

WHY BAN BOVINE GROWTH HORMONE? Science, Social Welfare, and the Divergent Biotech Policy Landscapes in Europe and the United States

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In the late 1980s, proposals circulated in European Union policy-making institutions that called for adding a new criterion—dubbed the ‘fourth hurdle’—to the standard three dimensions across which new veterinary technologies were evaluated for marketing authorization in the EU. To the traditional three criteria of safety, efficacy and quality, some policymakers and activists wanted to add an evaluation of socio-economic effects. That is, proponents of the fourth hurdle wanted the decision to permit commercialization to be based not just on whether the technology was safe, effective, and of good quality, but also on what kind of impact a new technology might have on the social structure of European agriculture if commercialized.

In the EU, the ‘fourth hurdle’ became a legitimate policy consideration. Furthermore, despite the failure to formalize the fourth hurdle in the EU’s marketing authorization procedure, there is evidence to suggest that the EU’s moratorium on the use of recombinant bovine growth hormone (rbGH) is based on the fourth hurdle ‘by the back door’. In other words, even when other justifications for banning rbGH were used, the ongoing (and now permanent) moratorium appears motivated, at least in part, by socio-economic concerns. Why did discussions of socio-economic effects have such resonance in Europe and not in the US? Why did a moratorium on rbGH—motivated by socio-economic considerations—remain intact for over a decade in the EU, while in the United States the federal government could not find justification for banning the drug for more than 90 days? And finally, why, despite considerable support

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for the idea, did the fourth hurdle fail to be accepted as an official part of the approval process for veterinary drugs in the EU?

The fourth hurdle concept has received some attention from social analysts (Ashford, 1996; Koch, 1996; Lacy, 2000), but no effort has been made to explain the trajectory of this EU policy proposal (but see Collier, 2000; Koch, 1996). In this paper, we propose such an explanation. Our argument is that two levels of factors shaped the trajectory of this concept: discursive (cf. Levidow and Carr, 1997; Levidow *et al.*, 1997) and organizational (cf. Brickman *et al.*, 1985; Kleinman, 1995; Skocpol, 1985).

We believe that discourses of the market, science, and technology bias discussions of policy away from the use of socio-economic criteria in determining whether to permit commercialization of a technology. One can see these discursive factors at work in US Congressional debates about biotechnology and more specifically in the US controversy around the commercialization of recombinant bovine growth hormone (rbGH), also called bovine somatotropin (rbST). But in the European Union, the fourth criterion was given serious consideration and embodied in limited term moratoria on the commercialization of rbGH, despite the presence of these three discursive factors. We suggest that an historically-based countervailing social welfare discourse created a legitimate space for consideration of the fourth hurdle in the EU and, combined with the particular structure of EU policymaking, led to the establishment of these moratoria on rbGH. At the same time, however, the organizational structure of the EU, combined with the requirements of global trade agreements and bodies such as the WTO, contributed to the ultimate failure of the fourth hurdle to be formally institutionalized. Together we might call the discursive terrain, structure of policy organization, and international trade agreements the 'culture' in which technology policymaking takes place (see, for example, Abraham, 2002).

Our approach stresses the explanatory importance of both discourses and policymaking structures in shaping the outcome of policy debates, and in particular, defining the contours of technology-relevant policies. These discourses and policymaking structures in the EU are best illuminated through comparison with those in the United States. Thus, we provide considerable detail about the dis-

courses and policymaking structures involved in biotechnology policy and particularly the evaluation of rbGH in the US, as well as the EU.

Our paper is organized into five major sections. In the first section, we highlight the discourses that shape debates about technology in both the United States and Europe. Then we provide a brief analysis of US biotechnology regulation—particularly focused on the evaluation of rbGH—in light of these discourses. This serves as a backdrop for the third section in which we analyse the emergence of the fourth hurdle in the EU, a concept which was inextricably linked to regulation of the commercialization of rbGH. To address the role of policymaking structures in the outcome of the fourth hurdle/rbGH debate, in the fourth section we discuss the organizational factors affecting policymaking in the European Union. Finally, we consider the mix of discursive and organizational factors that shaped the policy debate over the fourth criterion and rbGH in the European Union and made that debate different from arguments in the US.

■ DISCOURSE IN TECHNOLOGY POLICY DEBATES

Debates about technology (policy) occur on a terrain of overlapping and often contradictory discourses (Hall, 1982). As Buttel notes, ‘discursive practices are ... pervasive and potentially efficacious resources in political struggles’ (1998, p. 1152). Although there are always secondary or subordinate discourses, generally, *dominant* discourses within which actors commonly think through important social matters often define the boundaries of debate and what are legitimate policy considerations. Sometimes drawn on self-consciously and strategically and other times utilized with little reflection, these are the most efficacious resources, and whether used self-consciously or not, they provide a kind of cultural authority to actors who deploy them (Schatzberg, 1999, p. 5).

The power of these discourses is greatly enhanced by the extent to which the truth of their basic claims is *taken for granted* by social actors (Meyer and Rowan, 1977; Kleinman and Kloppenborg, 1991; Schatzberg, 1999). In any attempt to promote a policy position, actors draw on a particular set of discourses, and those with *historical resonance* are the ones that are likely to hold the discursive high ground, eclipsing those that lack historical force and consequently

legitimacy (Kleinman and Kloppenburg, 1991; see also Hall, 1986). In fact, actors pursuing a line of argument that challenges the dominant perspective will often attempt to manipulate that discourse in a way that can increase the legitimacy of their position (Kleinman and Kloppenburg, 1991).

In the following four sub-sections, we discuss the main discursive factors present in the rbGH debates in the US and the EU. We find that while the same discursive elements appear in both contexts, different factors take the discursive high ground in the two policy-making arenas. In the US, discourses of technological progress, the free market, and scientism are stronger than a social welfareist discourse. In the European Union, on the other hand, a discourse of social welfare constitutes a significant counterweight to the discourses that are dominant in the US.

□ *Technological progressivism*

A central discourse in shaping ideas about technology and, indeed, technological development and technology policies in the United States and Europe might be labelled *technological progressivism*. This notion has its roots in the Enlightenment. In this period, progress became highly valued—a good in itself—and technology came to be seen as a tool in progress.

These ideas were deeply embedded in the thinking of eighteenth century leaders, especially in the United States (Smith, 1995); and in the US, but elsewhere as well, enthusiasm for technology grew with the onset of nineteenth century industrialization (Hard and Jamison, 1998; Smith, 1995). As Leo Marx put it, new mechanical devices certified ‘the reality of progress’ (quoted in Schatzberg, 1999, p. 14), and according to Eric Schatzberg, by the late nineteenth century, most Americans came to ‘define progress in material and technological terms ...’ (1999, p. 14). Technological development took on an historical inevitability in the minds of many (Fries, 1983, p. 6).

Indeed, by the end of the nineteenth century, this idea of technology-based progress ‘had become hegemonic in society as a whole ...’ (Noble, 1983, p. 21). Thus, although criticism of the social effects of technological development has a long history, with Luddism and its precursor movements marking important early counter-developments (cf. Randall, 1991), technological progres-

sivism has commonly defined the bounds of respectable discourse, especially in the US, since the nineteenth century (Noble, 1983; Kleinman and Kloppenburg, 1991).

While, of course, not all novel technologies have been successfully associated with progress, examples of the efficacy of this discourse are abundant. Eric Schatzberg's (1999) study of airplane development between 1914 and 1945, for example, shows the influence of technological progressivism in shaping the debate over the appropriateness of wood versus metal as an aircraft building material. Metal was seen as novel and therefore, superior, despite arguments that wood would serve the purpose adequately. More recently, early proponents of biotechnology took pains to associate this new development with progress and to brand critics as opponents of progress. For example, a 1986 pamphlet produced by Monsanto urges readers not to 'turn away' from this progressive new technology; and a 1988 issue of *The New Republic* called one critic of genetic engineering 'a tireless champion of technological stagnation' (1988).

□ *Scientism*

As we suggested, technological progressivism has a deterministic component. Technological development is understood to occur outside of human affairs, in a sense beyond society (Kleinman and Kloppenburg, 1991), and the social and the technical are viewed as unambiguously distinct. Accordingly, adherents to this discourse tend to argue or assume that determinations about the development of a new technology can be made on what are viewed as strictly technical grounds immune from social values.

Scientism is rooted in precisely this perception of the separation of science and values, a boundary that was cultivated in the earliest efforts to create science as a profession, but dates back at least to Plato (see Bruce, 1987; Daniels, 1967; Gieryn, 1999; Proctor, 1991). *Scientism* is the notion that values should not be allowed to mix with facts, and, further, should not be considered in decisions about science and technology. The discourse asserts not only that facts and values are distinct, but also that facts are superior to values in terms of credibility and cognitive authority.

Why this discourse would be effective is readily apparent. The

authority of science rests on its claims to be value-free and politically neutral (Nelkin, 1995; Proctor, 1991). While numerous social scientists have posed challenges to these claims of value-freedom, the neutrality of science is commonly taken for granted. Dorothy Nelkin explains that for the most part, 'the interpretations and predictions of scientists are judged to be rational and immune from political manipulation because they are based on data gathered through objective procedures' (1995, p. 452). Therefore, science and scientists are considered to be the best possible arbiters of controversy, clearing away the tangle of politics and opinion to reveal the unbiased truth.

Evidence of the unflagging resilience of scientism can be found in controversies over new technology. In many disputes over new technology, especially in the United States, those who oppose the technology because of the expected undesirable social effects or moral/ethical concerns gain legitimate entry into the debate only when they focus on issues, such as the environment, health and safety, that are widely understood to be matters for scientific evaluation. A good example of this is the reduction of moral concerns about foetal research into technical debates about the precise point at which life begins (Nelkin, 1995, p. 453).

Similarly, US activists opposed to genetically engineered foods have found it strategically effective to focus primarily on environmental impacts and food safety and not to openly base their opposition on concerns about the socio-economic impacts on small farmers or moral opposition to the commodification of nature (Tokar, 2001). Social impacts and moral concerns are typically considered to be based on value judgements, and are therefore viewed as less credible; by contrast, debates about health and safety issues are viewed as adjudicable in scientific terms. Such discussions are thus considered more legitimate.

In United States Congressional debates over recombinant bovine growth hormone, scientism was a dominant discourse, leaving very little room for discussions of (value-laden) social and economic considerations. In European Union policymaking bodies, on the other hand, the discourse of scientism was not so powerful as to exclude discussions that mixed 'values' with 'facts'. The suggestion that socio-economic considerations should have equal weight to technical (scientifically measurable) considerations in the evaluation

of certain new technologies was a rejection of scientism that gained a considerable amount of support in the EU. In the US, on the other hand, regardless of the arbitrary nature of the distinction between facts and values, a discourse that assumes their separation has faced few significant challenges.

□ *Free marketism*

A third discourse relevant to the rbGH/fourth hurdle debate is what we refer to as *free marketism*. The idea of a self-regulating ‘free’ market, like technological progressivism, is rooted in the eighteenth century. The concept is found in the work of Adam Smith (Block, 1990, p. 47). Classic economic liberalism holds that ‘the untrammelled free market—decentralized decision making in response to the incentive for private gain—yields the greatest output and hence the greatest total wealth. Because the greatest efficiency comes from private calculations, the task of the government is to leave the market alone’ (Gourevitch, 1986, p. 37). In the US, an anti-statist individualism is closely linked to the idea that markets, not governments, should solve economic problems (Weir, 1992, p. 189; Rimlinger, 1971, p. 62).

A discourse of free markets shaped US federal policy in the 1920s (Arndt, 1944, p. 17), and even though the Depression of the 1930s undermined ‘classical liberal orthodoxies’ (Weir and Skocpol, 1985, p. 107), the principle of limiting government intervention in the economy remained powerful, especially after the revival of the US economy during the Second World War and afterward. Although the force of free marketism has waxed and waned in the US, the election of Ronald Reagan in 1980 ushered a return to the dominance of this discourse as a guiding force for economic policy (Weir, 1992, p. 207).

Importantly, the success of this discourse does not depend on its precise realization in practice; its significance is fundamentally symbolic. In the US, particularly in the period since the election of Ronald Reagan, a discourse that challenges free marketism has become increasingly difficult to mount successfully (cf. Holt and Schor, 2000; Slaughter and Leslie, 1997, p. 35; Thompson, 2001); and although this discourse has always had a place in Western Europe, especially in Great Britain, its significance in the region has

been bolstered by globalization (Beck, 2000) and the emergence of institutions for the regulation of the global economy.

For technological development, the importance of this discourse is clear: technologies that meet the standards of a free market should be developed and commercialized; those that do not will rest on the proverbial ash heap of history. Thus, free marketism has been used to explain the slow development of solar technologies in the US and to justify pushing forward with agricultural biotechnology worldwide.

□ *Social welfareism*

In contrast to the discourse of free marketism dominant in the US, we believe that a discourse, largely missing in the US context and certainly subordinate there, created an opening for discussions in the EU of a policy that would assess the appropriateness of commercializing a new technology at least partially based on socio-economic factors. We call this discourse *social welfareism*.¹

Social welfareism is the idea that the market and private mechanisms cannot solve all social and economic problems. As a consequence, it is often appropriate for the state to intervene on the basis of implicitly agreed social values. By and large, while this discourse probably has roots in the late nineteenth century, its development is primarily a product of the post-World War II period.

Social welfareism is reflected in an array of policy initiatives across Europe. Roughly speaking, state action occurred along two dimensions. On the one hand, some European states in the post-war period developed a practice of intervening in the economy to promote national economic development objectives. On the other hand, in some form, most states developed a social safety net, involving components such as a right to health care, unemployment insurance, and old age pensions.

In terms of economic policy, France provides perhaps the clearest case of European government intervention to promote economic development objectives—a policy that directly contradicts free marketism (Hall, 1986; see also Shonfield, 1969 [1965]). In Sweden, to take another case, an active labour market policy was the centre of post-war economic policymaking (Shonfield, 1969 [1965], pp. 201, 202).

On matters of social policy, although there is variation across

countries, it is fair to say, as Harmut Kaelble does, that 'Europe has been the true bastion of the modern welfare state throughout the twentieth century. Nowhere did it grow to such proportions, nowhere else was it imbued with such vigor' (1990 [1987], p. 74). By the outbreak of World War I most western European nations offered state run or state supervised social security for industrial accidents and sickness as well as old age pensions. After 1945, the scale of state social security increasingly converged. Nearly all wage earners enjoyed health, unemployment and retirement benefits (Kaelble, 1990 [1987, 1989]).

One can see this social welfareist discourse in the commitment to agrarianism embodied in the EU Common Agricultural Policy, or CAP. The majority of west European countries have elected to preserve economic and social features of rural and agricultural life that are 'quite at odds with the usual social and economic structure of an industrial urbanized society' (Rieger, 1996, p. 98). The EU aims to insulate the farming economy from industrialization and urbanization. The premise of the CAP is that the agricultural community of member nations ought to be guaranteed a fair standard of living. Price guarantees are a central feature of this programme. Here, obviously, the market is not permitted to operate freely. According to one analyst, the CAP should be viewed as 'an integral part of the west European welfare state and its particular moral economy' (Rieger, 1996, p. 100).

Although, as noted, this discourse is typically absent in US debate and when present lacks widespread legitimacy, this is not always the case. US history is punctuated with cases of social welfareist justification for government intervention in the economy (Shonfield, 1969). Perhaps most prominent is US agricultural policymaking, which, between the mid- and late-twentieth century bore similarities to related European policies. In the US, from the mid-1930s until the late 1990s, agricultural programmes aimed to provide farmers with a 'safety net' and to maintain some stability to commodity markets. An array of interventions into the market made this possible. However, while agricultural policy in Europe should generally be understood in the context of a wider history of industrial and welfare policy and as comfortably justified by a discourse of social welfareism, in the US, agricultural policy must be viewed as a

prominent exception to a policy history fundamentally shaped by a discourse of free marketism.

Some analysts explain the success of the Agricultural Adjustment Administration, the basis for much successful agricultural policy in the US after 1933, in terms of unusual administrative capacities in the US Department of Agriculture (USDA). According to these analysts, these capabilities made possible social welfareist policies in the farm sector that were unrealizable in the industrial sector (Skocpol and Finegold, 1982). Deeply institutionalized, US agricultural policy stood as a marked exception to the dominance of free marketism, until its displacement in an environment of neoliberalism in the 1990s—a discursive terrain that permitted fewer and fewer exceptions and where farmers no longer had the political prominence they registered earlier in the century (Brasier, 1998).

We believe that the established resonance of this discourse in the EU made it possible for politicians to articulate a policy for evaluating technology that would theoretically prohibit the development of certain technologies if they did not meet the social goals of the Union. It was legitimate, indeed reasonable, to explicitly assert that not all economic problems can be resolved in or by the market. It allowed proponents of the fourth criterion to be taken seriously when they asserted, against a form of technological progressivism, that ostensibly technical criteria commonly used to assess veterinary technologies—measures on which criteria about health, safety and efficacy were agreed—provided an insufficient basis for evaluating rbGH and that a new technology was not automatically good or beneficial.

■ BIOTECHNOLOGY POLICY AND rbGH IN THE UNITED STATES

One can see the discourses we described at work in the early policy debates over biotechnology in the US. The 1975 Asilomar Conference on biohazards marked a pivotal point in US biotechnology policy debate. Scientism fundamentally guided the boundaries of discussion and the claims made at this conference. Asilomar embodied the basic principle that scientific development is a technical matter for scientists to assess without public intervention. According to Sheldon Krimsky, ‘In the critical planning period of Asilomar, the

controversy over rDNA research was reduced to a set of technical problems related to biohazards in the research laboratory' (1982, p. 99). Indeed, Krimsky argues that the issues at Asilomar were defined in such a way that qualification to participate in discussion remained the monopoly of scientists (1982, p. 153), and Asilomar set the framework within which early Congressional debate over biotechnology occurred.

When the first Congressional hearing on rDNA research occurred in April 1975, Stanley Cohen, one of the developers of rDNA technology, made it clear in his testimony that 'ethical issues are quite peripheral to ... biological safety questions ...', which are the central matters for consideration by policymakers (US Senate, 1975, p. 2). The power of scientism in this hearing is made clearer still by the fact that even a critic of the standard scientist position argued not that the line between facts and values is blurred on these matters (how much is safe enough? what is a good measure of safety?), but only that the public should give scientists 'informed consent' (US Senate, 1975, p. 14).

By 1983, Congressional attention in the US turned from human protection from rDNA research to the potential environmental hazards of the deliberate environmental release of genetically engineered organisms as part of agricultural research. Despite a change in the substantive focus of the hearings, the terrain of discussion, while including a broader range of voices, remained similar. The problem to be resolved was framed as a technical matter of determining appropriate scientific criteria of risk (US House of Representatives, 1983).

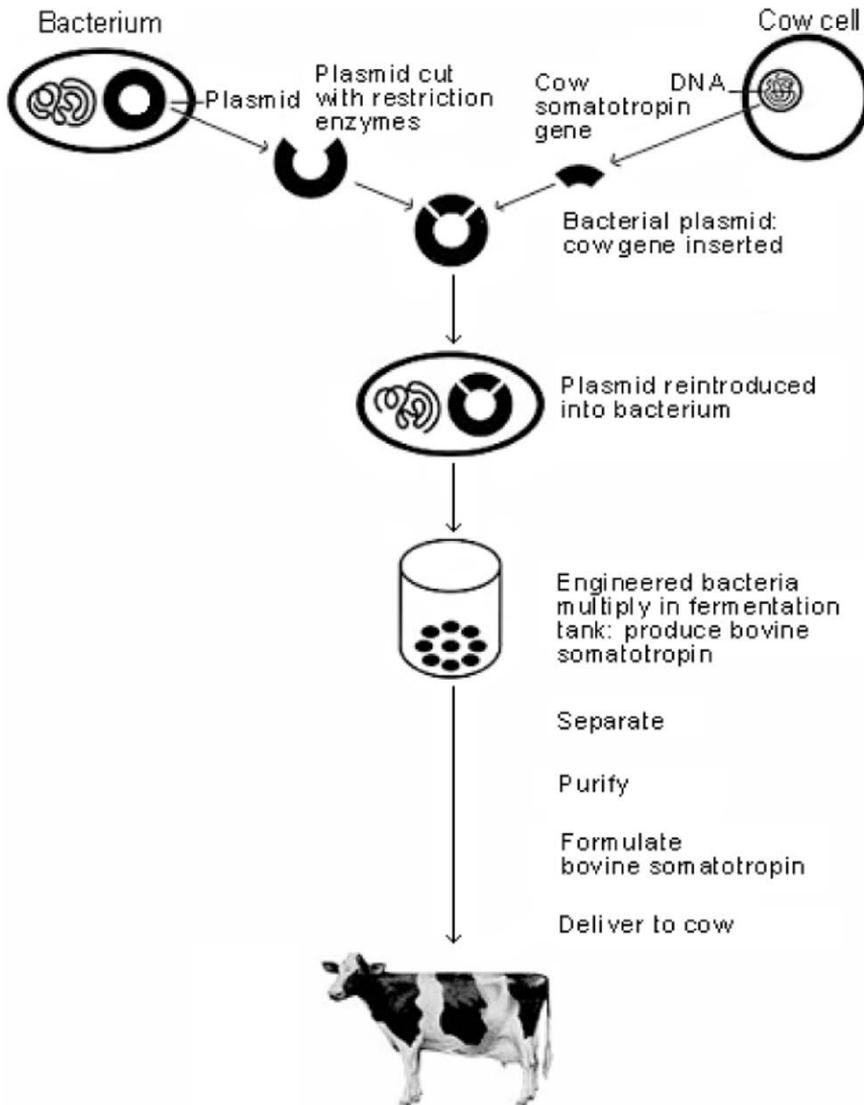
Moving beyond scientism, a variant of free marketism entered Congressional debate in 1984 as the commercial potential of rDNA technology for agriculture became clear. Corporate representatives and government officials warned members of Congress against imposing 'overly restrictive' regulations that might hurt the ability of US firms to compete internationally (US Senate, 1984). Let the market work seemed to be the essential claim.

By the mid-1980s, public controversy over biotechnology in both Europe and the US centred on rbGH. The first product of genetic engineering to be considered for commercial release, rbGH was the focus of a storm of debate among farmers, consumers, the dairy industry and proponents of biotechnology. In 1986, the US House of

Representatives held the Congress' first hearing on the substance, and the terrain of discussion was largely bounded by an extension of free marketism and a clearly articulated technological progressivism. Several witnesses rejected the idea that policymakers should be concerned about the potential impact of the commercialization of rbGH on the structure of family farming in the US. Instead, proponents of the new technology argued that efficient farmers would benefit from rbGH, but it would not 'turn an inefficient manager into an efficient one' (US House of Representatives, 1986). Presumably the market should select between the efficient and inefficient farmer.

The inherent value of progress embodied in rbGH came out clearly in these hearings as well. As one trade association representative noted, rbGH is 'just the latest generation of change that has placed the American dairy industry on the leading edge of productivity improvements ...' (US House of Representatives, 1986, p. 189). rbGH is just one technology in a path of constant improvement, according to this line of thinking. The inevitability of technological progress is made clear in this hearing by several speakers who, like Representative Jim Jeffords, note that 'we can't really stand in the way of progress' (US House of Representatives, 1986, p. 16). Finally, the manner in which a dominant discourse—here technological progressivism—establishes what appears reasonable comes out clearly in a statement by Representative Tony Coelho, who chaired the session. He said: 'I would like to ... make one clarifying statement; that is, I don't think any of us are (sic.) against scientific progress' (US House of Representatives, 1986, p. 4).

This is not to say that a social welfareist discourse with agrarianist elements did not have an impact on the trajectory of rbGH policy in the US. The path leading to federal approval of rbGH for use in the US actually began before the 1986 hearing, and issues of the socio-economic impacts of this technology were significant in bringing the matter to public attention. In 1984, Robert Kalter, an economist at Cornell University, published a study in which he concluded that 30% of dairy farmers would go out of business within five years of the approval of rbGH (Collier, 2000, p. 157). Other studies published in the late 1980s and early 1990s suggested that rbGH would reinforce or accelerate the structural transformation of



BOVINE SOMATOTROPIN PRODUCTION.

Credit: Monsanto Company, <http://www.monsantodairy.com/about/history/>.

the US dairy industry away from small-scale producers (Office of Technology Assessment, US Congress, 1991; Barham *et al.*, 2001).

In the US, many of the most vocal opponents of rbGH, particularly in the debates in the mid-1980s, based their opposition to the drug on socio-economic concerns. One analysis suggests that criti-



OPPONENTS CAST BGH AS A HARMFUL DRUG DEPENDENCY.

Credit: Organic Consumers Association, <http://www.organicconsumers.org/rbghlink.html>.

cism of rbGH based on socio-economic concerns had an important influence in government regulatory bodies—turning rbGH into a dairy policy issue (Browne and Hamm, 1988). Concerns about the survival of the family farm, combined with worries that an increase in milk supplies would overburden the federal dairy support programme, were effective in mobilizing a grassroots movement against rbGH.

In 1989, critics of the new technology petitioned the US Food and Drug Administration (FDA), asking the agency to study, among other things, the socio-economic impacts of rbGH (Sinclair, 1986). In that same year, Wisconsin and Minnesota passed moratoria on the use of the substance in those states. In both cases, opponents of the technology were concerned about its potential socio-economic impacts, but also expressed fears about rbGH's human and animal health effects. In Minnesota, the ban was justified in terms of the time it would provide for further study of the drug's potential effects on animals and humans (Schneider, 1990). In Wisconsin, in addition to funding studies on human and animal health during the moratorium period, the bill signed by the state's governor included support for research on the potential effects of rbGH on family dairy farms (Walters, 1990).

Thus, there certainly was concern in the US about the potential socio-economic effects of rbGH, but this was never central to public policy debate. It was never seriously considered by policymakers as a basis for regulating the new technology, and it never found its way into policy proposals in the US (or at the state level). Instead, the ultimate decision about the commercialization of rbGH in the US was rooted in technological progressivism and scientism, along with free marketism. Proponents of the drug used the language of technological progress, scientism and free market efficiency to gain American support and delegitimize criticism based on such 'emotional' issues as the negative impact rbGH would have on family farms.

When the US Food and Drug Administration (FDA) commissioner announced agency approval of the technology, he said rbGH was clearly safe. According to the Commissioner, David Kessler,

There is virtually no difference in milk from treated and untreated cows. In fact, it's not possible using current scientific techniques to tell them apart. We have looked carefully at every single question raised, and we are confident this product is safe for consumers, for cows, and for the environment (quoted in Schneider, 1993).

The FDA, however, did not consider the socio-economic effects of rbGH (Schneider, 1993).

Shortly after FDA approval, the US Senate voted to establish a 90-day moratorium on the commercialization of rbGH, a decision characterized in the media as a 'behind-the-scenes deal' linked to a budget reconciliation bill and pushed by Senator Russ Feingold of Wisconsin (*St. Louis Post-Dispatch*, 1993). Feingold hoped the 90-day period would be used to study the economic effects of the hormone and to look for a 'legislative solution' to prevent its commercialization (Dunne, 1993). However, at the end of the moratorium, US lawmakers saw no further justification for banning rbGH, and manufacturers were free to sell the drug in the United States (Mills, 2002). By some accounts, this temporary halt in use of the technology was justified by the need to establish a Post-Approval Monitoring Program to assess the impact of the use of the rbGH on cattle health and milk quality (Collier, 2000, p. 158). Cattle health and milk quality were presumably believed to be issues that could be resolved based on unambiguous and agreed technical criteria.

By 1999, when the FDA reaffirmed the safety of the technology for humans (Collier, 2000, p. 158), socio-economic issues were nowhere on the federal agenda.² In contrast, social welfareist concerns, particularly agrarian ones, were a central driving force behind rbGH regulation in the European Union.

■ LEGISLATIVE HISTORY OF THE FOURTH HURDLE AND rbGH IN THE EU

If technological progressivism, scientism, and free marketism defined the terrain on which the debate over biotechnology was fought in the US, it would be misleading to suggest that these discourses are absent from related debates in Europe. Indeed, to take but one example, even the European Commission was anxious to ‘avoid being labelled as “hostile” to progress in the biotechnology industry ...’ (*Europe Environment*, 1992). The Commission clearly recognized the force of technological progressivism. At the same time, several EU policy decisions made in the case of rbGH constitute explicit and thorough rejections of the discourses dominant in the US. At several distinct points, moratoria were imposed on the commercialization of rbGH in the EU. In these cases and at several other points in policy discussion, a central consideration was what this new technology would mean for the social structure of the dairy industry in EU countries and to what extent the commercialization of rbGH would lead to changes in dairying that contradict commitments established in longstanding EU policy.

These concerns were embodied in what was referred to as a fourth hurdle or criterion: the idea that approval for market introduction of a new technology should be based in part on its likely socio-economic impacts and the consistency of these impacts with existing policy determinations and the values underlying those policies. The assumption underlying this criterion of assessment is that it is reasonable to prohibit the development of a technology if policymakers determine that the social costs of its introduction are unacceptable.

This line of thinking contradicts at least two of the discourses we believe dominate similar debates in the US. The fourth criterion amounts to a rejection of technological progressivism. It does not assume that all technology is progressive and beneficial. By claiming

the right to prohibit the commercialization of a technology it amounts to a rejection of the idea that technological development proceeds automatically and beyond social control. Equally, the fourth criterion constitutes a rejection of any claim that an unencumbered market should be the adjudicator of what technology is developed and that efficiency criteria, as defined by free markets, are the appropriate measures for determining whether a new technology will succeed or fail.

Depending on how it was formulated, the fourth hurdle may or may not have constituted a rejection of scientism. Many arguments in favour of considering socio-economic impacts in the evaluation of rbGH implied that policies that affect the future of technologies cannot be strictly technical and left to 'experts' to determine. In response, opponents of the fourth hurdle relied heavily on the discourse of scientism to criticize both the moratoria on rbGH and plans for a fourth hurdle, calling such considerations 'politically motivated' and 'subjective' (*Daily Telegraph*, 1990).

On the other hand, British Labour MEP Ken Collins, the most ardent advocate for a fourth criterion, used the discourse of scientism to make a case for the necessity of a formalized evaluation of socio-economic impacts. For example, in a 1991 debate in Parliament, Collins argued that 'The real problem here ... is that we do not have any rational way of introducing social, economic and environmental measures into the assessment of products such as this that come on the market. So we proceed by uncertainty. We proceed by irrationality frequently' (European Parliament, 1991a, p. 295). While Collins apparently sought to displace science from its position of final authority, he also used the rhetoric of rationality and certainty characteristic of scientism. This suggests that the discourse of scientism, even while being disputed as a basis for policy, could not be ignored.

The trajectory of the fourth hurdle is complicated because it unfolded simultaneously with the controversy over the commercialization of rbGH in the EU, a larger debate over productivity-enhancing drugs, and a complex revision of the authorization process for veterinary drugs. Two main tracks are important to distinguish. First, beginning in the late 1980s, members of the European Parliament expressed concerns about hormones in beef (Vogel, 1997, pp. 15–24). At this time, the European Commission was in the

process of reviewing its policy for licensing veterinary medicines across the EU. Thus, on this path, concerns about growth promoting and productivity increasing veterinary medicines became intertwined with a more general revision of licensing procedures. Second, and more prominently, the mid-1980s through to the 1990s witnessed growing concern in Europe and ultimately among EU policymakers with the development and likely commercialization of rbGH. The concerns about rbGH were sometimes tied to the revisions of veterinary medicines directives and sometimes acted on and expressed independently.

For us, the central story begins in 1987, when Monsanto and Elanco requested marketing authorization of their rbGH products in Europe. Following EU guidelines, these products were sent for review to a central EU evaluation body, the Committee for Veterinary Medical Products (CVMP). In response both to rbGH and the controversy over hormones used in beef production that raged during the earlier part of the decade, in July 1988 the European Parliament adopted a report on the effects and risks of growth hormone use (including rbGH) in the dairy and meat industries.

In this report, Parliament expressed concern about the socio-economic effects of growth hormones and called for a special study on ‘its long-term socio-economic effects, particularly on the smaller farm’, prior to commercialization (European Parliament, 1988b). This statement opened the door to the decade of ‘fourth hurdle’ controversy that followed. In fact, in the debates preceding the EP’s adoption of the report, Ken Collins suggested that ‘[The Commission] has to turn its attention to a fourth point—not just safety, quality and efficacy but also some measure of socio-economic impact’ (European Parliament, 1988a, p. 19).

In discussion of the report, Members of the European Parliament (MEPs) expressed a range of opinions on the topic, but many expressed a clear rejection of the discourses that dominated the US rbGH debate. For instance, Dutch MEP Ulburghs used the language of social welfareism and opposed reliance on scientism, stating: ‘The use of the BST hormone does increase unfair competition and social inequality, both between producers and between regions. Technology should be judged primarily in qualitative, not quantitative terms’ (European Parliament, 1988a, p. 17).

Spanish MEP Cervera Cardona similarly rejected technological

progressivism, arguing that ‘it would be unfortunate if this Assembly were to subscribe to the false paradox of regarding anyone proffering unqualified support for the achievements of science as having a progressive outlook, while branding as reactionaries those with reservations about the unbridled exploitation of such achievements’ (European Parliament, 1988a, p. 15). But a French MEP countered these arguments. Drawing on the discourses of scientism, technological progressivism and the free market, he argued that

If the use of BST were authorized in the Community, the first thing we should know is the opinion of science on the matter. When science has spoken, then it will be for the Community to face up to its responsibilities ... Are we from now on going to oppose all progress in biotechnology and allow our adversaries to defeat us with impunity in the world market? (European Parliament, 1988a, p. 14)

Despite similar opposition by other members, Parliament accepted the report.

The following year, angered by US action to punish the EU for refusing to use hormone-treated beef, the EP released a report ‘on the USA’s refusal to comply with Community legislation on slaughterhouses and hormones, and the consequences of this refusal’ (European Parliament, 1989). In this report, the EP first articulated the fourth hurdle as a dimension across which all new veterinary medicines, particularly those that increase productivity, should be assessed before commercialization. Written by MEP Ken Collins, the report called

on the Commission, in its review of veterinary medicine licensing, to distinguish clearly between therapeutic products and products which might be used to increase production and to take into account, especially for the latter, not only safety, efficacy and quality, but also the socio-economic and ecological consequences of their use, together with an examination of the impact on agricultural structures and compatibility with the aims of reducing surpluses and promoting extensive farming (European Parliament, 1989, p. 9).

In the early 1990s, proposals for an official fourth hurdle like the one described above circulated in the European Parliament and the

Commission. While none of these proposals ever became an official recommendation for a resolution, let alone being passed by the Council, as a group, they were widely discussed, and industry organizations expressed particular concern.

On behalf of the EP's Committee on the Environment, Public Health and Consumer Protection, Ken Collins continued working on specific proposals for a fourth hurdle for several years (European Parliament, 1990b, 1990c, 1991a, 1993, 1996). The EP's Committee on Agriculture, Fisheries and Rural Development also called for consideration of the socio-economic impacts of growth-promoting drugs (European Parliament, 1990a). Not simply urging a ban on rbGH, these Committees specifically wanted a new measure of evaluation added to the approval process for growth and yield promoting veterinary products. Under this proposed regulation, veterinary drugs that failed a fourth hurdle, meaning that they caused unacceptable socio-economic impacts, would be banned (Erlichman, 1991).

While some support for this kind of regulation was evident in Parliamentary debates, in 1990 the full Parliament rejected proposed amendments that called for an official fourth hurdle (*Daily Telegraph*, 1990). Then, in 1991, the EP's Committee on the Environment and Consumer Affairs, at that time led by Luis Valverde Lopez, not Ken Collins, began to take a vastly different stance on the issue. Lopez opposed the fourth hurdle, and under his leadership, the Environment Committee rejected an amendment proposed by the Commission that appeared to introduce a fourth hurdle to the drug evaluation process (European Parliament, 1991b; *European Report*, 1991b).

Division over the fourth hurdle existed in the Commission as well. The Directorate General for Agriculture and the Environment expressed support for a fourth hurdle, while the Directorates General for the Internal Market and for Scientific Research and Development condemned the idea (*Europe Environment*, 1991b, 1991c; see also Peterson, 1989; Koch, 1996). In early 1991, reports circulated in the media that the European Commission was working on fourth hurdle legislation (*Europe Environment*, 1991a; Erlichman, 1991). Powerful industry groups reacted strongly against such a possibility.

Evidence of compromise between these opposing sides of the fourth hurdle debate can be seen in an April 1991 document,

published by the European Commission, which would be crucial to decisions on rbGH to follow. The document, 'Promoting the competitive environment for the industrial activities based on biotechnology within the Community' upheld the three criteria of quality, safety and efficacy but reserved the right to act contrary to scientific advice in some cases, taking into account other Community policies and objectives (Commission of the European Communities, 1991; see also Cantley, 1995).

The document disappointed people on both sides of the debate, failing to endorse the fourth hurdle, but leaving enough ambiguity to frustrate the biotechnology industry (*Daily Telegraph*, 1991). Because the approval of rbGH appeared to run contrary to the objectives of the Common Agricultural Policy (CAP), this justification could now be used to prohibit the marketing of rbGH in the European Union. Nevertheless, the document made clear that the Commission did not support an official fourth hurdle.

This rejection of the fourth hurdle was simultaneously backed by an EEC-wide Veterinary Advisory Committee representing agribusiness, farmers and consumers (*Europe Environment*, 1991b, 1991c). Although the EP, the Commission and the Veterinary Advisory Committee all rejected the fourth hurdle in 1991, as described above, debate on the topic continued at least into 1993. At the BioEurope conference in Brussels in that year, representatives of the biotechnology industry expressed serious concern about the fourth hurdle idea (*Biotechnology Business News*, 1993). Despite these reactions, in 1996, the European Parliament again proposed the idea in an Own-Initiative Opinion (European Parliament, 1996).

In addition to these debates over potential revisions to the veterinary drug approval process, EU policymakers also discussed the fourth hurdle as they considered the future of one drug in particular: rbGH. By the beginning of the 1990s, both the Parliament and the Commission were expressing concerns about the potential impacts of rbGH, if it were to be approved for market through the normal process. In late 1989, the Commission proposed a 15-month delay in commercializing rbGH in the EU. The moratorium was proposed as a result of concern among commissioners over the human health effects of rbGH, but also reflected worries in the Commission over the economic impacts of commercializing rbGH,

in light especially of the fact that the EU already suffered from a dairy surplus (Buchan, 1989).

Reaction in EU policymaking institutions to the Commission proposal was positive. The advisory Economic and Social Committee (see McCormick, 1996, pp. 190, 191) came out in support of the Commission's plan for a temporary ban on the hormone. In its 1989 opinion document, the Committee pointed to the complexity of the issue in justifying a moratorium and suggested the need to study an array of possible socio-economic impacts, including the effect of rbGH on production structures, production factors and the supply and demand for dairy products and meat (Economic and Social Committee, 1989). The EP Committee on Agriculture, Fisheries and Rural Development, under the rapporteurship of Jose Happart, agreed that there was a need for further study, and placed particular emphasis on the importance of developing authorization criteria that included evaluation of socio-economic consequences of new 'growth accelerating and yielding substances in agriculture' (European Parliament, 1990a). In short, the Agriculture Committee called for the development of a widely applicable fourth hurdle in assessment for commercialization of an entire class of new agricultural technologies.

Following these discussions, the first ban on rbGH in the EU was passed on 25 April 1990. Over the following decade, the Council passed a series of moratoria on the production and use of rbGH in the European Union, culminating in a permanent ban which began in January 2000. The stated justifications for each of these six successive moratoria varied, but as a growing number of non-EU nations approved the commercial use of rbGH, and the EU's own drug assessment body, the CVMP, concluded that the drug met quality, safety and efficacy standards, the socio-economic motivations for the ban became obvious, if not always explicitly stated. In a 25 January 1991 debate in the EP, MEP Adriana Ceci used the language of social welfareism, asking the Parliament to be honest about its motivations for pursuing the ban on rbGH:

we know very well that this lack of a decision is in fact conditioned by other factors. I should therefore finally like to be told, in the interest of clear consumer information, on what exactly this decision will depend. Does it perhaps depend on

a socio-economic type of problem? That would be nothing to be ashamed of. We can easily say that we are dealing with a relatively safe product, but that we have no intention of using it in the Community because it would bring with it socio-economic problems (European Parliament, 1991a, p. 293).

Even though, as discussed above, clauses adding a fourth criterion to the traditional three had been removed from proposals for new Veterinary Medicines Directives by 1991, opponents of socio-economic assessment accused EU policymakers of sneaking in the fourth hurdle 'by the back door'—in other words, of proposing to ban rbGH for socio-economic reasons, despite the lack of an official fourth criterion in the drug evaluation process (*Europe Environment*, 1991a; *AgriService International Newsletter*, 1994b). Supporters of the moratorium did not deny that this was the case. In 1991, CVMP recommended approving Monsanto's rbGH product, saying it passed the three criteria of quality, safety and efficacy (*European Report*, 1991a). Yet the Council continued to issue moratoria on the drug, as recommended by the Commission and the Parliament.

Industry groups were deeply concerned about these developments. One biotechnology lobbying group drew on the language of scientism, arguing that the threat of a ban without 'objective' justification would inhibit innovation (*European Report*, 1991b). Another group used similar language calling for regulation based on 'sound scientific principles', suggesting that without such an approach European industry's competitive position could be jeopardized (*Biotechnology Business News*, 1991).

By 1993, fourth hurdle-related discussion centred on the issue of a permanent ban on rbGH. At that time, M. Rene Steichen, the EU's Agriculture Commissioner, wanted to ban the drug on the grounds that it would have socio-economic impacts inconsistent with existing EU policies (*European Report*, 1993a). The Commission expressed concern about the possible negative impacts introducing rbGH into the European market would have on small dairy farmers and pointed out that the commercialization of rbGH runs counter to the CAP (Commission of the European Communities, 1993a). Following this logic, the Commission submitted a proposal for a Council decision in favour of a ban on rbGH until the end of the existing milk quota regime (Commission of the European Communi-

ties, 1993b). As long as quotas were necessary to limit milk production, the introduction of rbGH would conflict with the objectives of the CAP (*European Report*, 1993b).

In response, the EP Environment Committee, again under Ken Collins, and the Agriculture Committee, under Mr Vasco Garcia, also called for a ban on rbGH. These committees could be said to have urged a stronger line than the Commission, as they favoured a ban on the basis of rbGH's likely socio-economic effects, but rejected formally linking the ban with the milk quota regime, which was for a limited time (European Parliament, 1993).

With a ban on the commercialization of rbGH still in place, trends toward a globalized economy and rules governing it began to influence EU policy. In December 1993, the Council extended the ban as the Commission proposed, asserting that all issues surrounding rbGH had not been fully assessed. The Council did not, however, link its extension to the milk quota regime and implemented the ban for only one year (*Biotechnology Business News*, 1994; Council of the European Union, 1993). According to one source, the decision to limit the ban was influenced by the US decision in June 1993 to authorize use of rbGH (*Biotechnology Business News*, 1994).

A year later, amidst continued opposition to rbGH within EU policymaking institutions (*Agri Service International Newsletter*, 1994a; Committee of the Regions, 1995) and among a vocal conglomeration of activist and citizen groups (*European Report*, 1994a, 1994b) because of its likely socio-economic effects, the Council again extended the ban, this time until the end of the decade. The Council justified its extension on the same grounds as the Commission: the contradiction between commercializing rbGH and the EU system of milk quotas (*Europe Environment*, 1994; Council of the European Union, 1994). However, the Council's decision also made reference to international trade issues, particularly the approval of rbGH in the United States.

By the end of the 1990s, the EU was under growing pressure to justify its ban on rbGH to the global economic community. One manufacturer of rbGH, Lilly Industries, brought a case to the European Court of Justice, arguing that their product was unfairly handled by EU policymakers. The 1998 Court of Justice ruling declared that, explicit statements notwithstanding, the reason for the rbGH ban was not that the substance did not meet the criteria of

quality, safety and efficacy, but rather was grounded in socio-economic concerns. This ruling did not overturn the moratorium, but it drew attention to the EU's use of an unofficial fourth criterion in its decisions on rbGH. This, combined with US and World Trade Organization (WTO) opposition to the ban, may have pushed rbGH opponents to pursue a new line of argument against the hormone.

Still committed to a ban on rbGH, European opponents of the substance turned to the accepted 'scientific' dimensions of evaluation in search of justification for a moratorium. Suggesting a concern that international trade partners would demand a scientific rationale for the ban, the Council decision called for a 'Working Party of independent scientists, in collaboration with the Member States ...' to assess the effects of using rbGH (Council of the European Union, 1994). At least one newspaper reported that this turn to a 'scientifically measurable' justification for the rbGH ban came as a response to World Trade Organization pressure (Riley, 1999). The European Commission used studies that found that the use of rbGH results in 'painful and debilitating' conditions for cows regularly injected with the substance, 'leading to significantly poorer welfare of the animals' (Health and Consumer Protection Directorate-General, 1999; Scientific Committee on Animal Health and Animal Welfare, 1999) as a 'scientific' justification for a final, permanent ban (*Europe Daily Bulletins*, 1999; *European Report*, 1999a; Commission of the European Communities, 1999).

With support from the Economic and Social Committee and the European Parliament, EU ministers voted to approve the Commission's proposal of a permanent ban on rbGH in December 1999 (Council of the European Union, 1999; Economic and Social Committee, 1999; *European Report*, 1999b). The permanent moratorium on the marketing and use of rbGH in the EU went into effect on 1 January 2000.

■ SOCIAL ORGANIZATION OF POLICYMAKING IN THE EU

Our claim thus far is that debates about technology in the US and EU are fought out on divergent discursive terrains. The dominance of scientism, technological progressivism, and free marketism is unambiguous in the United States. Challenges to these discourses are relatively easily dismissed. In the EU, these three discourses are

also prominent, but not unequivocally dominant, and social welfareism serves as a counterweight on the EU discursive landscape, making consideration of the fourth hurdle a plausible and legitimate undertaking. However, that a claim is widely considered reasonable and/or legitimate does not mean that it will become institutionalized in policy. We turn to the organization of policymaking in the European Union and the influence of the World Trade Organization to tentatively explain the establishment of the several moratoria on the commercialization of rbGH, based to differing degrees on fourth hurdle considerations.

There are three attributes about EU policymaking that are critical to understanding the trajectory of the fourth hurdle. First, EU policymaking is fragmented. There are several different bodies involved in policymaking, and they have overlapping and sometimes conflicting responsibilities (Abraham and Lewis, 2000). Second, there are multiple veto points for proposed legislation. In other words, there are many points at which legislation can be sidelined. Finally, governance is not identified with a majority party with a clear and consistent agenda, and, insofar as political parties play a role in the EP, they are not able to enforce discipline on members. This makes for a pluralistic and often fragile policymaking process (Streeck and Schmitter, 1991; Wallace, 1996, p. 33).

Policymaking in the European Union falls to four institutions: the Council of Ministers, the European Commission, the European Parliament, and the European Court of Justice. The Council is the major decision-making body of the EU. Although the Council cannot make policy proposals, it ultimately determines what proposals become law. Made up of representatives selected by member governments, the Council is really several different councils made up of ministers for distinct policy areas (e.g. agriculture and foreign policy) (Wallace, 1996, p. 61; see also McCormick, 1996, p. 140; Peterson, 1989, p. 467).

The Commission is headed by some 20 commissioners and is composed of a number (23 in 1996) of individual directorates general (DG), each with a distinct policy area for which it is responsible. The European Commission initiates the lawmaking process by generating policy proposals. However, since the Council ultimately determines what policies become law, the Commission seeks to issue only proposals that have a good probability of accept-

ance by the Council. This need for Council approval means that the Commission is likely to work closely with the Council in an effort to produce acceptable legislation.

The European Parliament is the only EU policymaking body whose members are directly elected to serve in the European governance process. With the exception of Great Britain, every member country uses a system of election that varies on the theme of proportional representation (McCormick, 1996, p. 149). This allows for a greater diversity in political views than is permitted in a winner-take-all system like the US has. Significantly, although MEPs are selected by their national parties, each has an independent mandate meaning that European Parliamentary politics lacks the kind of party discipline one typically finds in traditional parliamentary systems (McCormick, 1996, p. 155).

Most of the significant work done in the EP takes place in standing committees (of which there were 19 in 1996). Seats on these committees are determined by the balance of political party groups, seniority in the parliament, and national interests (McCormick, 1996, p. 146). The *rapporteur* is the central figure in a parliamentary committee. The rapporteur prepares initial discussion on committee matters, provides draft texts and legislative amendments, presents the committee's report to the plenary of the Parliament, and discusses Parliamentary amendments prior to final voting (Abels, 1998, p. 50). Rapporteur positions 'are distributed on the basis of a quota of points according to the rapporteur's political party's size' (Abels, 1998, p. 50). This can allow even small parties a substantial voice, as the parties can use their entire complement of points to gain a rapporteurship on an issue to which the party is deeply committed.

Each branch of the European Union policymaking apparatus has a different mandate and a different constituency, and none can act entirely without consideration of the others. In addition, there is fragmentation within these bodies. This situation leads to the constant need for compromise. As we described, in the case under consideration, there was division of viewpoint in the Commission: the Directorate General for Agriculture supported the fourth hurdle, while the Directorates for the Internal Market and Scientific Research and Development opposed it, and the Commission's 1991 report called for a compromise in which the traditional three criteria

remained the mainstay in assessment, but in which the possibility of including other factors on some occasions was retained.

More generally, the determination to allow the fourth hurdle in by the back door appears to reflect a compromise. Recall that the Council as a body is intended to mirror the spectrum of interests of member countries, and EU nations represented a wide range of opinions on the commercialization of agricultural biotechnologies. In addition, note the division among members of the EP on the matter and that no party in the Parliament had a majority with which it might have pushed through a singular position. Finally, remember that the European Court pressed policymakers by ruling that explicit statements notwithstanding the 1998 decision really amounted to a fourth hurdle-based ban.

Looking at the Parliament itself, we see at least one instance in which a change in rapporteur altered the position of a committee. Recall that the replacement on the Environment Committee of one rapporteur with another resulted in a reversal of the Committee's position on the fourth hurdle. Without governance by a disciplined majority party, it was impossible for the Parliament to present a single clear and consistent position. Although existing documents do not allow us to clearly see additional instances like this one, it seems plausible that change in explicit justification for the various temporary moratoria on rbGH reflects the fragile and highly pluralistic environment in which EU policy is made.

In the context of a fragmented and relatively unstable policymaking process, pressure from the World Trade Organization (WTO) certainly affected the justification used for the final rbGH ban. WTO rules required that a ban on rbGH be based on 'scientific' rationale. Pressure from the WTO would certainly have given ammunition to opponents of the fourth hurdle and pushed those who supported the use of socio-economic criteria of assessment and favoured a ban on rbGH to compromise to save the ban and perhaps allow the fourth hurdle in through the 'back door'.

One might respond to this analysis by saying that in the end it is really discourse that explains the very different policy outcomes in the US and EU. After all, the characteristics of policymaking that we highlight in the EU case might be used equally to describe the process of governance in the US. And indeed, it seems more than a bit plausible that the one moratorium on the commercialization of

rbGH passed by the US Congress reflects fragmentation and lack of party discipline within that body. This situation demands deal making, and the temporary ban might very well reflect some sort of trade-off.

It is certainly the case that the structure of policymaking in the United States is fragmented and highly permeable. However, policy on rbGH in the US was ultimately not a legislative concern, and it is in this domain that fragmentation and permeability matter most. Instead, questions of the appropriateness of commercializing rbGH were understood to be largely matters for administrative regulation. In this context, it is important to note that while social welfareism is deeply and broadly institutionalized in EU policies and the policies of many EU member nations, it is only institutionalized in a limited manner in US policy.

In particular with regard to this case, the social welfareism embodied in US agricultural policy from the New Deal until passage of the Federal Agricultural Improvement Reform Act in 1996, reflected not a deep societal commitment to the values underlying this discourse, but the unusual administrative capacities of the US Department of Agriculture (USDA) during the New Deal. As Skocpol and Finegold have noted, at the onset of the Great Depression, the USDA was ‘an island of state strength in an ocean of weakness’ (Skocpol and Finegold, 1982). This history notwithstanding, by the mid-1980s when rbGH was put on the regulatory agenda, there was a growing push to break agricultural policy from its social welfareist history. Even absent of this initiative, however, regulation of rbGH fell under the mandate of the US Food and Drug Administration and not the USDA. The FDA has no tradition of including social criteria of assessment in regulation. Consequently, a strategy based on arguments, like those used in the EU, that commercializing rbGH would contradict agricultural policy commitments was not viable.

■ CONCLUSION

In this paper, we have explored why socio-economic considerations—possible impacts on the structure of dairy production—had a legitimate place in the policy debate in the European Union over the commercialization of rbGH, but were not seriously considered in

legislative and executive debate about this technology in the United States.

More generally, we have stressed the explanatory roles of discursive and organizational factors in understanding technology policy-making. In particular, we show how the discursive terrain shaped the contours of debate over rbGH-related policy, and we illustrate how this terrain interacted with the structure of policymaking to shape the divergent contours of policy around rbGH in the US and the EU.

Tracing discourses, we show that technological progressivism, scientism and free marketism are deeply embedded in the history of discussions and policies about new technologies in the US. These discourses are clearly and regularly articulated in early debates in Congress on biotechnology and, indeed, in federal discussions about rbGH. Within the 'halls of power', it is clear that safety and efficacy, as these are limited by these three discourses, were, by and large, viewed as the only legitimate bases for regulating biotechnology and halting the development and commercialization of rbGH. And although US critics of rbGH argued on the margins for consideration of what might be viewed as fourth hurdle factors in determining whether the substance should be commercialized, in general, they lacked discursive ground to stand on. Critics were told in no uncertain terms that we cannot 'stop progress', that science, not values, must be the basis of policies, and that we should let the market decide which technologies succeed and which fail.

We contrasted this history with a view of the discursive landscape in Europe. We suggested that while certainly technological progressivism, scientism and free marketism can be found in the language of policy debate in Europe, they do not dominate to the same degree as is the case in the US. Most importantly, a social welfare discourse provided an alternative to the dominant discourses in the US. Not only was this an alternative, but this discourse was widely drawn on by EU politicians debating the future of rbGH, and furthermore, it is institutionalized in one of the EU's most fundamental policy programmes: the Common Agricultural Policy. Social welfareism became a substantial surface of the discursive terrain on which EU policy toward rbGH was debated.

All that said, it would be foolish to conclude that consideration of discourses alone provides a sufficient basis to understand the history of rbGH policy and the fourth criterion in the EU. In addition, the

structure of EU policymaking played a role in shaping this outcome. A fragmented and fragile structure made compromise likely, whereas a more centralized parliamentary system with highly disciplined political parties might arguably have institutionalized a fourth hurdle in Europe.

In the US case, biotechnology regulation was debated in the legislative arena, where we see the dominance of the discourses of technological progressivism, scientism and free marketism. Representatives of interest groups and members of Congress did occasionally criticize rbGH on social welfareist grounds, but these claims were never central to legislative debate, suggesting the subordinate nature of this discourse in the US context. In any case, the legislature did not attempt to make regulatory policy for biotechnology in general or rbGH in particular. That responsibility fell to the US Food and Drug Administration. In contrast to the US Department of Agriculture, which has a tradition (if an uneven one) of implementing social welfareist policies in the agricultural sector, such a tradition is lacking for the FDA. FDA regulation generally reflects a deep commitment to scientism and technological progressivism (on the FDA see Abraham, 2002).

There is one curious piece to the stories we tell—especially for the EU case—that is worth highlighting. Scientism often seems to involve (as it does to a greater or lesser extent in both of our cases) a lack of specificity about where in the technoscientific realm values enter. On both sides of the Atlantic, it seems typical for opponents *and* proponents of agricultural biotechnology to assume not only that the traditional three criteria of assessment are subject to scientific evaluation, but that they themselves are scientific. For the traditional three criteria, there may be questions about what is safe enough, what is good enough, and what is efficient enough, and actors may recognize that answering these questions is a matter of values, but there seems little recognition that the choice of specific dimensions across which to undertake an evaluation is itself a matter of values too. By contrast, actors on both sides of agricultural biotechnology debates seem to conflate socio-economic *criteria* of evaluation and the *means* of evaluation, assuming both are value-laden.

Why this is, we cannot say for certain. One possibility is that a relatively broad consensus on the means of measuring safety, quality, and efficacy leads actors to overlook the fact that the choice of these

criteria is fundamentally value-laden, and this blindness may be reinforced to the extent that there is consensus on what counts as acceptable levels of safety, quality, and efficacy. By contrast, because there is less agreement about how to measure socio-economic impacts or on what would count as acceptable levels of, for example, social dislocation resulting from the introduction of new technologies, the value-laden character of assessing socio-economic impacts of newly introduced technologies is broadly assumed. These issues demand further research.

Through our analysis of the discursive and organizational factors that have affected agricultural biotechnology policymaking in the US and the EU, we do not mean to suggest that the future character of policies affecting the development of biotechnologies in the US and EU is certain. It is true that in the US, if anything, the position of the dominant discourses seems increasingly secure. Beyond the EU rbGH controversy, however, efforts to establish fourth-hurdle type policies, resting on social welfareism, have had substantial support in individual European countries (see Seifert and Torgersen, 1997). At the same time, proposals for fourth-hurdle type policies in global trade governance are considered with increasing seriousness (Halweil, 2000), and one can imagine that, despite the power of free marketism as a discursive resource in the global context, pressure could build to make US policies compatible with those of other countries who participate in world trade governance regimes and favour fourth-hurdle type policies.

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□ NOTES

1. This discourse is multi-faceted. Indeed, to call it a single discourse is somewhat misleading. For, of course, Europe (for our purposes primarily Western Europe)

is made up of a number of countries, and each has a distinct history and consequently distinctive variations on this discourse. There is a sense, therefore, in which our discussion of social welfareism must be treated as a kind of ideal type. In each Western European country social welfareism certainly has a distinct tinge, and as clearly, the relative dominance of this element will vary from country to country. At the same time, there is enough overlap that it is reasonable to refer to social welfareism as a distinct discourse.

2. While we contend that technological progressivism, scientism, and free marketism constitute the dominant discursive space in debates over biotechnology in the US, we do not mean to suggest that there are no alternatives. Opponents of rbGH at the 1986 Congressional hearing challenged the arguments of rbGH advocates. One method critics deployed was to redefine, rather than displace, dominant discourses (see US House of Representatives, 1986, pp. 211–212). Others posed more direct challenges (see US House of Representatives, 1986, pp. 181, 182).

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