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Local variation or global convergence in agricultural biotechnology policy? A comparative analysis

Daniel Lee Kleinman, Abby J Kinchy and Robyn Autry

The history of attention to local variation in science and technology studies notwithstanding, there is a growing emphasis in the study of science policy on global convergence. In this paper, we undertake a multi-state comparative study of agricultural biotechnology policies, illustrating the continuing value of attending to policy variation and the factors that mold it. We acknowledge the growing influence of supranational entities and transnational cultural exchanges in shaping policy. However, our research does not indicate the homogenization of agricultural biotechnology policies across the globe. Instead, we find three broad models of agricultural biotechnology governance: 'liberal science-based' regulation, 'precautionary science-based' regulation, and 'social values-based' regulation. While states are constrained by global and local factors, they actively shape policies by blending parts of these three policy models in distinct ways.

ARE GLOBAL-LEVEL FACTORS prompting a convergence of science policy orientations worldwide, or does local variation persist and proliferate? While there remains a strong strain of comparative analysis in the study of science and technology policies (e.g. Jasanoff, 2005), there is also a growing emphasis on policy and institutional convergence among analysts of science policy (see especially Drori *et al*, 2003; Meyer *et al*, 1997; Finnemore, 1996; Jang, 2003). Probably the most prominent approach to science policy convergence is outlined by Drori and her colleagues. These authors contend that 'Across many different domains, countries appear to be enacting common models or scripts of what a nation-state ought to be' (Drori *et al*, 2003: ix). A central feature of these scripts is the 'institutionalized cultural authority of science' (Drori *et al*, 2003: 10). Science has become an authoritative part of governance around the globe.

While there is surely something to the claims made by convergence theorists, much is lost in their approach to science and technology policy. Among other things, we are led to ignore the variations in the *effects* divergent policies have on people on the ground, and would-be challengers to dominant policies are less likely to study policy innovations from far afield, alternatives that might provide the basis for efforts to craft policy solutions potentially superior across important dimensions to dominant approaches.

Through an analysis of agricultural biotechnology (ag-biotech) policy-making, we wish to reinforce the value of undertaking a comparative approach to science policy, a focus that attends to variation and the factors shaping it. At the same time, like the convergence theorists, we acknowledge the growing influence of supranational entities and cultural interchanges in shaping policy. Indeed, there are ways in which the World Trade Organization and the UN, as well as commonalities between cultures, explain resemblance in biotechnology policy across cases. Furthermore, we recognize that the US and several European countries dominate the global

Daniel Lee Kleinman (corresponding author) is at the Department of Community and Environmental Sociology, University of Wisconsin-Madison, 3rd Floor, Agricultural Hall, 1450 Linden Drive, Madison, WI 53706, USA; Email: dlkleinman@wisc.edu. Abby J. Kinchy is at the Science and Technology Studies Department, Rensselaer Polytechnic Institute, Sage Lab Bldg, 5403, 110 8th Street, Troy, NY 12180-3590, USA. Robyn Autry is at the University of Minnesota, 909 Social Sciences Building, 267 19th Avenue South, Minneapolis, MN 55455, USA.

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Daniel Lee Kleinman is professor and chair of the Department of Community and Environmental Sociology and director of the Robert F and Jean E Holtz Center for Science and Technology Studies at the University of Wisconsin-Madison (USA). His work over the past decade has focused on three areas: the commercialization of the university; democracy and science; and agricultural biotechnology policy. He is the author of three books, including *Science and Technology in Society: From Biotechnology to the Internet* (Blackwell, 2005), and the editor/co-editor of three others, including (with Karen Cloud-Hansen, Christina Matta and Jo Handelsman) *Controversies in Science and Technology: From Climate to Chromosomes,* vol 2 (Mary Anne Liebert Publishers, 2008).

Abby Kinchy is an assistant professor in the Science and Technology Studies Department at Rensselaer Polytechnic Institute (USA). She received a PhD in sociology from the University of Wisconsin-Madison in 2007. Her research focuses on historical and present-day social movements as they intersect with scientific and technological change. Her work on the advocacy activities of the Ecological Society of America, the effects of the atomic bomb on the early civil rights movement, and the regulation of agricultural biotechnology appears in the journals: *Science as Culture*, *Social Studies of Science*, *Technology and Culture*, and *Rural Sociology*. She is currently writing a book on contemporary anti-genetic engineering movements in Mexico and Canada.

Robyn Autry is a postdoctoral fellow in the Departments of Sociology and History at the University of Minnesota. She received her doctorate in sociology from the University of Wisconsin. In fall 2009, she will join the Sociology Department at Wesleyan University. In addition to her interests in science and technology, her research focuses on: the politics of museum development, collective memory, and history in post-conflict societies. She is currently writing a book comparing the debates about historical museums in post-apartheid South Africa and post-civil rights America.

market and international policy debate about genetically modified crops. Still, our findings suggest, at a minimum, that the claim that the forces of economic globalization and an expanding world culture are producing homogenization of public policy must be explored on a policy-arena-by-policy-arena basis. In the area of ag-biotech, we find that states continue to construct novel and counter-hegemonic approaches to regulation. Indeed, rather than convergence on a common policy model, we find three distinctive approaches of regulation at play, often combined in ways that are unique to a particular country. To understand this variation, we explore the diverse histories of how these policies came to be adopted. Thus, our substantive contribution is a discussion of three types of ag-biotech policy, how they are differently blended in five countries and the EU, and the factors that influence the distinct policy outcomes in each case.

In a single paper, we cannot offer the kind of detail found in book-length comparisons of two or three policy-making entities (see Jasanoff, 2005; Gottweis, 1998; Wright, 1994); however, our study provides an opportunity to examine a greater variety of institutional settings and discursive landscapes than this type of work typically engages. The diverse array of cases we study are valuable because they permit us to characterize a more complete range of the ag-biotech policy approaches found around the world. We are primarily interested in identifying the varieties of existing approaches to ag-biotech policy. Thus, we selected cases that would increase the level of variation, even if this makes it difficult, if not impossible, to pinpoint a general explanation for divergences in policy outcomes.

In order to capture a broad range of institutional settings and policy outcomes, the five states we consider are: the US, Kenya, Austria, China, and India. We also consider the EU. We chose the US because of its economic and policy dominance in the area of biotechnology. The EU constitutes an obvious counter-weight to the US and is one of the undeniably important supranational policy entities on the contemporary scene. For the purposes of this study, we treat the EU as a 'state', roughly equivalent to other national states, although we recognize the significant complexity of the relationship between European countries and the EU governance structure. EU member nations do not necessarily share the EU's orientation toward biotechnology regulation, and for this reason, we chose to include Austria as a comparative case. The other cases represent a variety of blended approaches to biotechnology policy taking shape in the non-Western world. Kenya, while surely distinctive, provides one example of a nation from the Global South, interesting both for the ways its policies are affected by its place in global markets and the policy orientation of its European allies. China has potentially huge markets for biotechnology products and a strong desire to export widely, and its structure of governance is unique. India, a developing country in Asia and the world's largest democracy, offers yet another case of the varied factors that can shape policy outcomes.

Our argument proceeds in several parts. First, we describe three divergent models of ag-biotech regulation that are presently in use around the world. These include two different 'science-based' models as well as a 'social values-based' model of regulation. We then look at an assortment of different processes that have led to these policy outcomes. In each of our cases, domestic policy-making structures and discursive fields, as well as global markets and governance institutions, affect how the three approaches to ag-biotech policies are combined in distinctive manners. We are also attentive to the ways in which both coercion and legitimacy pressures contribute to the adoption of science-based policies. In the concluding section, we summarize our findings, pointing to the value of comparative analysis in overcoming some of the blind spots in scholarship that stresses increasing global policy convergence.

Three models of genetically modified organism regulation

Three relatively distinct models of ag-biotech or genetically modified organism (GMO) regulation are

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found in our cases. The first, most closely associated with the US, we refer to as conventional or standard *liberal science-based regulation*, often euphemistically referred to as a 'sound science' approach. Here, without scientific evidence of risk to human health, animal health, or the environment, permission to experiment with, and ultimately commercialize, agbiotech is granted. Of the three approaches to regulation we consider, this orientation is the narrowest with regard to the grounds for restricting commercialization. Most consistent with free market or neoliberal policies, this model does not take into account the economic effects of new technologies on consumers or producers (Kinchy *et al*, 2008).

At the global level, the World Trade Organization (WTO) advocates this model of regulation. The Sanitary and Phytosanitary (SPS) Agreement of the WTO was reached during the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) negotiations (1986–1994). The SPS agreement does not specifically deal with GMOs, but with food issues more generally. It aims to allow countries to protect the health and life of consumers, animals, and plants against pests, diseases, and other threats to health, while preventing the use of health measures in an unjustified, arbitrary, or discriminatory fashion. That is, the agreement allows countries to block imports of food products that pose a clear and measurable health risk, but not to selectively block imports from certain countries while allowing the same products to be imported from other countries or to be produced domestically. To meet this objective, the SPS agreement requires that the measures countries take either be based on conventional scientific risk assessment or comply with the standards of one of three existing international bodies (which use similar approaches to scientific risk assessment).[1]

The second model of regulation of trade in agbiotech products relies on *precautionary science-based regulation*, or the so-called precautionary principle. This model accepts science as the means for determining the appropriateness of release and commercialization of genetically engineered organisms, but flips the burden of proof on its head. While standard, liberal regulation views the absence of evidence of harm as a green light to proceed with release and/or commercialization, precautionary systems require evidence of an absence of harm. In the traditional language of science, liberal science-based regulation accepts false negatives more readily than false positives. That is, advocates of the conventional approach are willing to accept 'the risk' that they will miss evidence of harm when there is such evidence, while advocates of the precautionary approach would prefer to mistakenly conclude that harm is likely, when closer review might ultimately reveal no evidence of probable damage. The precautionary approach is more cautious in terms of public and environmental health and safety than the conventional approach, but does not intrinsically call for regulation in terms of the social or economic impacts of new technologies. The approach, however, has sometimes been used to shape the social and economic impacts on consumers or producers of the prospective introduction of new technologies by framing risk in social and economic terms.

Widely used in Europe, precautionary science-based regulation was recently institutionalized at the international level in the Cartagena Biosafety Protocol of the UN Convention on Biodiversity. UN member countries negotiated the regulation of international trade and release of agricultural biotechnologies. The objective of the Protocol was to minimize the risks to biodiversity posed by GMOs. The Biosafety Protocol, adopted by over 130 countries in January 2000, essentially affirms the right of countries to regulate GMOs and to review information about GMOs before they are imported. The Protocol contains language establishing a precautionary approach to biotechnology regulation. In addition to European use of the precautionary principle and its integration into the Biosafety Protocol, among our cases, we see varieties of the precautionary principle utilized in India and Kenya.

While both liberal and precautionary policy are premised on the virtues of science, suggesting a type of policy convergence, their opposing perspectives on error can have significant impacts on which products are permitted to reach the market. These are real differences that matter in policy implementation. But beyond these two models, our research suggests a number of cases premised, at

Liberal regulation views the absence of evidence of harm as a green light to proceed with release and/or commercialization; precautionary systems require evidence of an absence of harm

Social values-based regulations do not claim to draw exclusively on narrowly defined scientific evidence. Instead, the possible social benefits and costs of releasing and commercializing new technologies are considered

least in part, on a third model of ag-biotech regulation, an approach that does not seek legitimacy from global faith in science. With *social values-based regulation*, policy analysts do not claim to draw exclusively on narrowly defined scientific evidence. Instead, such regulation attempts to characterize the possible social benefits and costs of releasing and commercializing new technologies. Determination of benefits and costs are, in these cases, admitted forthrightly by supporters of this approach to be value-based, and such regulation aims to prohibit release and commercialization where the social cost passes specified thresholds. Efforts at social regulation are most often under-girded by the recognition that 'value free, neutral, or objective' principles are impossible to establish. An important premise of social regulation is that science alone is not sufficient to govern policy decisions around ag-biotech. This type of regulation is a prominent feature of Austrian policy, but is also present to some extent in the EU and Kenya. Article 26 of the Cartagena Biosafety Protocol lends some legitimacy to this approach, by identifying circumstances in which socioeconomic impacts are relevant to decision-making about GMOs. The Article also encourages consideration of the relationship between socioeconomic impacts, sustainability and the maintenance of biological diversity in regulatory decisions.[2]

Across our cases, there is significant variation and blurring of types. Table 1 indicates that not only can we see the presence of the three regulatory models in our cases, but that most of the states we investigated exhibit features of a combination of two of these models. Indeed, in our cases, mixtures of regulatory models, rather than rigid distinctions, characterize ag-biotech regulation. The table makes the boundaries between policy models look sharper than they are in practice and ignores local variants of interpretation in each case. A more accurate understanding of these complex cases requires attention to the processes that led to policy outcomes.

Table 1. Blended regulatory policies

	Liberal science-based	Precautionary science-based	Social values-based
USA	Primary		Debated
Kenya		Primary	Secondary
EU		Primary	Secondary
Austria		Secondary	Primary
China	Primary	Secondary	
India	Secondary	Primary	

What explains the emergence of these diverse combinations of regulatory approaches for biotechnology? Many factors contribute to the formation of policy over time, and our six cases indicate multiple paths toward the establishment of formal policy for the regulation of biotechnology. We are particularly attentive to the discursive terrain and the governance structures present in each case (Kleinman and Kinchy, 2003), but we do not attempt to produce a general explanatory model. In each case, a unique combination of factors led to six different 'blended' approaches to biotechnology regulation.

Six paths to biotechnology policy

An earlier high-profile mode of comparative analysis depended on the independence of the cases explored in order to make its arguments (Skocpol, 1984; cf. Sewell, 1996). Importantly, our cases are far from independent. Although we are not comprehensive in pointing to the array of discourses at play in ag-biotech debates, the range of discourses available across the globe is limited and actors in our cases draw from the same discursive field. Furthermore, the governance bodies in our cases all exist within the same global economy and polity. Their locations, economically and politically, shape how their policies are affected by this global environment, but they are certainly not independent. Given the lack of independence of our cases, it is perhaps surprising that they do not converge on a single model. While they do not share a single orientation, what they have in common is that each (with the possible exception of the US) blends bits of at least two of the three models we discussed in the previous section. However, no two entities share precisely the same balance of models. As we show, none of the combinations is exactly the same, and this happens because shared models, discourse and political and economic terrain are funneled through locally specific conditions.

US: Triumph of scientism over social regulation

Any comparative discussion of ag-biotech regulation must consider the US. Indeed, it is probably fair to say that the international model for conventional scientific risk-based biotechnology regulation is the US.[3] From the outset, official discussion in the US of any potentially undesirable consequences of the release of GMOs was narrowly technical, centering on potential biohazards in research laboratories. Thus, in 1983, when Congressional attention in the rDNA debate turned to the potential environmental

hazards of the deliberate release of GMOs as part of agricultural research, the central issues were framed within a scientific discourse of risk assessment (US House of Representatives, 1983).

Today, there are three US agencies responsible for evaluating GM crops and foods: the US Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). This kind of regulatory fragmentation is typical of the US system of governance. Companies seeking approval for a new GM product may need all, or none, of the three agencies to sign off, depending on the characteristics of the product. The FDA is concerned with food safety and regulates GMOs if they are understood to be substantially different from their conventional relatives (which are already understood to be safe). Because most GMOs are assumed to be substantially equivalent to ordinary food products by the FDA's standards, the agency tends not to require pre-market approval for GMOs. The USDA is responsible for plant pests, and, therefore, is concerned with the possibility that GM plants may have unintended effects, such as increasing weeds or vulnerability to pathogens. The EPA is responsible for regulating pesticides, and, thus, has had an important role in the approval of crops that produce their own pesticides. While the EPA has expressed greater concern for the risk of GMOs to the environment than the two other agencies, in a divided executive branch, an always precarious need to balance divergent orientations combined with the dominance of discourses of science and free markets has led to the world's most unambiguously liberal science-based system for the regulation of ag-biotech (Prakash and Kollman, 2003: 625; Kleinman and Kinchy, 2003). Thus, throughout this administrative network, regulation is kept to a minimum in the absence of clear evidence of risk to human health or the environment.

Even though a conventional, liberal science-based model currently prevails, viewing the US as the quintessential case of this model of regulatory policy ignores a more complex history in which we find an explicit struggle between advocates of social regulation and supporters of liberal science-based regulation. The debate around the regulation of biotechnology in the dairy industry in the US is a case in point. In the mid-1980s, a model of regulation based on socio-economic concerns entered policy discussions. At that time, public controversy over biotechnology in the US centered on recombinant bovine growth hormone (rbGH), a substance that could be used to increase milk production in dairy cows. Many of the most vocal opponents of rbGH broadened the debate beyond scientific risk assessment by using anticipated socio-economic concerns to frame their opposition, particularly the apparent advantage it offered large producers over small farmers. Several of these opponents argued that rbGH would reinforce or accelerate the structural transformation of the US dairy industry away from small-scale producers (Collier, 2000: 157; see also Office of Technology Assessment, 1991; Barham *et al*, 2001). Despite nearly a decade of prior public opposition, in 1993, the commissioner of the FDA initially announced agency approval for the technology, ignoring the possible socio-economic effects of rbGH (Schneider, 1993). By 1999, after several additional years of discussion about potential socio-economic impacts, the FDA reaffirmed the safety of the technology for humans (Collier, 2000: 158), based on a liberal scientific model of risk assessment.

Still, despite the dominance of this conventional approach, there were periods during the struggle over rbGH in which advocates of socio-economic regulation gained visibility and legitimacy. While their attempts were ultimately unsuccessful, various state and local moratoria on the commercialization of rbGH prior to FDA approval were couched at least in part in a socio-economic discourse. Furthermore, the development of rbGH regulation in the US was shaped less by commitment to a single scientific model than by the US governance structure, particularly the federal system and the division of labor between the legislative and executive branches of government. The federal governance system in the US allowed for the passage of two state-level socio-economically justified temporary moratoria in Minnesota and Wisconsin. And nationally, Congress established its own temporary moratoria based on socio-economic concerns, which reflected a political compromise between competing interests (Kleinman and Kinchy, 2003).

In the end, the actual regulation was left to the executive branch, where the fragmented character of administrative rule-making and the histories of US regulatory agencies were pivotal. The question of whether to permit commercialization of rbGH was understood to be an administrative matter and was left to the FDA and not the Department of Agriculture, which may have been more sensitive to socio-economic considerations due to the deep influence of the New Deal on its 20th century history. Significantly, the FDA has no tradition of socio-economic regulation, basing its policies on narrowly defined criteria of safety and efficacy, the hallmark foci of a conventional, liberal science-based risk assessment model.

In sum, here we find a case where debate and conflict influenced decision-making, and ideas about the appropriateness of ag-biotech were filtered through an array of institutional structures and interests. A complicated discursive field and a fragmented policy-making structure produced a twisted path to a policy outcome that reflected the specificity of national politics and institutional configurations.

China: Market-driven shift from liberal science-based regulation to precaution

Like the US, China uses conventional, liberal science-based risk assessments as a means for setting

regulatory standards. The Implementation Regulation on Agricultural Biological Genetic Engineering was put in place in 1996. The Ministry of Agriculture (MOA) is charged with reviewing and evaluating proposals for large-scale research and commercial use. Within the MOA, the Administrative Office for the Safety of Biological Genetic Engineering and the Committee on Safety of Agricultural Biological Genetic Engineering (CS) are responsible for accepting applications for GM research/production and for making decisions to approve or reject applications, respectively. Paarlberg (2001: 130) notes that, 'the structure and composition of the CS favors agricultural interests and science-based decisions' because its two highest positions, chair and vice-chair, are occupied by the vice minister of agriculture and an MOA director, respectively. Further, one-third of the membership of the CS is comprised of MOA staff, and the remainder come largely from the scientific community.

Although not immune to local protest and various forms of popular dissent, the Chinese state is relatively impermeable to civil society interests. Chinese biotechnology policy reflects the country's system of highly centralized planning. In this context, Chinese biotechnology policy generally echoes the views of strategically located government officials. Even the preference of the State Environmental Protection Agency for policies oriented toward national biosafety guidelines did not have a significant impact. Still, despite the absence of a thoroughly open civil society, China has witnessed a perceptible movement from a liberal risk assessment-based policy to a more precautionary orientation. Indeed, according to Huang and Wang (2002), China is moving toward a more precautionary position on GM research and production in response to fears that GM products from China will be prohibited entry to European markets. The EU's decision to ban Chinese soy sauce produced with US soybeans largely fueled Chinese concerns, which are also reflected in the country's reluctance to import GM soybeans from the US (Huang and Wang, 2002). In this case, officials were significantly influenced by export market demands. We might call this coercion of the market, and, formally, this has led to a regulatory policy that balances liberal science-based risk assessment with a more precautionary approach.

In short, the original character of Chinese policy clearly reflected a governance structure relatively immune from social movement pressures and where more powerful government bodies faced little pressure to compromise with less powerful agencies. Yet subsequent Chinese policy appears to have been shaped by the coercive pressures of foreign markets and, indirectly, public opposition at a great distance.[4]

EU: Precaution and semi-official social regulation

Prominent among the governments that rely on a substantially precautionary approach is the EU. The EU has demonstrated commitment to the taken-for-granted virtues of science in the evaluation of products of biotechnology. However, the precautionary focus of the EU makes its policy in practice different in important ways from entities that rely on a conventional, liberal science-based regulatory model, like the US. In the EU case, the precautionary principle effectively means that decisions can be taken to prohibit the release or commercialization of GMOs in the absence of positive evidence of environmental and health risk, where there remains a high level of uncertainty about the extent and likelihood of these risks. Indeed, the EU decided to uphold national bans on GMOs in eight European countries, despite the fact that those countries produced no scientific evidence of harm to justify their rejections of GMOs (Brown, 2005).

In the EU, the precautionary principle effectively means that decisions can be taken to prohibit the release or commercialization of GMOs in the absence of positive evidence of environmental and health risk

As in many countries, the fragmented structure of policy-making in the EU can shape the contours of the policies implemented (Kleinman and Kinchy, 2003). The European Commission is composed of 20 directorates general (DGs). Some are more influenced by discourses of the market and science, others frame discussion in terms of risk and uncertainty, and for still others the language of social welfare dictates regulatory practice. The Environment DG has served as the lead agency in ag-biotech product matters and has promoted a precautionary orientation (Prakash and Kollman, 2003: 625). Precautions guided the Council Directive 90/220/EEC which established policy on field trials and the marketing of live GMOs (Prakash and Kollman, 2003: 625, 626; Levidow, 2001: 848, 849). For its part, according to Jasanoff (2005: 83), the European Parliament 'partly in consequence of its limited in-house technical capacity, proved receptive to an informal network of European and American ecologists and activists who emphasized uncertainty and urged a precautionary stance on GM technology.'

Efforts at social regulation can also be found in EU policy, making it yet another example of the 'blending' of regulatory models. The EU policy document creating the European Food Safety Authority (EFSA) (Regulation [EC] No 178/2002 of the European Parliament and of the Council of 28 January 2002) establishes a precautionary scientific risk model for the regulation of ag-biotech but also notes

'that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.' Such factors are not incorporated into the policy or the evaluation criteria, and EFSA's GMO Panel formally focuses only on precautionary-oriented scientific risk assessment. Nevertheless, the door is left open to alternative kinds of assessment, approaches that are not premised solely on the authority of science.

As in the US, the politics of rbGH had an important role in shaping the trajectory of EU biotechnology policy. Throughout the 1990s, the European Council passed a series of moratoria on the production and use of rbGH in the EU, culminating in a permanent ban issued in January 2000. The stated justifications for each of these moratoria varied, but socio-economic motivations were explicitly stated in several instances. However, by 1998, faced with industry opposition, an EU Court of Justice ruling, and US and WTO pressure, European opponents of the new technology turned to the accepted 'scientific' dimension of evaluation to justify the ban. The European Commission drew on studies that found that the use of rbGH produces 'painful and debilitating' conditions for cows regularly injected with the substance, 'leading to significantly poorer welfare for the animals' (Health and Consumer Protection Directorate-General, 1999; Scientific Committee on Animal Health and Animal Welfare, 1999) as a 'scientific' justification for the final permanent ban. In the end, while the model of regulation based on socio-economic criteria was sidelined or masked, opponents of rbGH successfully banned its commercial use.

A deep and extensive history of welfare state development and EU agricultural policy, often described as social welfare for farmers, made discussion of social regulation legitimate in the EU (Kleinman and Kinchy, 2003). And at an organizational level, as in the US, fragmentation was pivotal in the EU rbGH case. Several bodies with overlapping and sometimes contradictory responsibilities (Abraham and Lewis, 2000) were involved in shaping policy on rbGH regulation. Also, the convoluted nature of EU policy-making introduced many opportunities for opponents of policies to halt or disrupt implementation. Finally, the policy-making process was made fragile and pluralistic by a lack of rules for enforcement of political party discipline. Early in the EU-rbGH history, division between two European Commission directorates (one for agriculture and the other for science) led to a 1991 compromise report that included watered down language about socio-economic regulation. Within the European Parliament, the nature of successive moratoria and policy recommendations fluctuated depending on which European Member of Parliament had oversight responsibility, and this varied due to arcane parliamentary rules and the absence of a majority party.

Sorting through the details of the processes leading to policy, scientific discourse did not dominate public debates in the EU and was not understood as the sole legitimate basis for framing of policy decisions. Indeed, but for coercive pressure from the US, using the WTO, the countervailing discourse of social welfare protection would probably have led to explicitly social regulation of rbGH, and perhaps other products of biotechnology, in Europe. However, in the context of this fragmented and relatively unstable policy-making structure, such pressure certainly affected the way in which the final ban was framed, and, in turn, reinforced scientific (but precautionary) criteria as the legitimate basis for biotechnology regulation.

Kenya: Donor pressures for precaution

Although policy continues to develop in Kenya (Odame *et al*, 2002, 2003; USDA, 2006), it is fair to characterize the country's current orientation as broadly precautionary (Paarlberg, 2001: 44). The country's official biosafety policy is outlined in its 'Regulations and Guidelines for Biosafety and Biotechnology in Kenya' from the late 1990s. In the face of uncertainty concerning the risks of GMOs, Kenya requires that genetically engineered crops be segregated from non-genetically engineered biological materials and that special safety procedures be used in the handling of GMOs. The precautionary slant in Kenyan policy does not mirror the indigenous discursive field or the balance of forces within the Kenyan polity alone. Instead, this policy orientation also reflects the influence of outside donors, particularly the Netherlands, on Kenya's biotechnology objectives and interests.

The key 'Regulations and Guidelines for Biosafety and Biotechnology in Kenya' was largely funded by the government of the Netherlands, and, according to Paarlberg, 'the guidance documents used by the drafters included biosafety regulations in use in the Netherlands, plus those used by the Stockholm Environmental Institute in Sweden' (Paarlberg, 2001: 51). Dutch biotechnology and biosafety regulations use precautionary language not only on questions of scientific uncertainty, but also with regard to the possible social and ethical implications of GM research and production (Schenkelaars, 2005). Dutch assistance to Kenya included workshops, training, and expert assistance to create a comprehensive biotechnology regulation system. The Foreign Ministry of the Netherlands gave $5 million in biotechnology assistance to Kenya (Cohen and Paarlberg, 2004). Finally, beyond the role of the Netherlands in shaping Kenyan ag-biotech policy, fear of losing Europe as a market for its exports has also driven Kenya's precautionary biotech policy.

While outside donors were instrumental in shaping Kenya's biotechnology policy in the 1990s and insisting on the inclusion of precautionary language, the implementation of these policies faced multiple difficulties. Most of the issues relate to poor linkage and conflicting interests between policy-makers, scientists, and small farmers at the local level. Even though smallholder farmers account for most of Kenya's agricultural production, they were not invited to participate in policy-making that was deliberately framed as a collaborative effort between government agencies, scientists, and the international community (Odame *et al*, 2002, 2003). Due to this lack of participation, many of the concerns of small farmers were invisible during negotiations and in the final policies. Indeed, exclusion of small farmers meant that their socio-economic concerns (about the cost, accessibility, and utilization of GM technologies) went unheard. While scientists and farmers were interested in different aspects of biotechnology, both favored a more liberal regulatory model. However, Kenyan officials opted for a more precautionary approach in the light of financial and technical assistance from outside agencies and countries, most notably the Dutch.

Here is a complicated picture. The character of policy in Kenya cannot be understood to reflect simple local political structures or discourses as such. Instead, the economic dependence of the country made it subject to the influence of one of its prime benefactors. In a sense then, Kenyan policy echoes the European discursive landscape as funneled through the Netherlands. European nations have largely promoted precautionary regulation for biotechnology. This can be seen in debates over EU policy on trade in GMOs. But note that while Kenyan policy is best characterized as precautionary (a science-oriented policy) there is a social regulatory impulse among some policy leaders (Odame *et al*, 2002, 2003), and as policy continues to unfold, this could shape the country's orientation. Again, this points, at least in part, to the importation of a discourse of social welfare protection by foreign aid patrons and analysts.

India: Divided between promotion and precaution

India's 'Revised Guidelines for Biosafety in Biotechnology' were introduced in 1994 and constitute a modified version of an earlier policy from the 1980s that governed the use of recombinant DNA. Altered again in 1998, the guidelines outline safety procedures for research and the release of GMOs. Indian policy borrows from the risk assessment approach used by the USDA and only permits scientifically demonstrated risks to be considered in determining whether to allow GMOs into the environment or on the market (Paarlberg, 2001: 103). But this description oversimplifies Indian policy and practice. Policy-making regarding ag-biotech in India has been marked by protest and conflict within the government, mirroring a broader controversy in civil society. India takes a permissive or even promotional stance toward rDNA research, but has a more precautionary orientation toward the release and use of GMOs.

All GM research and activities are monitored by two agencies with competing interests. While the Review Committee on Genetic Manipulation (RCGM), with its close ties to industry and the Department of Biotechnology (DBT), is favorable toward GMOs, the Genetic Engineering Approval Committee (GEAC) takes a more precautionary approach. The RCGM is responsible for small-scale research and is comprised of scientists and members from the DBT, the national agency explicitly concerned with promoting biotechnology as a development strategy for India. This structure produces a favorable environment for biotechnology development. The GEAC, on the other hand, regulates large-scale research projects and the actual release and use of GMOs (including import/export). Unlike the RCGM, this agency is part of the Ministry of Environment and Forests (MoEF). Paarlberg describes the GEAC, chaired by a member of the MoEF, as the 'biosafety policy gatekeeper' (Paarlberg, 2001: 103). While the GEAC also has representatives from the DBT and other government agencies, the MoEF has the strongest influence. Public opposition and the strong environmental focus of the GEAC have resulted in a precautionary approach to the release and marketing of GMOs.

Contradictory discourses are partly responsible for the formation of this mixed approach to the regulation of biotechnology. The discursive field here is characterized in part by a 'mistrust of international companies' (Paarlberg, 2001: 96), which opens the biotechnology industry to critique, while the nation's history of colonialism (Baber, 1996) means that a Western cultural model of scientism is questioned, rather than taken for granted. At the same time, pro-growth/development forces in India certainly push a pro-biotechnology agenda premised on liberal science-based regulation. Indian scientists and government officials generally concur on the virtues of biotechnology, favoring extensive research, industrial use, and commercial release.

In short, a contradictory discursive field and a divided political structure are associated with a policy that is far from uniform, but rather fragmented and contradictory. In India, then, although research policy does reflect the cultural authority of science (and the influence of the US), Indian ag-biotech policy does not rest on a single model of regulation.

Austria: Longstanding commitment to social regulation

The Austrian case adds considerable complexity to the picture we have thus far painted. Austria's Genetic Engineering Act of 1994 represents an effort to implement the social regulation of biotechnology.

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According to section 63 of the Act, genetically engineered products will not be licensed if they are found to create social unsustainability (*soziale Unverträglichkeit)* (Seifert and Torgersen, 1997: 305). A genetically modified product cannot be placed on the market if commercialization will impose 'an unbalanced burden on society or on social groups' or impose unacceptable economic, social or moral costs (Seifert and Torgersen, 1997: 302). According to a member of the commission that conceptualized section 63, the aim was to permit Austria to cope with the prospect of structural social changes resulting from the introduction of new technologies (Seifert and Torgersen, 1997: 307). As analysts of the legislation Seifert and Torgersen (1997: 308, 309) have noted, although the notion of social sustainability was not given precise definition in the legislation, its use would clearly require reliance on *non-technical* criteria. Thus, unlike liberal scientific risk regulation or precaution-based risk regulation, this legislation dispenses with the illusion of objective or neutral criteria for regulation. Here, there is a frank admission that values matter in determining what kinds of technology to commercialize and under what conditions.

Although there was significant debate about genetic engineering in Austria in the 1980s, this dispute did not gain the attention of the larger public or the press. Representatives of industry and the research community supported liberal regulation based on a conventional scientific risk analysis model. Critics, including the Greens, argued in favor of more restrictive precautionary regulations. At the time, rDNA research and the possible release of GMOs in Austria were regulated by existing rules put in place for other purposes. With the establishment of a coalition government in 1990, the state, reflecting pressure from new social movement organizations and the widespread desire to have a biotechnology policy prior to entry into the EU, called for development of a uniform genetic engineering act attentive to social/cultural factors in Austria.

In 1991, the parliament voted unanimously to establish a parliamentary commission to explore the matter of technology assessment for the case of genetic engineering. The commission's report, issued late in 1992, 'demanded', according to one source, 'that *Sozialverträglichkeit* [social sustainability] be taken into consideration in addition to the ethical requirements and environmental impact' in the regulation of biotechnology (Seifert and Torgersen, 1997: 307). Notwithstanding industry opposition, this social sustainability orientation toward the regulation of ag-biotech remained in the final legislation, which became law on 1 January 1995.

As we suggest above, a discourse of social welfare protection is widespread in Europe and, certainly, *Sozialverträglichkeit* reflects that discourse. More concretely, according to Seifert and Torgersen, Austrian advocates of restrictive genetic engineering regulation took their cue from debates in Germany at the time, and the term *soziale Unverträglichkeit* (social unsustainability) comes from German social science discussion on the uses of nuclear energy in the late 1970s (Seifert and Torgersen, 1997: 308). Thus, proponents of social regulation clearly had a discursive legacy on which to draw. At the same time, while parliamentary systems can sometimes avoid the kinds of compromise required in the US's fragmented and permeable policy-making apparatus, inclusion of a commitment to restrict commercialization of socially unsustainable technology appears to have been part of a negotiated agreement. Members of the coalition government in favor of social regulation accepted more economically liberal regulation in other areas. Moreover, precautionary language figures in Austrian ag-biotech policy (Torgersen, 2002). Finally, as Seifert and Torgersen (1997: 310, 311, 314, 316, 320) have noted, at the time the Uniform Act was implemented, the term social sustainability lacked a precise definition making future regulatory use of the concept open to question. The absence of tightly crafted terms in the legislation reflects the relative lack of experience in Austria and elsewhere with the social regulation of technology.

Conclusion

There can be little doubt that the globalization of culture and economy as well as the emergence of supranational governance bodies has changed the ways in which national policies are made and implemented. However, our comparative analysis of ag-biotech policy should lead us to be circumspect about broad claims of convergence and homogeneity. Our cases suggest not a flattening of difference and convergence on a single model of regulation of ag-biotech, but instead a wide array of variation. There are, of course, cross-national differences in culture, history, and governance structure that produce diversity even as a single policy model (such as 'precaution') is implemented. Convergence theorists typically predict that such variety will diminish over time. However, we view this as unlikely because,

globally, there is not one, but multiple, models for constructing policies to address ag-biotech. Given the availability of alternative schemas for action, we do not predict convergence on a single, taken-for-granted governance model. In this context, countries do not settle on single models of regulation, but instead blend, in distinctive ways, the three basic approaches we have described.

While at some level, the US reflects the purest liberal science-based model, even that country, given its highly fragmented policy-making system, has struggled over the prospects of social regulation, and proposals for non-traditional alternatives to the current model remain in discussion at federal and state levels (Prakash and Kollman, 2003). China, by contrast, finds itself divided. The US approach is appealing to some Chinese regulatory bodies, but concerns for access to international markets have pushed China toward a more precautionary approach. Indeed, the motivation for China's regulatory position is clearly economic development. The country aims to use both liberal and precautionary science-based approaches as a form of social policy.

The precautionary principle underpins EU biotechnology regulation, but this orientation is blended with elements of social regulation. The nature of the mixing here reflects the fragmentation of policy-making as well as international pressures. Kenya, like the EU and reflecting the pressures of its Dutch patrons, is governed primarily by a precautionary perspective, but one also finds undercurrents of a social regulatory impulse there. Different still, India balances the divergent orientations of its regulatory bodies and the pressures of the field of national political interests, mixing precaution and liberal science-based regulation. Finally, in Europe, we find Austria with its own very distinctive 'brand' of ag-biotech regulation. A coalition government pushed through an unambiguously socially based legislation, but the entire regulatory system is inflected with liberal economic and precautionary elements.

While any general conclusions we might draw based on an analysis of one policy domain must be limited, our discussion should at least make analysts circumspect about making grand claims about the convergence of science and technology policies across the globe. Put simply and briefly, convergence analysts are certainly on to something in stressing the cultural hegemony of science, but the discursive terrain for science policy-making, while perhaps dominated by 'science', is not monolithic. Social regulation of biotechnology, while by no means typical, stands in contrast to the dominant science-based approaches in a variety of contexts. Furthermore, even where 'science' shapes biotechnology policy, it doesn't do so in a singular uniform way. At the simplest level, we illustrate cases of liberal risk regulation and the precautionary approach, both of which are premised on 'science'. These approaches to regulation are different and have divergent impacts on what kinds of technologies can be developed and commercialized. Thus, it is a mistake to flatten the differences between conventional, liberal risk-based assessment and the precautionary approach by terming them both 'scientific'.

Convergence oriented approaches do remind us that in an increasingly interconnected world cases are not independent. But this does not necessarily mean that cultures and policies worldwide are converging. Indeed, science policies are crafted in environments where ideas circulate widely. They are not generated or reproduced in isolated places. Furthermore, in a global environment, pressures from powerful entities (e.g. the US and the WTO) can influence the less powerful and the demands of markets in one region can affect policy in another. Thus, if we must be cautious about making claims about policy convergence, equally, comparative approaches premised on the independence and equivalence of cases are not appropriate either (Skocpol, 1984; cf. Sewell, 1996). Instead, if the global environment in which policy-making takes place today is not homogenous and monolithic, but diverse, complicated, and contradictory, we need comparative analyses that are not rigid and formalistic, but sensitive to a wide variety of actors internal and external to policy-making entities where the ultimate goal is understanding the causes and character of variation. We hope our discussion has contributed to such an understanding.

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Notes

1. These international bodies include: Codex Alimentarius for food safety standards; International Plant Protection Convention (IPPC) for plant health standards and Office of International Epizooties (OIE) for animal health standards. The WTO's overview of the SPS Agreement is available at <http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm>, last acessed on 15 May 2009.
2. This provision is much weaker than earlier proposals on social regulation put forward during negotiations of the Protocol (Kleinman and Kinchy, 2007), and indeed, the punch of Article 26 is open to question, since it includes a statement that any social regulation must be consistent with international obligations, and members of the WTO are prohibited from regulating GMOs on non-scientific grounds. At the same time, some analysts are optimistic about the provision's likely efficacy (McAfee, 2003).
3. It is important to note, as one reviewer of this paper suggested, that while it is possible to sketch the basic contours of liberal scientific risk-based regulation, this approach is applied differently in different contexts. Indeed, it is even possible to imagine this approach to regulation being used toward social ends (see Note 4 below).
4. As one reviewer of this paper pointed out, our typology notwithstanding, under some circumstances, liberal risk-based

regulation can be viewed as a mode of social regulation. As this reviewer suggests, in the Chinese case, liberal science-based regulatory policy might be viewed as a mechanism to promote economic development, and this could lead us to characterize it as a social policy.

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