise and lead to modifications that can be fully characterized and understood.[11] This precision, the committee felt, provided sufficient safeguards against unpredictable behaviour by the resulting organisms. Assessing the social or political risks of biotechnology would have been out of place in a report that self-consciously disciplined uncertainty through technical language; indeed, no explicit discussion of social or political issues contaminated the apparent specificity of NRC's scientific analysis.

Debates concerning the 'scope' of regulation gave further evidence of US policymakers' reluctance to treat the risks of biotechnology as different in kind from those of more traditional biological manipulation. The 1986 Coordinated Framework, for instance, proposed two definitions for organisms requiring review: intergeneric organisms (that is, organisms formed by combining genetic material from sources in different genera), and pathogens.[12] During public comment, these proposals were severely criticized on the ground that they focused – inappropriately in the view of many scientists – on the process by which an organism was produced rather than on the probable riskiness of the product.

Arguments about the scope of regulation continued to divide official opinion for several years, with EPA's staff and scientists favouring a different approach from that of FDA and USDA. In 1990, EPA's biotechnology advisory committee

proposed a quite inclusive and process-based definition of scope ('organisms deliberately modified by the introduction into or manipulation of genetic materials in their genomes'), from which it proposed to exclude all organisms that did not raise new risk assessment issues. The BSAC felt that this approach was broad enough to address potential risks, yet flexible enough to cover future developments in biotechnology. Critics complained, however, that EPA's formulation still displayed an excessive tilt toward process over product as the framing concept for regulation and that this stance contravened the recommendations of the NRC report.[13]

The existence of the NRC report allowed EPA's critics to legitimate their attacks on EPA's scope proposal through an appeal to scientific consensus. But 'science', as socially constructed in US regulatory debates, is often a double-edged sword, and it served as the discourse of choice for EPA's supporters as well. In particular, BSCC, the expert inter-agency coordinating committee that many saw as hostile to EPA, was itself attacked for straying beyond its charter, holding closed meetings, and impeding EPA's scientific inquiry. At the committee's December 1989 meeting, Margaret Mellon of the National Wildlife Federation expressed scepticism based on 'the composition of the BSCC – all high-level administrators, not scientists'.[14] Others accused the committee of unlawfully and heavy-handedly appropriating the review functions of the Office of Management and Budget (OMB), whose own intervention into issues of regulatory science had become a matter of considerable notoriety during the Reagan administration. By late 1990, these challenges led OSTP to rename the BSCC as the Biotechnology Research Subcommittee of the Committee on Life Sciences and to scale down its involvement in policy making.[15]

Confusion in regulatory circles, and associated boundary disputes over expertise and authority, rekindled interest in a legislative solution to managing biotechnology, but political pressure was insufficient to overcome a settled congressional reluctance to do anything that might endanger the US industry's competitive position. Instead, actions by the FDA and the White House, acting through OSTP, consolidated the policy position that only the characteristics of specific products were legitimate objects of regulatory assessment. Labelling theirs a 'risk-based' or a 'science-based' strategy of safety evaluation, these agencies continued to harp on the theme that any negative consequences of biotechnology could be adequately controlled product by product, without creating barriers against 'useful innovation'.[16]

The courts, which in the American political context might have provided an independent spur to a broader public debate on biotechnology, proved unusually quiescent throughout the period of policy development. In *Diamond v. Chakrabarty*,[17] the US Supreme Court held by a narrow five-to-four majority that

biologically modified microorganisms could be patented under an existing law whose operational language had been drafted 200 years before the advent of biotechnology. The decision on its face dealt with a narrowly legal question: whether living things constituted patentable subject matter under the Patent Act. Researchers and industry, however, found more grounds for rejoicing in the decision's subtext, for by relying on existing law the Court implicitly rejected the argument that the risks of biotechnology were so novel as to require special legislative attention. Even the *Heckler* decision, which some had taken to be a sign of awakening judicial activism in matters of biotechnology regulation, refused to require a programmatic evaluation of all deliberate releases, and it proved in any event to be an anomaly rather than a trend-setter with respect to later judicial decisions. Most subsequent challenges to proposals for environmental release from groups like Jeremy Rifkin's were curtly dismissed for lack of standing to sue.

Britain – biotechnology as process

Events in Britain suggested that the government was prepared to take a somewhat more expansive view of biotechnology's risks than were federal policy makers in the United States. Since 1978, laboratory work involving 'genetic manipulation' had been controlled through regulations issued under the Health and Safety at Work Act of 1974. Applications to conduct such activities had to be approved by the Genetic Manipulation Advisory Group (GMAG), replaced in 1984 by the Advisory Committee on Genetic Manipulation (ACGM)[18] to the Health and Safety Commission (HSC), Britain's lead agency for worker protection. Biotechnological work with environmental implications was further reviewed by the Department of the Environment, which obtained expert advice from its own interim Advisory Committee on Introductions. By the late 1980s, however, it became clear to British authorities that many biotechnological activities, including large-scale industrial production and deliberate releases into the environment, could not properly be controlled through the existing regulatory structure for occupational safety.[19]

Developments within the European Community provided additional impetus for Britain's decision to enact more formal statutory controls. In April 1990, the Community adopted two directives relating to biotechnology: one on contained experiments and one on deliberate release of GMOs. Recognizing the need for new legal authority to implement the latter directive, the British government introduced into the Environmental Protection Act of 1990 (the so-called Green Bill) a new Part VI governing GMOs. Meanwhile, environmental and health and safety authorities decided to replace their existing expert committees with a single

new committee to review applications for releasing GMOs into the environment. The resulting interdepartmental Advisory Committee on Releases to the Environment (ACRE) held its first meetings in July 1990.

Debate on the Green Bill provided a focal point for environmentalists to demand more public participation in decisions about GMOs, and the government responded by agreeing to include an environmental representative on its new advisory committee on environmental release. The first person selected for this position was Julie Hill, a member of the Green Alliance, an environmental lobbying group spun off from the Liberal Party that had been particularly active in commenting on the Green Bill. Within Britain's normally closed and consensual policy culture, Hill's appointment marked at once a blow to tradition and a concession to long-standing regulatory practice. Asking an environmentalist to sit on ACRE affirmed the state's acceptance of the lay public's interest in biotechnology as significant enough to be represented in future negotiations over safety, but after the appointment, as before, the power to make decisions remained closely held within an expert advisory body.

Broadening the range of participation on ACRE appeared on the surface to be more responsive to the special social and political risks of biotechnology than comparable actions of the US government. It was almost as radical a move in the British context, according to one observer, as inviting Jeremy Rifkin to give advice on biotechnology might have been in America. Sceptics note, however, that the new committee was formed under the aegis of the HSC, the most participatory of Britain's regulatory agencies; under the Health and Safety at Work Act, HSC and its various operating committees are required to be constituted as 'tripartite' bodies, representing industry, labour, and local governments. Given this tradition of participation, it was perhaps easier for ACRE to accommodate a new interest (environmentalism) than it would have been for less broad-gauged scientific committees, such as those attached to the Ministry of Agriculture, Fisheries and Food.[20] Further, the move came at a time when the conservative government was seeking to expand its ties among moderate environmentalists. For British government and industry, the Green Alliance may well have represented environmentalism with a human face – a voice of reasoned dissent that could be internalized without seriously jeopardizing the evolution of technology. In constructing an appropriate advisory committee on deliberate releases, then, the government simultaneously constructed an official form of green participation that regulatory authorities were prepared to live with.

In Britain as in the United States, a well-timed report by a prestigious expert body helped reinforce the government's efforts to sort out its legal and institutional arrangements for dealing with biotechnology. The Royal Commission on Environmental Pollution (RCEP), a standing body charged with advising the

government on environmental matters, decided that the time was ripe for a thorough evaluation of deliberate release, looking both at the possible consequences of releasing GMOs and at procedures for identifying, assessing and mitigating their risks.[21]

Issued in 1989, like its US counterpart, the Royal Commission's report was both more expansive in its treatment of impacts and more open in admitting uncertainty than the corresponding US document. Thus, instead of dwelling on benign past experiences and the precision of molecular techniques, the British experts emphasized how much was still unknown – and hence how little could be predicted with assurance about the likely behaviour of GMOs in the environment. With respect to genetically modified plants, for example, the RCEP report considered a broader range of possible risks than the NRC and seemed unwilling to dismiss any of these risk scenarios as wholly improbable. Thus, the RCEP felt that the historical experience with exotics could be highly relevant if a GMO were released into an environment where it was not native.[22] With respect to herbicide resistance, the Commission considered not only the possibility that the resistant gene might spread to weedy species, but also that the genetic engineering of plants resistant to herbicides could lead to greater use of environmentally damaging herbicides.[23]

The RCEP's stance, acknowledging the unpredictability of nature, was echoed in official British policy. In its guidance note on environmental release,[24] the ACGM subcommittee on releases spoke of possible differences between natural evolutionary processes and results obtained through genetic manipulation, noting for example that the release of a novel organism could involve the introduction of larger numbers than in the case of natural mutations. In sum, the subcommittee concluded as late as January 1990 that 'the deliberate release of novel types to foreign habitats could occasionally disturb the natural equilibrium of those habitats'.[25]

British authorities seemed to accept without question the Royal Commission's recommendation that all GMO releases, to start with, should be subject to regulatory scrutiny. Put differently, this amounted to accepting the principle (denied in America) that the process of genetic modification was an appropriate basis for defining the scope of policy action. Officials at both DoE and HSE acknowledged that risk categories might eventually be established that would either exempt some products from evaluation or subject them to reduced oversight.[26] But they indicated that any such relaxation would have to be based on actual experience, that is, on empirically observed data from earlier releases. These views were seconded by Dr John Beringer, the first chairman of ACRE, who thought that all GMOs should in principle be subject to review, although it might eventually be possible to move to a two-tier system of clearances for new

GMOs – a 'fast track' for relatively familiar organisms and a slower track for all others.[27]

Having agreed to a case-by-case approach, British regulators were most concerned to ensure that the approval process would flow as smoothly as possible from the standpoint of the applicant. The creation of a single 'postbox'[28] in the form of ACRE bypassed the possibility of inter-agency differences of the kind that arose in America. This committee was to review all applications for release regardless of whether the product was a food, drug, pesticide or crop plant. Moreover, the risk assessment guidelines and notification procedures adopted by the ACGM subcommittee on deliberate release, ACRE's predecessor, were to serve as the blueprint for new interdepartmental regulations.[29] In particular, the guidance note outlined a risk assessment procedure, spelling out what information applicants should provide on an interdepartmental form to facilitate unified submissions. The instructions accompanying the form were symptomatic of the extent to which deliberate release in Britain had been redefined from an exercise in assessing uncertainty to a matter of following bureaucratic routine: 'Continuation sheets should be used wherever necessary. These should be in A4 format and clearly marked with the number of the item to which they relate.'[30]

Additional steps toward normalizing the regulatory treatment of biotechnology were taken with the publication of the Royal Commission's report on 'GENHAZ', a systematic approach to evaluating proposals for environmental releases of GMOs.[31] The Commission acknowledged that each release was likely to be unique, and hence that blanket exemptions were not warranted for any products of genetic modification. Nevertheless, the risk assessment procedure the Commission outlined provided reassurance on at least two levels. First, the proposed analytic approach was based on a method already in use in the chemical industry, a fact that tended to make biotechnology look more like another, less novel form of hazardous activity. Secondly, the procedure assumed that an experienced, interdisciplinary team of experts would be able to imagine the possible hazards of release, and hence to guard against potentially unacceptable consequences. This presumption essentially negated the possibility of significant hazards lying beyond the imaginative reach of the trained scientific mind.[32]

Germany – a programmatic view

The three major dimensions of biotechnology's risks – physical, social, and political – were perhaps most fully deconstructed, or thematized, in the German case, although public debate was slower to take shape in Germany than in Britain or the United States. The regulatory history of genetic engineering in Germany

began in the early 1960s with a top-down decision by the federal government to target biology as an area for state-supported R & D. The biotechnology programme received a further boost with the creation in 1972 of the Federal Ministry for Research and Technology (BMFT), whose central mission was to channel funding toward designated 'key technologies'. Paralleling the work of NIH in the United States, BMFT supervised the German response to the Asilomar conference, where researchers first expressed concern about the risks of genetic manipulation. Guidelines closely modelled on NIH's were issued by a restricted, *ad hoc* committee of experts, including at first neither labour nor industry, though these interests were later represented in a twelve-member implementing commission.[33] Through the early 1980s, the strategy of containing regulatory debate within carefully structured expert committees ensured a relatively narrow focus on the physical risks of rDNA research and correspondingly muted attention to the social and political consequences of the new technology.

The rise of new social movements and the waning of previously controversial issues such as nuclear power opened the way for a more participatory politics of biotechnology by the mid-1980s.[34] The Green Party was first elected to the Bundestag in 1984 and soon created a working group on genetic technology. In the same year, an alliance between the Greens and the Social Democrats led to the formation of a parliamentary Commission of Inquiry (*Enquete-Kommission*) to examine the opportunities and risks associated with developments in genetic engineering. As the state's policy on biotechnology was subjected for the first time to systematic, institutionalized criticism, two views emerged concerning the novelty of the problem confronting policy makers. The Greens and the Social Democrats argued that the risks of biotechnology were sufficiently unsettling – uncertain, potentially catastrophic, perhaps irreversible – to require a new political order for their management and control. Key to this new order would be a more pronounced voice for the public, institutionalized through new forms of public participation. The Christian Democrats insisted, to the contrary, that biotechnology was amenable to control through established forms of assessment by technically trained experts.

Green opposition to biotechnology led in due course to litigation. In an unusual lawsuit against Hoechst chemical company, German environmentalists in Hessen challenged a planned facility for the production of genetically engineered insulin on the ground that the state had not sufficiently guaranteed the safety of biotechnology. Existing laws, they argued, could not be construed as providing an adequate basis for controlling risks whose unique characteristics required explicit legislative authorization, just as nuclear power had done a decade earlier. The administrative court of Hessen accepted this representation of uniqueness and, in a move that went beyond the actions of any US court, ordered the cessation of

Table 15.1. *Thematization of risk*

	Physical	Social	Political
US product	High	Low	Low
UK process	Medium	Medium	Medium
Germany programme	Medium	Medium	High

industrial biotechnological activity until a suitable legal framework was in place. Within a year, however, the German parliament set aside this inconvenient roadblock by passing the 1990 Genetic Engineering Law, a statute that critics denounced for repudiating the inroads made by participatory politics on the government's insulated, bureaucratic–technocratic structures of control.

By combining the functions of protection ('*Schutz*') and promotion ('*Forderung*') within a single law, the legislature affirmed the state's presumed capacity to undertake these potentially conflicting tasks without compromising the values or rights of its citizens, but early implementation of the law raised questions as to whether this optimism was justified. As a partial concession to public concerns, the law opened up participation on the government's key advisory committee and created a new public hearing process for deliberate release applications. These procedural innovations seemed responsive to the theme of political risk articulated during the controversy preceding the law's enactment. In practice, however, the first public hearings deteriorated into administrative wrangles and rhetorical stand-offs that led the government in 1993 to rescind the hard-won right to a hearing. The environmentalists' position on the safety evaluation committee, too, appeared likely to become bureaucratized, as the Greens, unable to pay for their representatives, considered replacing them with sympathetic government officials.[35]

The political construction of risk and resistance

I have argued thus far that the risks of biotechnology, particularly as regards their novelty, were construed in fundamentally different ways within the regulatory frameworks of three advanced industrial nations – the United States, Britain and Germany. The divergences during the 1980s are most strikingly apparent if one looks in retrospect at the dominant characterization of biotechnology as a regulatory problem in each country and the impact of this problem definition on later debates about risk. See Table 15.1 for a two-dimensional, and hence necessarily oversimplified, representation of the cross-national differences in the thematization of risk.

Table 15.2. *Resistance and response*

	Forms of resistance				State responses			
	Scientific debate	Legislative debate	Litigation	Party politics	Expert committees	Administrative rules	Legislation	Judicial action
US	yes	some	yes	no	new	yes	no	yes (pro-development)
UK	some	some	no	no	new/ expanded	yes	expanded	no
Germany	no	yes	yes	yes	expanded	yes	new	yes (anti-development)

The focus in the United States was increasingly on the *products* coming into the market-place and the physical risks they may pose to human health *or* the environment. In Britain, regulators appeared initially more prepared to accept the *process* of genetic modification as the frame for policy making, with concurrent attention to the physical and social dimensions of risk. But this acknowledgment of the technique's specialness was undercut to some degree by a bureaucratized hazard evaluation procedure that stressed routine and internalized possible opposition from environmentalists. German political debate on biotechnology was unique in taking as its domain the entire *programmatic* relationship between technology and society, as mediated by the state, a position that led to a full-blown discussion of risks. Eventually, parliamentary action, in the form of a special law on genetic engineering, confirmed that the state's programme of promoting and regulating biotechnology was sufficiently novel to require explicit legislative licence. (See Table 15.2 for a summary of the main forms of resistance in each country and the associated variations in the state's responses to public challenge.)

In the remainder of this chapter, I will argue, first, that these cross-national variations were consistent with previously noted features of each country's political culture and regulatory style; secondly, I will suggest that the divergent forms of political accommodation worked out in each country were similar in result – in each case, the selected policy initiative blocked significant avenues of public dissent and smoothed the way for a relatively untroubled further development of biotechnology.

The US case illustrates the well-known national preference for according science a central role in public decision making. US regulators have generally been more inclined to justify their actions with appeals to objective knowledge than their European counterparts. Extensive scientific records, mathematical

modelling of risk and uncertainty, and detailed procedures for peer review and quality control, all bear witness to the US decision maker's need to enlist the impartial authority of science in support of costly and controversial policy decisions. Confronted with scientific uncertainty, American agencies are reluctant simply to admit ignorance and exercise subjective judgment. If an extrapolation must be made from limited data, it has to be according to prestated rules of decision that spell out technical methods for dealing with uncertainty.[36] More generally, science in the US frequently serves as a resource with which political adversaries seek to trump their opponents in the regulatory arena. Scientific disputes thus become a surrogate for unstated ethical or economic conflicts.

Not surprisingly, then, every major US player with a stake in biotechnology policy stated publicly that decisions in this area should be based on sound science. Competition among these actors to justify their positions in scientific terms underscored the power of science as a legitimating rhetoric in politics. EPA, the most risk-averse of the US agencies (and, in the Reagan–Bush years, also the most politically vulnerable), created a new scientific advisory committee, BSAC, to shore up its credibility in the politics of regulation. When the White House tried to seize control of biotechnology policy, it created the BSCC, ostensibly to provide *scientific* coordination across the government, but in practice to serve as a counterweight to possibly recalcitrant regulatory agencies. BSCC, in turn, relied on the National Research Council for a still more authoritative exposition of the scientific principles that should govern the regulation of biotechnology. In due course, the NRC report provided scientific ammunition for OSTP scientists, Vice-President Dan Quayle's Competitiveness Council, and others who wished to challenge EPA's cautious regulatory approach.

Scientific pluralism, the result of scientific claims being produced by parties with competing claims to authority, is inevitably a feature of American regulatory politics, showing that the effort to tame uncertainty through technical discourse does not necessarily resolve conflicts. The multiplicity of agencies (EPA, FDA, USDA, NIH) and committees (BSCC, BSAC, NRC study committee) with an active interest in biotechnology virtually guaranteed that multiple technical accounts of risk would proliferate in the public domain once decision making was narrowed to questions of physical risk and safety. The protracted battle over the scope of regulation was but one example of the fracture lines that arise when American political actors draw upon 'scientific principles' to justify their agendas with respect to risk.

The British style of policy making, in contrast to the American, tends to be informal, cooperative, and closed to all but a select inner circle of participants. Disputes are resolved as far as possible through negotiation within this socially

bounded space, and the power of the judiciary is seldom invoked even for enforcement purposes. These differences have had an impact on the production and use of regulatory science (science used as a basis for policy),[37] which tends in Britain to be less diverse and less admitting of uncertainty than in the United States (Wynne and Mayer, 1993). Early attempts to manage the deliberate release of GMOs, however, showed British scientists and regulators as apparently more receptive than their US counterparts to admitting the special status of biotechnology and to recognizing a broad range of possible hazards, from the ecological to the social and (to a lesser degree) political.

This finding seems inconsistent at first blush with observations previously made in the area of chemical regulation, where British experts consistently represented the risks as less severe than their counterparts in the United States. While American regulators often banned substances based on animal evidence alone, British health and safety authorities refrained from aggressive action except in cases where there was observable harm to human health. At a deeper level, however, Britain's seemingly higher tolerance for chemical risks and lower tolerance for biotechnological risks can be traced to similar underlying views about what constitutes acceptable evidence for political action. The British policy maker's classic preference for empirical proofs, attested to by credible communities of experts, explains why so few of the risks of biotechnology were initially ruled out as improbable, just as it explains why chemicals were so often exonerated when they only damaged the health of test animals but showed no effect on humans. British caution over biotechnology proceeded from the fact that no one had yet had the opportunity to *see* how gene-altered organisms might behave in the environment, removed from the physical containment of laboratories. In the absence of direct evidence, it was easy for all sides to agree that experience alone could guide the making of regulations, including the establishment of risk criteria and classes of exemptions. Biotechnology thus classically lent itself to the case-by-case regulatory style favoured by policy makers in Britain; it was a style well suited in this instance to permitting incremental adjustments to the new technology.

Britain's sensitivity to the need for broader political representation in biotechnology policy was also consistent with that country's established practices for managing risks to health and safety. The framework of tripartite decision making in the field of worker protection was easily adapted to include a representative of the environmental community. Giving the 'greens' a formal role in ACRE at least temporarily neutralized the threat of public discontent. At the same time the move, which left the state in charge of choosing its environmental partner, seemed unlikely to upset the science–government–industry consensus that normally drives policy in Britain. Many observers of the British regulatory

scene saw the expansion of ACRE as yet another instance of successful political cooptation whereby a potentially troublesome 'outsider' voice is brought into – and contained within – the channels of closed, consensual, and expert-dominated decision making.

Relations among science, technology and the state have historically been less transparent in Germany than in the other two countries, and public disputes among experts are something of a rarity in the regulatory arena. Yet, the German environmental movement scored early and relatively pronounced political success, winning representation in parliament at a time when British environmentalists were hardly visible as a national political force. Confrontations over technological risk in Germany have been intensely political, even violent at times, as in the case of anti-nuclear protests in the late 1970s and early 1980s. Again, these dynamics reproduced themselves with reasonable accuracy in the context of biotechnology. The German policy debate was most directly tied to the agendas of the major political parties. Perhaps in consequence, it was also most successful in forcing an open public discussion of the social and political ramifications of biotechnology, avoiding the strictly scientific framing that accounted for so much of the American discourse on risk. In a society where expertise is normally the prerogative of the few, insistence on the value implications of biotechnology (rather than exclusively on its technical uncertainties) powerfully legitimated citizens' claims that they should be accorded a wider role in the direction of the new technology. Yet, by enacting a comprehensive regulatory law, the state in the end re-established the very bureaucratic culture of risk management that had initially aroused public protest. The 1990 law permitted technology to develop without substantial fear of widespread citizen mobilization.

Conclusion

I have devoted much of this essay to the theme that political and regulatory culture counted in the way that members of three technological societies imagined, characterized, delimited, and controlled the products of their scientific ingenuity. In each country, an early phase of protest seemed at first to expand the vocabulary of resistance to a new and fearful technology. Contingent and culturally specific accountings of risk led in the 1980s to divergent national conceptualizations of the problem facing regulatory authorities. Cultural influences surfaced most strikingly in the science-centred definition of risk in the United States, in the political adaptation of existing expert bodies in Britain, and in the comprehensive legislative response to citizen mobilization in Germany.

The final twist to the story, however, becomes apparent only when we ask what

these preliminary characterizations of risk meant in terms of the future of biotechnology. It is difficult to avoid the conclusion that all three countries, despite their culturally conditioned ways of constructing biotechnology as a policy issue, converged in their willingness to make the technology possible. In each country, the dominant political framing appeared to rule out one or more of the expected forms of public resistance, thereby ensuring that scientific uncertainty would not spill over into social and political unrest. Thus, in the United States, congressional and judicial inaction left the discussion of biotechnology's risks within a bureaucratic framework where the issue was most likely to be analysed in the relatively narrow terms of physical hazards. Moreover, the absence of legislation foreclosed new opportunities for judicial review and sharply restricted the dissenting public's least constraining avenue of access. Similarly, in Britain, despite an initially more expansive reading of biotechnology's uncertain consequences, decision making was soon channeled into a framework of carefully structured expert committees that provided assurance by internalizing dissent. Finally, legislation in Germany re-established a working state–industry partnership that formally bowed to citizen concerns but closed down the kind of open-ended political debate that had preceded the enactment of the genetic engineering law. In all three national settings, then, historical contingencies and political culture proved equally amenable to accommodating the determined thrust of biotechnology's forward movement. Explanations for this ultimate convergence lie in all probability in the theatre of international relations, where national protest politics confronted, and eventually succumbed to, the rhetoric and politics of global competitiveness.

Notes

1 Harvey Brooks, "Technology, Evolution, and Purpose," *Daedalus* 109 (1980), p. 66.
2 In the mid-1970s leading molecular biologists declared a moratorium on research with recombinant DNA until the risks were properly explored and regulated. A scientific meeting at Asilomar in 1976 laid the conceptual basis for research safety guidelines that were formally adopted by the National Institutes of Health (NIH).
3 European countries that have legislated on this issue include Denmark, Germany and Britain. In the Netherlands, regulations governing deliberate releases were developed under the Environmentally Hazardous Substances Act. As noted below, on 23 April 1990, the European Community adopted a directive on the deliberate release of genetically modified organisms. Member states were required to implement the directive by the end of 1991.
4 The 1976 NIH guidelines prohibited deliberate release experiments. Just two years later, NIH decided that the prohibition could be waived on a case-by-case basis.
5 See, for example, Sheila Jasanoff, *Risk Management and Political Culture* (New York: Russell Sage Foundation, 1986).
6 *Foundation on Economic Trends v. Heckler*, 756 F.2d 143 (D.C. Cir. 1985).
7 National Research Council, *Field Testing Genetically Modified Organisms – Framework for Decisions* (hereafter referred to as *Field Testing*) (Washington, DC: National Academy Press, 1989).

8 Among the agencies participating in the Coordinated Framework, EPA's positions tended consistently to diverge from those of FDA and USDA.
9 Henry I. Miller, Robert H. Burris, Anne K. Vidaver, Nelson A. Wivel, 'Risk-Based Oversight of Experiments in the Environment,' *Science* 250 (1990), p. 490.
10 NRC, *Field Testing*, p. 52.
11 See, for example, NRC, *Field Testing*, Executive Summary, pp. 3–4.
12 *Federal Register*, 26 June 1986.
13 EPA Memorandum, p. 2.
14 'BSCC Urged to Hold More Meetings, Open Process', *Pesticide and Toxic Chemical News*, 27 December 1989, p. 7.
15 Jeffrey Merves, Congress and Administration Closer to Regulating U.S. Biotech Industry, *The Scientist*, 4 (22) (1990), p. 12.
16 See, for example, Office of Science and Technology Policy, 'Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introduction of Biotechnology Products into the Environment,' *Federal Register*, February 27, 1992, pp. 6753–6762. See also, David A. Kessler et al., 'The Safety of Foods,' *Science* 256 (1992), pp. 1747–49 and 1832.
17 *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
18 To deal with the issue of deliberate release, ACGM had created an Intentional Introductions Sub-Committee (IISC). ACGM's own name subsequently was changed to Advisory Committee on Genetic Modification.
19 Existing regulations were deemed defective not only because of their limited scope but because they referred to the no longer existent GMAG. See *The Impact of New and Impending Regulations on UK Biotechnology*, report of a meeting sponsored by the Department of the Environment, the Health and Safety Executive and the Bioindustry Association (hereafter cited as *Impact*) (Cambridge: Cambridge Biomedical Consultants, 1990, p. 12) (remarks of Richard Clifton, Health and Safety Executive).
20 I am indebted to Les Levidow for calling my attention to this point.
21 Royal Commission on Environmental Pollution, *The Release of Genetically Engineered Organisms to the Environment* (hereafter referred to as *Release of GEOs*), Thirteenth Report (London: HMSO, 1989). Although the Commission spoke of genetically engineered organisms (GEOs), the term genetically modified organism (GMO) eventually took over as the international standard term for organisms produced by genetic engineering. In this chapter, I follow the international usage.
22 RCEP, *Release of GEOs*, p. 21.
23 RCEP, *Release of GEOs*, p. 20.
24 ACGM, 'The Intentional Introduction of Genetically Manipulated Organisms into the Environment,' Guidelines for risk assessment and for the notification of proposals for such work, HSE Guidance Note 3 (revised), January 1990.
25 HSE Guidance Note 3, p. 5.
26 See comments of Richard Clifton and Douglas Bryce in *Impact*, pp. 15, p. 24.
27 Interview with John Beringer, London, July 1990.
28 Comments of Richard Clifton, *Impact*, p. 15.
29 HSE Guidance Note 3.
30 HSE Guidance Note 3, Interdepartmental Proposal Form, p. 1.
31 Royal Commission on Environmental Pollution, *GENHAZ* (London: HMSO, 1991).
32 Although GENHAZ looked like a further attempt to routinize biotechnology regulation, British industrialists were less than enthusiastic about this labour-intensive, cautiously empirical approach to safety assessment. As of the summer of 1993, it looked as though this Commission

proposal would probably remain on the drawing board except for isolated trial applications. The European Commission's efforts to streamline regulation, somewhat on the U.S. model, seemed likely to swamp any distinctively national assessment efforts.

33 Sheila Jasanoff, 'Technological Innovation in a Corporatist State: The Case of Biotechnology in the Federal Republic of Germany,' *Research Policy* 14 (1985), pp. 23–38.

34 See, generally, Herbert Gottweis, 'German Politics of Genetic Engineering and Its Deconstruction,' *Social Studies of Science* (in press).

35 Interview with Jens Katzek, German Bundestag, Bonn, July 1993.

36 Thus, in regulating chemical carcinogens, U.S. regulatory agencies have developed complex principles and mathematical models for extrapolating human risk estimates from animal data. British regulators have never adopted comparable analytical methods.

37 For an extended discussion of the properties of regulatory science, see Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Cambridge, MA: Harvard University Press, 1990).

References

ACGM, ADVISORY COMMITTEE ON GENETIC MANIPULATION (1990). *The intentional introduction of genetically manipulated organisms into the environment. Guidelines for risk assessment and for the notification of proposals for such work.* HSE Guidance Note 3 (revised), January 1990.

BROOKS, H. (1980). Technology, evolution and purpose. *Daedalus* 109, 66.

GOTTWEIS, H. (1995). German politics of genetic engineering and its deconstruction. *Social Studies of Science* (in press).

JASANOFF, S. (1985). Technological innovation in a corporatist state: the case of biotechnology in the Federal Republic of Germany. *Research Policy* 14, 23–38.

JASANOFF, S. (1986). *Risk management and political culture.* New York: Russell Sage Foundation.

JASANOFF, S. (1990). *The fifth branch: science advisers as policymakers.* Cambridge, Mass: Harvard University Press.

KESSLER, D. A. *et al.* (1992). The safety of foods. *Science* 256, 1747–9 and 1832.

'IMPACT' (1990). *The impact of new and impending regulations on UK biotechnology.* Report of a meeting sponsored by the Department of the Environment, the Health and Safety Executive and the Bioindustry Association. Cambridge: Cambridge Biomedical Consultants.

MERVES, J. (1990). *Congress and administration closer to regulating U.S. biotech industry. The Scientist* 4(22), 12 November, p. 12.

MILLER, H. I., BURRIS, R. H., VIDAVER, A. K. & WIVEL, N. A. (1990). Risk-based oversight of experiments in the environment. *Science* 250, 490.

NRC, NATIONAL RESEARCH COUNCIL (1989). *Field testing genetically modified organisms – framework for decisions.* Washington, DC: National Academy Press.

OSTP, OFFICE OF SCIENCE AND TECHNOLOGY POLICY (1992). Exercise of federal oversight within scope of statutory authority: planned introduction of biotechnology products into the environment. *Federal Register*, 27 February, pp. 6753–62.

RCEP, ROYAL COMMISSION ON ENVIRONMENTAL POLLUTION (1989). *The release of genetically engineered organisms to the environment.* Thirteenth Report. London: HMSO.

RCEP, ROYAL COMMISSION ON ENVIRONMENTAL POLLUTION (1991). *GENHAZ.* London: HMSO.

WYNNE, B. & MAYER, S. (1993). How science fails the environment. *New Scientist*, 5 June, pp. 33–5.