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TRADING UNCERTAINTIES: THE TRANSATLANTIC DIVIDE IN REGULATING BIOTECHNOLOGY

SHEILA JASANOFF**

Introduction

On 13 May 2003, the US Trade Representative's office announced that the United States and several cooperating countries had filed a case at the World Trade Organization (WTO) against the European Union's "illegal, non-science based moratorium" on biotech food and crops, which was "harmful to agriculture and the developing world" (Office of the US Trade Representative 2003a and 2003b). Elaborating on that message, Robert B. Zoellick, the US Trade Representative, wrote, "As we have waited patiently for European leaders to step forward to deploy reason and science, the EU moratorium has sent a devastating signal to developing countries that stand to benefit most from innovative agricultural technologies (Zoellick 2003)." In July of the same year the EU drew up new regulations on the labeling and traceability of foods containing genetically modified ingredients, claiming that European consumers now had a reliable means of choosing between GM and non-GM food. Nevertheless, in August the United States called for a WTO dispute settlement panel to address the issue of genetically modified organisms (GMOs). David Byrne, the EU Commissioner for Health and Consumer Protection deplored the US action, stating, "Only a month ago we updated our regulatory system on GMOs in line with the latest scientific and international developments. Clear labelling and traceability rules are essential to help restore consumer confidence in GMOs in Europe (EU Institutions Press Releases 2003)." On 7 Fe-

bruary 2006, the WTO panel issued a 1,050 page interim report holding that the EU had indeed maintained an unlawful de facto general moratorium on biotech products from 1999 to 2003. Further, the panel found that several member states had prohibited products already approved by the EU without scientific evidence and without the risk assessment required by the WTO treaty. A final ruling on 11 May 2006 affirmed these conclusions.

Few starker reminders could be found that the seemingly unstoppable global march of biotechnology had not brought policy harmonization in its wake. Indeed, what occurred in this case struck some observers as regulatory polarization rather than the convergence that producers and their state sponsors had hoped for (Bernauer 2003). Here were two of the world's economic superpowers disagreeing not only about whether and how to promote biotechnology in agriculture, but, even more astoundingly, about what counts as science for regulatory purposes and how science should be used in controlling the fruits of genetic manipulation. Zoellick's May 2003 statements implied that Europe's actions were not merely unreasonable but unreasoned – displaying blatant disregard for science, as well as indifference toward food shortages and nutritional deficiencies in the developing world. Opposition to biotechnology, in the official US view, amounted to a repudiation of progress and humanitarian responsibility.

On its face, the charge that several of the world's most advanced industrial nations had abandoned reason and compassion, not to mention technological progress, seems implausible. Can we, as social analysts, find explanations that make more sense? The need for better understanding of regulatory differences only grows more urgent if we differentiate the concepts of "Europe" and "biotechnology". Regulatory policies for biotechnology, after all, varied not only across the Atlantic but also among European countries and across different technological sectors. Of Europe's leading scientific and economic powers, Germany proved perhaps most cautious with respect to the adoption of both agricultural (green) and biomedical (red) biotechnologies.

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British policy was most permissive toward cloning and embryo research, but hostility toward GM crops was more pronounced in Britain than elsewhere in Europe. Italy paralleled Germany in high skepticism toward both biotechnological sectors, whereas France patterned with Britain in its relatively more lenient attitude toward biomedical research than toward the introduction of novel GM crops and foods.

In each of these countries, moreover, the alignment between public policy and popular response was far from perfect; the most notable example of divergence was the UK public's massive rejection of GM agriculture despite the government's firm support for this technology. Across the board, it may be fair to say that greater caution accompanied the introduction of biotechnology on the European than the American side of the Atlantic. Yet variations within Europe suggest that domestic politics significantly shaped the course of national biotechnology regulation. The US picture too becomes more complicated when one contrasts the rapid and largely uncontested introduction of GM crops with the long-drawn controversies over cloning and stem cell research.

Clearly, no single master narrative – not protectionism, nor economic interests, nor public misunderstanding of science – can do justice to the cross-national differences we see in regulatory policies for biotechnology, nor to the splits that have appeared in almost every nation between official enthusiasm and public hesitation. Instead, comparative analysis suggests that regulation takes its cue from enduring connections between institutional features of governance and public perceptions of risk and benefit. Accordingly, we find in national histories of regulation neither blind technological determinism nor rigid path dependency, but a complex interplay between people's desire for technoscientific change and their expectations concerning the right way to apportion responsibility for risks and uncertainties among the state, the market and citizens.

These expectations are foundational enough to each nation's political culture to function as a kind of unwritten constitution. Three elements of that constitution are especially determinative of regulatory outcomes: first, the balance between collective responsibility and private risk-taking or, put simply, between state and market with respect to innovations; second, the manner of providing expert advice to governments; and third, the assumptions of citi-

zens concerning the legitimacy of the state's knowledge and reasoning, in other words, a nation's "civic epistemology".¹ All three elements, as we see below, came actively into play when Western states attempted to regulate the new biotechnologies. At these moments of flux, prior understandings of life and nature were significantly disrupted, giving rise to uncertainties about the future. Not surprisingly, nation states and their citizens fell back on institutionalized patterns of coping with the unknowns that confronted them. The resulting policy disparities should be seen as windows onto alternative modes of managing innovation and as opportunities for cross-cultural learning rather than as grounds for transnational blaming, trade wars or other retaliatory actions.

Regulating risk: between market and state

How nations characterized, or framed, the risks of biotechnology reflected differences in the respective roles of the state and the market as regulators of uncertainty. In the United States, Britain and Germany, for example, three different framings of biotechnology emerged – as product, process, and program – each resting on distinctive assumptions about how to manage the consequences of innovation (Jasanoff 1995). The product-based approach particularly took hold in the United States, where it went hand-in-hand with the view that genetic engineering consists of highly specific interventions, entailing predictable and mostly negligible consequences for human health and the environment. European countries including Britain, by contrast, adopted a process-based approach that took into account the context as well as the products of genetic modification, admitted more uncertainty, and called for a precautionary approach to regulation. Partly under pressure from the Green Party, Germany took caution yet a step further by highlighting the political and ethical as well as the environmental risks of biotechnology – in particular, the possibility of a programmatic alliance between science, industry and the state that might lead to abuses of power unless biotechnology was strictly regulated.

The US framing of biotechnology as a stream of commercial products was consistent with a liberal democratic tradition in which the market frequently out-competes the state as the more powerful model

¹ For an extended discussion of this concept, see Jasanoff (2005).

of political legitimacy. Pro-market and anti-regulatory tendencies manifested themselves across the entire range of governmental responses to biotechnology, from the failure to enact comprehensive federal legislation in the late 1970s to the decision to adopt an explicitly product-based regulatory approach in the 1980s; and from the remarkably expansive decision on patenting life in *Diamond v. Chakrabarty* (447 US 303; 1980) to the active encouragement of university-industry technology transfer through the 1980 Bayh-Dole Act. The preference for market solutions grew during the 1980s, as the administration of President Ronald Reagan imported its deregulatory fervor into all areas of federal administrative practice. With the downfall of communism and the “end of history” proclaimed by the political analyst Francis Fukuyama (1992), the ideology of the market gained additional force. The resulting *laissez faire* policies expressed the American state’s chronic aversion toward incurring opportunity costs by forgoing innovation and its preference for devolving risk-taking to private actors.² Strikingly, this policy framework survived several episodes of unplanned contamination by GM products that carried enormous price tags for crop growers, food producers and the state, and eventually led to stricter controls (Winickoff et al. 2005).

The framing of biotechnology as products reflected and reinforced America’s history of seeing technological innovation as an instrument of progress and nature as ripe for appropriation through human ingenuity (see, for instance, Smith and Marx 1994). In this framing, citizens are seen as eager consumers of technology, constantly on the lookout for new goods and services to meet an ever-expanding array of desires and needs. Courts and ethics commissions, as well as Congress and regulatory agencies, all presume that their job is to set free the forces of innovation to serve these willing consumer-citizens. Thus, *Chakrabarty*’s elimination of the distinction between living and non-living “compositions of matter” expanded the domain of intellectual property rights for life science entrepreneurs and reduced uncertainties about the ownership of biotechnological innovations. A preference for utilitarian logics consistent with market values even characterized the pronouncements of some bioethics bodies. In the Clinton era, a presidential bioethics commission repudiated human cloning mainly on grounds of probable risks to the clone.

² Consider, for example, the crucial role of venture capital in the early growth of biotechnology in the United States (Office of Technology Assessment, US Congress 1984).

In Britain, the Tories under John Major also adopted a proactive state policy toward biotechnology, later enthusiastically embraced by Tony Blair’s Labour government. Nonetheless, regulatory developments in Britain framed biotechnology as a process meriting special public concern, the very position that US authorities had rejected as unnecessarily restrictive. Part of the reason for this discrepancy lies in a division of labor between state and market that is unique to Britain. While the state supports and even celebrates science for introducing productive innovations into the market, the adversities of life – ill health and aging for instance – remain very much the state’s responsibility. Despite periodic challenges, Britain is still importantly the state of the National Health Service, committed to taking care of those who are injured by innovations that fail. Accordingly, unlike the US government, the British state cannot absolve itself of responsibility for risk-taking gone wrong. In turn, that position of ultimate responsibility influences the state’s relatively cautious framing of technological risks; even potential medical benefits, such as cancer tests and treatments, are seen as carrying costs for a state that is required to pay for medicines.

Germany, too, adopted the process frame along with Britain and the European Commission, acknowledging that genetic modification calls for special oversight in all of its domains of application. But taming the risks of biotechnology in Germany proceeded in tandem with taming recalcitrant memories of past abuses of science, before and after the fall of communism in 1989 and the reunification of the divided state in 1990.³ Key to resolving the early political debates around biotechnology was the reaffirmation of Germany as a *Rechtsstaat*, a place where the rule of law enjoys supreme respect. In turn, this construction of the German state demanded principled behavior and strict adherence to basic constitutional norms, such as respect for human dignity and the state’s duty to protect its citizens against unreasonable risks.

Regulatory framings of biotechnological problems in Germany were designed to foster legal and moral stability. Difficult problems were avoided altogether or permitted only as limited, well-defined exceptions to a general prohibition. Not surprisingly perhaps, German legislative and regulatory enactments con-

³ On Germany’s wider struggles with historical memory in this period, see Maier 1990 and Buruma 1995.

cerning biotechnology in the 1990s sought to prevent some conceptually ambiguous entities, such as frozen embryos and stem cell lines, from coming into being. Thus, surrogacy was forbidden by a 1990 law, as was the creation of spare embryos for any purpose. Embryonic stem cells are not as yet permitted to be made in Germany. They can be imported, but only if they were created before a date clearly stipulated by law. Without such firm lines, it seems that the state sees itself as always in danger of a *Dammbruch* – a breaking down of normative high dams, with uncertain consequences for public morality, law and order. The result, especially by contrast with the United States, is a regulatory environment that seems hesitant to experiment with new forms of life, whether in nature or in culture. Innovation is managed, in effect, so as to limit uncertainty, not only uncertainties about the health and safety of German citizens but about the legitimacy of the state itself.

Experts and the state

A second feature of national politics that affects regulatory policies for science and technology is the relationship between experts and the state. Expertise figures in the integration of science and politics in three separate, but related, ways: through the bodies of knowledge and skill that experts represent (“good science”); through the experienced and impartial bodies of the experts themselves (independent experts); and through the collective bodies, or groups, that typically offer judgment in complex policy domains (expert advisory committees). Cross-national comparison suggests that national political systems depend to differing degrees on these three dimensions of expert legitimation and that these differences were consequential for the regulation of biotechnology.

The expert’s professional skills and standing count for more in the United States than the tacit knowledge and intangible sense of the public good gained through experience or the validation conferred by well-orchestrated group judgments. In a meritocracy that prides itself on individualism and on objective markers of intellectual merit (Carson 2004), the surest way to becoming an acknowledged expert is by climbing the ladder of professional recognition. What an expert achieves beyond the sphere of technical competence is of lesser consequence. To be sure, the capacity to work in the public interest plays a part in the nomination and selection of experts for

US advisory positions, and the law governing federal advisory committees explicitly requires a balance of perspectives, but in assuring the credibility of expert opinion, the expert’s knowledge credentials count for more than virtually any other factor. Group assessments, too, are validated first and foremost by peer review, on the basis of presumptively impartial criteria of intellectual merit.

Against this backdrop, it is significant that the early framers of the risks of biotechnology in the United States were leaders in the science that, more than any other, made genetic engineering possible: molecular biology. Nobel laureates and other scientific leaders, and eventually the US National Academy of Sciences, threw their authority behind a representation of the new technology that stressed precision and predictability at the expense of uncertainties arising from biotechnology’s environmental and social contexts. The conviction that genetic engineering could be precisely targeted and controlled did much to validate the conclusion that it was not the GM process that needed to be addressed, but only its products. At this formative moment, the predisposition of elite scientists converged with and strengthened a policy outcome that favored rapid introduction and a sorting out of consumer preferences through the market.

The politics of green and red biotechnology in Britain also reflected the role of experts in that nation’s political culture. Expert trustworthiness and reliability are powerful sources of legitimation for the British state, especially because there are few administrative channels by which citizens can question the reasoning of state agencies. In Britain, early state responses to biotechnology were informed and assisted by a consensual, elitist tradition of government that draws trusted voices to the policy table. This inclusiveness encompassed ecologists and environmentalists, who succeeded during the 1990s in canvassing a wider range of uncertainties associated with the dissemination of agriculture biotechnology than were seen as relevant in US assessments. Even before BSE (“mad cow”) disease became a household term, British scientists and policymakers favored a more precautionary approach to regulating biotechnology than their American counterparts, and the idea of regulating only the products of genetic technologies never took hold.

Expert credibility, however, took a body blow in the aftermath of the mad cow crisis, when official asser-

tions that the disease posed no threat to humans proved to be mistaken. British policymakers had to reinvent their advisory bodies, with visibly trustworthy leadership. The creation of the new Food Standards Agency (FSA) in 2000, headed by an administratively seasoned scientist and a consumer representative, exemplified the government's attempt to restore confidence with the aid of tried and true individuals.⁴ The government also attempted to widen the range of views concerned with GM crops through the creation of the Agriculture and Environment Biotechnology Commission (AEBC), a body that recommended the conduct of farm-scale trials and nationwide consultation on GM crops as necessary measures for rebuilding confidence. These activities, among others, broadened the range of inputs and kept alive a greater awareness of the uncertainties of agricultural biotechnology than in the United States.

In the context of embryo research, where the risks are more likely ethical and moral than environmental, trustworthy experts were able to carve out a protected space for British reproductive science and its biomedical offshoots. In part, this success can be attributed to the personal credibility of certain key experts, such as the philosopher Baroness Mary Warnock, who headed the committee that laid down the ethical foundations of Britain's 1990 law on embryo research. From the standpoint of British officialdom, Warnock proved her ability to serve the state when she shepherded her committee through to a satisfactory consensus with respect to a potentially divisive issue: when and to what extent it is permissible to experiment with incipient human life? Warnock proved her worth again when she contributed, along with other leaders of church and state, to a debate in the House of Lords that led to the ratification of the embryology bill. Her committee, as we see below, drew its legitimacy not only from a trusted and diplomatic leader, but also because it eschewed abstractions and appealed to common-sense notions of when human life begins.

The German state also legitimates its discretionary power through a network of largely anonymous expert committees, such as the Central Commission for Biological Safety. Unlike in Britain, these bodies

seldom rely on prominent individuals for legitimacy. German expert bodies pride themselves on making principled, apolitical, administrative decisions within the parameters of the law. The appearance of impartiality within expert bodies is achieved not through transparency and openness to legal and political challenge, as in the United States, but through a process of inclusion that draws politics into the insides of expert committees. Political judgments in this way are subsumed into expert reasoning; in practice, expert bodies help maintain sharp boundaries between technical and political decision-making. Expert judgments are seldom publicly contested in Germany, but this is because those who might dissent would, in the ideal case, have already had their say within the institutional framework of expert deliberations.

Such inclusive practices may tend to err on the side of caution, but they may also accommodate change without corrosive conflict. It was with the support of expert advisers, for example, that Gerhard Schröder's government was able substantially to reprogram the relations between the life sciences and the state. Compromises were made on many fronts so as to facilitate the growth of biotechnology: in the move away from a categorically prohibitive attitude to agricultural biotechnology under Renate Künast, Green minister for agriculture and consumer affairs; in the approval of GM foods and crops following the adoption of EU labeling and traceability rules; in the appointment of a separate bioethics council by the executive branch to liberalize policy for research with embryonic stem cells; and in the active sponsorship of bioregions to promote university-industry technology transfer.

Yet although these steps indicated a moderation of older policy hard lines, they left intact the state's central responsibility to regulate the ethical, economic and environmental risks of biotechnology and its commitment to precaution. Künast's opening the door to GM crops was counterbalanced by the promise of large public subsidies to organic agriculture. Even the creation of new public-private linkages in the bioregions remained, at bottom, a state-run effort to generate competition, with the state serving in effect as venture capitalist for new industrial formations. Put differently, the programmatic relations between science, technology and the state in Germany persisted into the new century with one salient difference: the politics of high moral anxiety of the 1990s, fearful of innovation in the industrialized

⁴ Sir John Krebs, the first FSA head, had successfully served as the head of the Natural Environment Research Council, one of the UK government's research funding agencies. His deputy, Suzi Leather, later became head of another important agency, the Human Fertilisation and Embryology Authority that regulates research on human embryos.

life sciences, was gradually supplanted by a more traditional German politics aiming at consensus-based management of the inventive process, with incremental accommodation of risks as they became apparent.

Civic epistemologies

The third element of domestic politics that helps explain convergences and divergences among national biotechnology policies is the nature of proofs and justifications demanded from a state by its citizenry. These tacit assumptions regarding the appropriate forms of public reasoning, or civic epistemologies, constitute an important part of a nation's political culture (Jasanoff 2005). Institutionalized in administrative processes, and reinforced through repeated performances by state actors, these disparate ways of knowing and reasoning by public authorities support potentially quite different approaches to regulating the hazards and uncertainties of technological advances. Examples from US, UK and German policies for biotechnology illustrate this point.

Central to US practices of validating knowledge for public use is the possibility of questioning expert opinion in adversarial settings. Both the commitment to pluralistic politics and the reliance on law to resolve political conflicts favor the public testing of expert claims. Indeed, it has long been an assumption of the common law that truth, or its closest approximation, is best attained when parties with opposing interests are allowed to take issue with each other's claims. These US cultural commitments lead to a preference for policy justifications that rest on the seemingly impartial authority of science and, where possible, on quantified calculations of risk and benefit.⁵ As already noted, it was important for the stabilization of the product-based regulatory framework that leading scientists called attention to the threats of recombinant DNA research and proposed the conceptual foundations for regulation. Propelled by genuine concerns for public welfare, American molecular biologists crafted narratives that influenced US policy for years to come but at the same time also reinforced their field's authority: narratives of scientific self-regulation and the responsibility of science; of genetic modification as a set of precise interventions; of health risk as the issue of largest concern;

and of physical and biological containment as the primary means of risk control.

Skepticism toward biotechnology erupted in the United States mainly in contexts that were already scripted for political conflict. Thus, the organic farming lobby successfully played on entrenched opposition to industrial agriculture to ensure that the label "organic" would not attach to GM products. Similarly, the politics of research with human embryonic stem cells built on the long-standing deep polarization between Christian fundamentalists and secular liberals. In more neutral territory, the authority of science prevailed, especially when the public was persuaded that the basis for policy had been and would continue to be openly debated.

In Britain, too, practices of political authorization worked in harmony with an important feature of British civic epistemology: the preference for empirical demonstrations that are credible to all citizens. In the contexts of both embryo research and agricultural biotechnology, repeated public appeals were made to proofs that ordinary people could see and understand. By the same token, failure to meet the demand for empirical justification generated uneasiness about the safety of GM crops even before the outbreak of the BSE crisis. British policymakers were notably reluctant to embrace the US position that most GM products are substantially equivalent to their unaltered counterparts, and hence safe. With the creation of the AEBC, additional skeptical voices from academia and environmental groups joined the UK policy debate, but this effort to build a stronger consensus in support of agricultural biotechnology led to a more extensive discussion of scientific unknowns than in the United States. Farm scale trials of GM crops and GM Nation?, the national consultation on approving them, were two of the more noteworthy results.

By contrast, a mutually reinforcing alliance of ethical and scientific authority drew a workable distinction between the less than fourteen-day-old "pre-embryo" and the embryo proper, allowing the former to be treated as an object of research. That line of demarcation had to be made publicly credible, however, and this in turn meant that key actors, such as the Warnock committee, had to construct a reality that citizens would accept. Here, the resources of British civic epistemology were successfully mobilized, in particular the insistence that policy-relevant distinctions must be witnessed in common in order to be

⁵ Brickman, Jasanoff and Ilgen (1985); for a historical account of the same tendencies, see Porter (1995).

considered authoritative. It was important to the Warnock committee, for example, that the primitive streak, precursor to the central nervous system, develops in the human embryo at around fourteen days. This was an observable and readily understandable line that almost all concerned parties – philosophers, scientists, politicians, and ordinary laypeople – proved prepared to accept for regulatory purposes, even though it went against the argument of most biologists that embryonic development is a continuous process with no bright lines separating its stages.

Civic epistemology came into play in the German context as well, but in a different guise. In postwar Germany, much energy has been devoted to ensuring the inclusion of society as a whole in the production and display of public reason. The state needs to show that it has consulted with all relevant parties and constructed forms of policy justification that address, and if possible incorporate, every relevant standpoint. This urge toward inclusion is reflected in the design of policy institutions, from the distinctive German parliamentary inquiry commission (*Enquetekommission*), which ordinarily includes both political representatives and experts of divergent viewpoints, to key advisory bodies, such as the commission that advises the government on the approval of GMOs. Bodies such as these maintain their legitimacy not through appeals to science or common sense, as in the United States and Britain, but through the demonstration that they have left out no important positions or arguments. As noted above, this commitment to inclusivity may account for Germany's particular brand of policy caution, but perhaps also for Germany's ability to accommodate sometimes quite radical change.

Regulatory divergence and democratic politics

Regulating biotechnology was not, on either side of the Atlantic, simply a matter of applying existing policy principles to new agenda items; nor was it a case of unwieldy political institutions trying with difficulty to catch up with rapid developments in science and technology. Still less – contrary to the pronouncements of the US Trade Representative in the WTO GMO case – did the ensuing policy differences reflect simple binary oppositions between Europe and the United States with respect to the pace of innovation, economic self-interest, concern for developing nations or public understanding of the life sciences. Rather, through their attempts to regulate biotechnology,

democratic nations on both sides of the Atlantic tested, and to some extent reaffirmed, their fundamental beliefs about who should be responsible for the risks and costs of technological change. Citizens trusted the state's expert judgments when they addressed uncertainties in a manner consistent with established civic epistemologies; policies that failed to meet such expectations were rejected as unconvincing. In this way, the politics of biotechnology reproduced key aspects of national political culture.

What lessons can be drawn from these histories for the future of biotechnology policy in a globalizing world? It seems clear, first of all, that informed citizens of democratic societies want more from regulation than simply the assurances of experts that no one will suffer physical or environmental harm. As important, if not more so, is the reassurance that the unintended consequences of innovation will be dealt with fairly, and that, if things go wrong, those harmed by technological change – economically, socially, or physically – will not be left without relief. It is clear as well that domestic politics matter profoundly in determining the forms of policy justification and action that citizens consider legitimate. All this implies that universal arguments in favor of biotechnology are less likely to gain acceptance in democratic societies than specific arguments addressing localized concerns arising within well-understood patterns of political responsibility.

The early history of biotechnology regulation reinforces a point long known to students of technology in society. Innovation succeeds only when novel artifacts can be seamlessly integrated into the ways in which people want to lead their lives. Regulatory policies in turn can only be effective if they confront the uncertainties that threaten to destabilize settled forms of life. It should be no surprise, then, that different cultures want to regulate novel technologies in different ways. This, too, is a valuable form of cultural experimentation, and it should be welcomed accordingly. It would impoverish the world if our experiments with remaking life itself were to produce too early and too ill-considered policy uniformity.

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