

Managing Trade in Products of Biotechnology—Which Alternative to Choose: Science or Politics?

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Biotechnology has triggered a spirited debate about how to assess risks, what rules to use, and where to vest the authority to decide. Post World War II, there has been a strong move to normalize and institutionalize a 'science-informed' system in international science and trade treaties. Recently there has been a pushback against the privileged role science institutions play in decision-making, especially regarding genetically modified crops. Some countries have tried to use legal derogations in institutions such as the World Trade Organization, while others have attempted to construct and implement competing power systems, mostly revolving around the Convention on Biological Diversity to supplement or replace science-informed decision-making with socio-economic considerations. Neither effort has been entirely satisfactory. The Americas generally follow the science-based regulatory framework, while Europe and Africa at times pursue a socio-economic-based regulatory framework. We assess the underlying information, valuation, and selection rules involved in the battle between 'science-informed' decision-making and rules incorporating socio-economic considerations in global agri-food trade, concluding that a generally accepted comprehensive approach to the regulation of products of biotechnology is unlikely in the foreseeable future.

Key words: GM crops and products, governance, international trade, knowledge management, science-based regulation.

Introduction

The development of genetically modified (GM) crops began in the 1980s, and the first GM products rolled out into the market in the mid-1990s with little or no consumer debate. As the products of science, they simply slipstreamed into the science-based international regulatory regime, with scientists largely filling in the missing pieces in the system. Even in Europe, products labelled as GM were leading sellers (Krebs, 2000). As the decade progressed, new voices with new concerns were heard, but they found little or no room in the science-based system for their views to be represented (Kerr, 2010). In response, some opponents and their governments attempted to find ways to broaden the scope of the scientific base that would be considered in product evaluations, using a variety of clauses in national legislation and international treaties such as the World Trade Organization (WTO), but often found that those systems could not fully incorporate their concerns. In response, there was an effort led by the European Union (EU) to develop complementary regulatory and treaty systems that would add an additional socio-economic filter to new product reviews. While some of these processes were incorporated into domestic law, the strong push throughout the 1990s and into this past decade was to

develop new international treaties that could complement or, at times, supplant the science-based approach with a broader set of perspectives and actors. Now, in 2013, we are faced with two parallel systems that acknowledge their differences and have at least accepted that duelling systems may not achieve either the efficiency of science-based review or the reflexivity of socio-economic consideration.

This article examines the task of defining what is acceptable, what rules we should draw, and where we should vest the authority to decide. Over the past few generations there has been a strong move to normalize and institutionalize a 'science-based' (or more accurately 'science-informed') system in international treaties, which offers a set of processes and experiences we can assess and consider. Meanwhile, the effort to construct a complementary or competing system based on socio-economic considerations is less developed. The authority to undertake such efforts is now embedded in a range of institutions, but the norms, practices, principles, and institutions that will deliver authoritative and repeatable evidence are not yet in place. In this article we use Ostrom's (2005) institutional analysis and development (IAD) framework to animate our institutional

analysis. This approach begins with the assumption that decision systems define the scope and way that relevant information is agglomerated, explicitly identify the normative value placed on that knowledge, and lay out the process of selecting a pathway of management in the context of constraints (e.g., a budget constraint or bounded rationality). Ultimately, this framework offers an approach to unpack the processes into multiple layers. We apply the framework to assess the underlying information, valuation, and selection rules involved in the battle between ‘science-informed’ decision-making and decisions informed by socio-economic considerations.

Next, the article offers a review of the evolution and state of understanding of the alternate and increasingly competitive decision-making systems, followed by a presentation of Ostrom’s IAD framework and how it is adapted to this area of analysis. The next section examines the history and evidence in the areas of science-based regulation and socio-economic considerations. Then, the article provides an assessment of the complexity of the international regulatory and trade environment in the face of the two competing paths. The article closes with some concluding thoughts and policy recommendations.

Background

In many ways, the agricultural biotechnology industry is at the leading edge of the battle between our largely modernist economy and society and the postmodernist critique (Kuntz, 2012). As a product of deductive, reductionist, corporate science, GM crops are in many ways the natural conclusion of more than 150 years of increasingly programmed, organized, and managed scientific advancement, where the universities, industry, and governments have collaborated to generate ‘progress’ in the name of and for their citizens and consumers. While there is much one might criticize about our modern economy and society, proponents of modernism can fairly assert that this power system has, for the majority of the world’s population, created unprecedented wealth and quality of life.

Most of the regulatory and governance systems and sub-systems erected in Organisation for Economic Cooperation and Development (OECD) countries accept and build upon the notion of economic and social progress as the ultimate goal of society. In the extreme, critics argue that the modernist enterprise represents a meta-narrative that asserts that humankind can and should discover ‘objective truths’ through scientific dis-

covery and apply those advances to increase the aggregate wealth of mankind (Lyotard, 1979/1984).

As early as 1870, at the height of the second industrial revolution, one can see the stirrings of a counter-revolution that challenged the notion of objective truth. A wide range of critics of modernism assert that all apparent realities are simply social constructs, reflecting the power relations of their time. What started as a critique of art, culture, and social structures has now evolved into an all-out critique of the structures and artifacts of modernism, including the systems that generate and govern the products of agricultural biotechnology.

While the modernist, scientifically-based system has continued to add to and refine its understanding of science and its uses, the postmodernist counter-revolution has worked to define and develop an alternate power system for adjudicating what should be done and by whom. The modernist science-based industrial and regulatory system accepts as given the power system and the norm of progress, then focuses on further modularizing the knowledge they believe is needed to optimize progress. Most of our existing national and international scientific and regulatory structures—such as the risk analysis framework that all OECD countries have embedded in their national regulatory systems, the specialty technical agencies of the United Nations (e.g., the International Plant Protection Convention [IPPC], the World Organization for Animal Health [OIE], World Health Organization [WHO], Food and Agriculture Organization [FAO], and Codex Alimentarius), the international trade regime (e.g., the WTO and its sub-agreements, World Intellectual Property Organization [WIPO], and regional trade agreements such as the European Union and North American Free Trade Agreement [NAFTA]), and the OECD itself—accept these norms and principles and, for the most part, operate as if they are unaware or at least uninterested in their critics’ desire for a more reflexive, open, and flexible range of decision-making systems and outcomes.

Postmodernists have worked both within the existing system and to create new systems to develop alternative decision-making rules. In the context of existing systems, there have been efforts to exercise the powers of derogation to make decisions that deviate from the central tendency of scientific justification and economic efficiency. In some cases this works; most often it is not effective.

As noted, governance and regulation of GM crops is a key ground for this battle. Both modernists and postmodernists acknowledge that transformative technological innovations like GM crops exhibit a range of the

attributes that challenge our ability to fully address all of the resulting questions in existing systems. A few elements of transformative technologies stand out. Transformative technologies involve disjointed, step adjustments in our productive and institutional capacity by displacing, destabilizing, or overturning precursor systems. In technical terms, they often are driven by new epistemologies, they offer significant complementarities (within and across sectors), and they tend to involve recombined or hybrid technologies (one might actually label them convergent technologies). Furthermore, although they often emerge wrapped in an optimistic fervor, they are hard to anticipate because they infiltrate and influence multiple sectors, markets, and domains over a long and variable timeline—in spite of the rhetoric, none of the identified technologies overwhelms society quickly. This makes it difficult to manage or govern them through established markets or authorities. The nebulous nature of transformative technology creates uncertainty, which tends to generate debate and controversy (Phillips, 2007).

These types of technologies not only challenge the modernist architecture for science, regulation, and intellectual property rights, they also open the door to new actors with new questions and new values, interests, and beliefs. In short, there is both criticism and competition within and between the modernist and postmodernist camps.

The modernist enterprise is well advanced in its efforts. The emergence of the WTO in 1995 provides a clear and unambiguous venue for advancing the science-based system. The WTO—and the earlier General Agreement on Tariffs and Trade (GATT)—is explicitly focused on optimizing economic welfare through trade, by implication, and design-minimizing international restrictions on trade in products of science and technology. The principles-based GATT has always allowed limited derogations based on a relatively wide range of ‘legitimate objectives’ (such as market making [Art. XI] and health, safety, morality, and protection of the environment [Art. XXb]), provided they accord with the principles of non-discrimination (Art. I, MFN clause) and national treatment (Art. III). Formal incorporation of the Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) sub-agreements into the WTO in 1995 appears to have closed most of the more aggressive derogations. Three key panel decisions related to SPS measures confirmed the limited scope for derogations—the EU hormones case (Kerr & Hobbs, 2005), the Australian salmon case, and the Japanese agricultural products case (Buckingham & Phillips, 2001). In

all three cases, a contested domestic SPS measure was struck down on the basis that there was no risk assessment completed to support the SPS measure, or the risk assessment was improperly done. This recognition of the pivotal importance of a proper science-based assessment is noteworthy. The salmon case decision in particular set out three key criteria for a ‘proper’ risk assessment: (1) it must identify the diseases whose entry, establishment, or spread a member wants to prevent within its territory, as well as the potential biological and economic consequences associated with the entry or spread of these diseases; (2) it must evaluate the likelihood of the entry, establishment, or spread of these diseases, as well as the potential biological and economic consequences of failing to prevent introduction; and (3) it must evaluate the likelihood of the entry or spread of these diseases according to the SPS measures that might be applied (WTO, 1998). If a risk assessment does not even refer to the SPS measure, it is doomed to failure before a WTO Panel. In short, nations that tested the new rules have discovered that while dispute settlement rulings accept derogations for legitimate objectives, they are very narrow in terms of their scale, scope, duration, and flexibility. Even where derogations are allowed, the strict rules of science and economics govern their application, which simply confirms the post-modernist assertion that these systems are more about power than universal truth.

Overall, the scientifically-informed economic model underpinning the WTO—which predicts and offers remedies only for cases where producers seek protection in search of economic rents—is unable to accommodate the demand of consumers, citizens, and belief-based non-governmental organizations (NGOs) who are seeking protection from, or control over, the decision-making system (Perdikis & Kerr, 1999).

To many, ‘science’ is simply not working. In the absence of any agreement on what makes a ‘scientific consensus,’¹ it is not clear when there is enough science. In that context, simply filling in Kuhn’s unknown-unknowns (i.e., where we either have known theory or evidence, but not both) will not satisfy postmodernists, as they assert paradigms are simply reflections of the prevailing power systems and not ultimate truths.

Those unwilling to simply continue the slow, patient work of filling in the unknowns fall into two camps. Some want a whole new set of rules that reflect new

1. Kuhn (1970) called consensus a ‘paradigm’ that incorporates known theories and known evidence, or his known-knowns.

norms, while others simply want a way to pause the process for a while. Both camps have looked to use the emerging norm of ‘precaution’ as a way to achieve a different outcome. All countries have some form of precautionary approach—either formally articulated or informally used—that enables them to delay or suspend judgment on a product that is suspected to pose unacceptable risks. The first articulation of precaution was in the World Charter for Nature in 1982. Since that time, the policy has been expressed in numerous national and international regulatory systems. Principle 15 of the 1992 Rio Declaration on the Environment and Development (United Nations Environment Programme [UNEP], 1992) states that

“(i)n order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”

The Commission of European Communities offered guidelines for using its version in a politically transparent manner:

“measures...must not be disproportionate to the desired level of protection and must not aim at zero risk.... Comparable situations should not be treated differently and...different situations should not be treated in the same way; unless there are objective grounds for doing so,...measures...should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available.... The measures must be of a provisional nature pending the availability of more reliable scientific data.... Scientific research shall be continued with a view to obtaining more complete data” (European Commission, 2000, p. 19-21).

While Canada and the United States reject the Convention on Biological Diversity (CBD) and EU conceptions of the precautionary principle (which they argue has been used to delay decisions excessively), they both have precaution as a guiding principle in their assessment systems. The difference would appear to be more in tenor and intent rather than general principles.

Those who want a more permanent change in the power system are seeking to place socio-economic considerations (SECs) at the center of other venues. As noted, WTO Articles XI and XXb and the SPS and TBT Agreements offer venues for further elaboration, albeit limited. Some assert that the scope for SECs is not fully tested. For example, the WTO’s goal is not “trade at any cost”; the preamble of the Marrakesh Agreement Establishing the World Trade Organization (1994) affirms “...the objective of sustainable development, seeking both to protect and preserve the environment....” How this might play out in the case of a dispute explicitly involving socio-economic considerations for GM crops has yet to be tested. It is not clear what flexibilities and policy space are available in the sub-agreements in particular. Risk assessment under the SPS Agreement, for example, already involves a mix of scientific and economic considerations. Article 5.3 of the SPS Agreement provides that in assessing risks to animals and plants,

“Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks” (Article 5.3).

In the meantime, other venues have emerged where socio-economic considerations are accepted and may become more influential than science in determining decisions. Article 8(j) of the CBD directs parties to consider traditional knowledge from a range of perspectives, which is then embodied and amplified in Articles 9 (farmers rights) and 13 (benefits sharing) in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR). More recently, Article 26(1) of the Cartagena Protocol on Biosafety (CPB) directs that member states may assess the impact on the conservation and sustainable use of biological diversity arising from the first transboundary movement, handling, and use of a living modified organism (LMO); the impact analysis may include the potential effects on biological diversity, which may include social or economic considerations. Article 26(1) also specifically mentions that the ‘value’ of biological diversity to indigenous and local communities may be considered, which links to Article 8(j) of the CBD and the ITPGR and could involve intrinsic valuation of knowledge, innovations, and practices of indigenous and local communities

embodying traditional lifestyles. These venues have all created space for SECs to be addressed but have yet to specifically discuss how they might create some norms and rules to use the quite diverse set of socio-economic methods. In April 2011, the CPB sponsored an online dialogue that highlighted the gap between the aspirations and realities of those seeking more formal SEC consideration.² A forthcoming edited volume (Ludlow, Smyth & Falck-Zepeda, forthcoming) will explore the dimensions the SEC challenge.

One feature so far not fully explored is the potential impact of poorly designed and structured rules based on SECs. We know from past experience in the trade world that when trade rules are poorly structured and adjudicated, private firms often find a way to extract an economic rent from the resulting market imperfections (Krueger, 1974). There is a real risk that firms or other rent-seeking actors will similarly use poorly operating systems based on SECs to extract a rent, with the likely outcome that both the economy and society will be poorer as a result.

Institutional Analysis and Development Framework

Elinor Ostrom's institutional analysis and development (IAD) framework can be used to explain the institutional underpinnings of many complex problems faced in today's world. The IAD framework helps to separate the nested layers of organizational environment, rules, actors, and outcomes in governance systems. The framework focuses on more than just the organizations; it also directs how one might interpret interactions between and among actors and the institutional rules and norms that govern their exchanges, thereby offering insight into the behavioral underpinnings of many developments. Importantly, the IAD framework accepts that interactions can be simple or complex. While some critics are concerned that this adds to the already complex and dynamic picture of institutional analysis, applied consistently it can help resolve much of the complexity surrounding any given problem without resorting to the reductionist simplification of many other approaches.

The IAD framework offers a systems approach to policy processes, specifically focusing on inputs, decision-makers, outputs, outcomes, evaluative criteria, and feedback effects. Ostrom argues that any complex sys-

tem can be viewed as being composed of sub-systems (she calls them 'holons') that interact with an overarching system. Each sub-system

“can be ‘dissected’ into its constituent branches on which the holons represent the nodes of the tree, and the lines connecting them the channels of communication, control, or transportation” (Ostrom, 2005, p. 12).

While this notion of nearly decomposable complex sub-systems has been around since Simon (1955), the IAD framework advances the approach by more clearly articulating the constituent parts and offering a framing for understanding how the components integrate into the meta-system. The approach reveals that many interactions within and across the sub-systems occur simultaneously and at multiple levels. The IAD framework therefore provides analysts the luxury of either analyzing the system as a composite or to focus on selected sub-systems independently or jointly. This very flexibility highlights the importance of the exogenous variables, the action arenas, and the rules and linkages between them.

The IAD framework helps to frame and interrogate the possibilities of polycentric governance—what McGinnis (2011, p. 171) defines as a system “in which authorities from overlapping jurisdictions (or centers of authority) interact to determine the conditions under which these authorities, as well as the citizens subject to these jurisdictional units, are authorized to act as well as the constraints put upon their activities for public purposes.” Most theories posit that knowledge-based economies, such as agbiotech, rely on polycentric systems of governance (e.g., Leydesdorff & Etzkowitz, 1998; Lundvall, 1992; Nelson, 1993; Porter, 1990). The IAD supports the analyses of these systems by targeting attention on the forces which exert influence on each sub-system and, in turn, on the overall system. In the context of research-based innovation systems, multi-sectoral and multi-functional polycentric governance dominate.

At its most basic level, the IAD framework consists of three elements: 1) exogenous variables, 2) an action arena, and 3) the interactions that generate outputs and outcomes (Figure 1). Ostrom defines exogenous variables to include biophysical or material conditions (e.g., the physical and biological constraints and challenges in different growing regions), attributes of community (e.g., the industrial structure and political systems governing agriculture), and rules (e.g., the overarching legal and institutional norms and practices that delimit

2. Discussions can be found at http://bch.cbd.int/protocol/cpb_art26/discussiongroups_se.shtml.

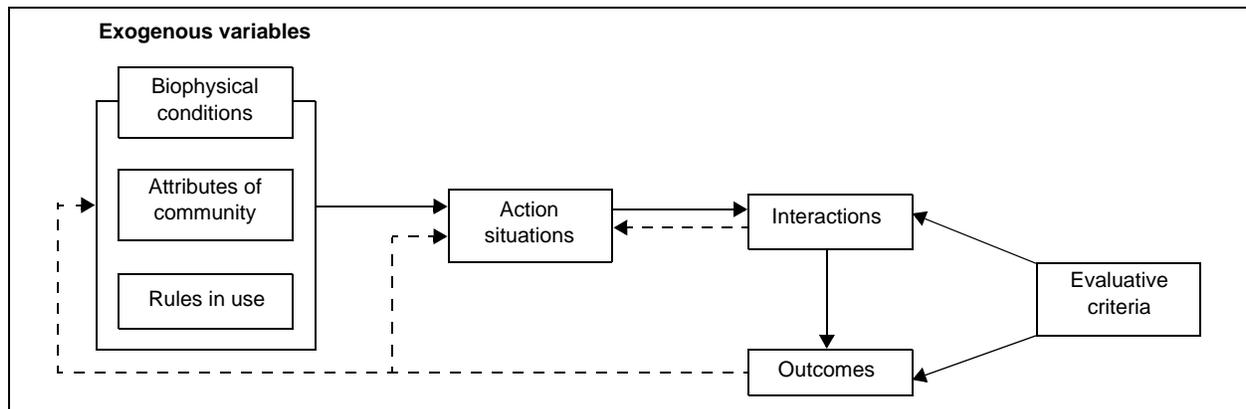


Figure 1. Components of the IAD framework.

Source: Ostrom (2005, p. 15)

choices). The action arena is composed of action situations and participants—variously defining problems, issues, policy areas, and networks or communities of individuals and organizations. Stone (1989) asserts that action areas are not so much found but rather constructed through causal stories. Interactions between action arenas and exogenous variables determine the outputs and outcomes, which are evaluated using criteria adapted from external systems or developed explicitly for the circumstances. Outcomes are continuously fed back onto the action arenas (and at times change the exogenous factors), which results in on-going transformations in the system (either at the level of the holons or sub-systems or at the more comprehensive system level). In this way, each of these variables are connected to each other, which leads to extensive learning-by-doing and change.

A New Intellectual Architecture?

Risk management is fundamentally the result of a nested set of sub-systems. While one can find an almost infinite number of sub-systems or holons, for the sake of this argument we start with the attribution and assignment of ownership—through both formal (codified) and informal (community-based) intellectual property rights—and then examine the engaged and latent sub-systems that can or could be part of delivering effective, efficient, and reflexive decisions on the introduction and use of new products of biotechnology.

Each holon can be framed by asking the basic journalistic questions—Who? What? Where? When? Why? How?

As for *who*, one basic assumption accepted by many is that governments are the only legitimate authoritative

actors in the field of risk analysis. While that may be true at times, there is ample evidence that sub-systems operating in the risk analysis framework are sometimes led or dominated by firms and a range of civil authorities—some are strongly values driven, some are fundamentally interests-based, and some primarily focus on enforcing epistemological norms (Phillips, 2007). In the context of GM foods, the epistemic civil authorities command key parts of the system. Epistemic communities have recognized expertise and competence in a particular domain and an authoritative claim to specific knowledge within that domain or issue area. These communities and their members have a shared set of normative and principled assumptions, shared causal beliefs, shared notions of weighing and validating knowledge in the domain, a shared technical vocabulary, and a common set of practices associated with a specific set of problems (Haas, 1992). Most epistemic communities in this area span international boundaries and have representatives in industry, government, and many other civil authorities. Unlike values-based social movements and interest-based groups (both of which often do not share causal beliefs), epistemic communities organized around disciplines or in professions share a set of causal understandings and a consensual knowledge base, but do not share principled beliefs or interests (which are the unifying feature of social movements and interest groups). For the same reason, epistemic communities do not cohabitate easily with markets or the state—their foundational commitment to a set of causal principles and consensual knowledge is inconsistent with the practical politics of legislators and bureaucratic agencies or the self-interested nature of market actors (Jasanoff, 1990). Nevertheless, epistemic communities are vital actors in the identification of what is known and

unknown about new technologies, how to evaluate the impact of a new technology, and the technical options for filling in our knowledge gaps. They are not, however, able to authoritatively define the boundaries of what is acceptable risk—that is inherently a political process, involving balancing of goods and harms (Raybould, 2012).

As for *what* gets normalized, natural scientists and risk analysis experts have developed a language and a common set of concepts, methods, and processes to address the science. With the advent of genomics, molecular biology, and an ever-expanding list of ‘omics,’ scientists have gone a long way to defining the structure of biological matter (using the four base pairs of AC and GT, chemistry, and proteomics to almost uniquely identify sources and functions of genes). At the same time, the regulatory community—involving many leading scientists—have worked within nations and at the international level to scope out the structure and function of the risk analysis framework (RAF) used to assess the products of this science (e.g., the Red, Blue, and Orange Books; National Research Council, 1983, 1994, & 1996) and then standardize it through international standards (e.g., OECD, 2005). The scientific and regulatory community has also developed a range of methods and mechanical tests to validate the presence and effect of specific traits—e.g., the western immunoblot analysis, mass spectral analysis, segregation analyses, Southern blot analysis, in-vitro fate studies, glycosylation, and enzyme-linked immunosorbent assays (ELISAs)—which have then been standardized in the academic literature and in international standards and normalized through multi-party ring-tests. The language, concepts, methods, and processes related to socio-economic considerations, in contrast, has not undergone such extensive normalization. While different fields will assert that there are strong norms with central tendencies, the simple diversity of approaches—ranging from deductive, experimental, highly-stylized social sciences (such as empirical economics) to inductive, discourse-driven humanist analysis—ensures that across the SEC space there is no central tendency. Who you ask and what you ask will determine the answer more often than not.

We have already discussed the *where* in some detail above. To some extent we are faced with a ‘forum shopping’ problem, with disputants choosing the venue based on what members it has, what evidence it accepts, and what it is attempting to optimize. Firms and scientists focused on commercialization generally look first to the science-based risk analysis systems operating in

many OECD countries as the primary source of evaluation and then rely on the science-informed decision-making in the international trade regime to backstop those decisions (e.g., in the NAFTA and WTO). Those seeking to optimize reflexivity, as discussed, have attempted to use the precautionary provisions in the RAF and derogations for legitimate objectives in the international trade system but, for the most part, have found more positive responses by working to frame many of the new international treaties to incorporate SEC at their core (e.g., CBD, CPB, ITPGR, and Kyoto Protocol).

The *when* is complicated, as transformative technologies deliver unpredictable results in often unexpected ways. Given that the emergence of new technologies is driven almost entirely by market proponents, even highly anticipated products may often be delayed due to market volatility or incomprehensible dynamics within firms. Most of the time, regulators and the broader community are unaware of the basic and applied research being done inside firms until a candidate product is almost ready for commercialization. Thus, it is very difficult to anticipate the issues and position the regulatory effort and social debate to address SECs before products emerge. This poses significant problems, as firms by then have sunk significant financial and strategic resources in the development of a product. The science-based, modernist compromise is that as long as something is ‘safe enough,’ regulators will allow new products to enter the market. Firms then are responsible for handling any resulting socio-economic considerations. While some firms have attempted to anticipate the social response to their offerings by operating ethics boards and industry advisory groups, these efforts have had mixed success. Monsanto, for example, as early as the mid-1980s worked with key NGOs and farmer groups to solicit their views and concerns about different GM crops, but still was roundly vilified when it introduced Roundup Ready soybeans and canola and Bt-resistant corn in 1995.

One thorny question that is often not asked is *why* do we care? Some modernists simply seek to ensure new products do not harm people or the environment. Others have broader goals, seeking to direct technological innovation to avoid (or achieve) general or specific socio-economic outcomes, such as enriching industrialized agriculture. Some engaged in the dialogue about regulation of GM foods simply see this as a good battleground for advancing their postmodernist agenda. The logic is that it is much easier to forestall the introduction of something we have not yet accommodated into our life-

style than to get people to give up something they already use and value. Given the diversity of goals, one can see that most disputants are likely to be dissatisfied, regardless of the outcome—values, beliefs, and interests do not converge or even overlap much.

The *how* warrants some further discussion. In one sense, ‘how’ helps to unpack a range of holons or sub-systems, where different participants act purposefully in narrow, specific action arenas, facing different exogenous variables, developing and using different evaluative criteria, and delivering different discrete outcomes that either support or undercut the RAF and the related science-informed governance system. Six specific holons or sub-systems present opportunities to refine or develop a new intellectual architecture for GM foods: nationalized regulation and governance; development of international specialized expertise; industry-based management; intergovernmental negotiation; references to ‘wise men’; and the development of case law through litigation and dispute settlement. One could imagine some of all of these holons engaging at various times in an effort to complete or renew the overall system.

Nationalized Regulation and Governance

In absence of evidence of credible efforts by others to develop norms, rules, and processes to handle scientific and socio-economic considerations, the state will need to respond. This has already happened in most nations developing, producing, and trading the products of GMOs. According to ISAAA, in 2013, the 17th year of commercialization of biotech crops, total accumulated area from 1996 to 2012 exceeded 1.5 billion hectares. About 30 countries planted biotech crops in 2012—the top 11 countries each grew more than million hectares, and for the first time, more than half of the crop area was in developing countries (James, 2013).

In one way or another, each of the states that is producing or importing biotechnology has developed some form of regulation and governance related to the introduction, cultivation, export, import, or use of the products. Given the close links between the scientific and regulatory epistemic communities, even radically different governments and countries are likely to adapt and adopt many elements of the language, methods, and processes that have been internationalized through the efforts of the major players (e.g., the United States and European Union), the international governmental organizations (e.g., the WTO, OECD, and Codex Alimentarius), and the science community itself (e.g., through scientific consensus reports commissioned by the US

National Academy of Science, FAO, WHO, OECD, Royal Society, and Third World Academy of Science and through hands-on extension by the Consultative Group on International Agricultural Research [CGIAR] system and its centers).

In one sense, this is not a bad place to start. Many regulatory and governance innovations in the past have come from national and sub-national action arenas, where many variables that hold up international negotiations are for all intents and purposes exogenous, allowing actors to interact relatively easily—often in close-knit communities—to develop rules that deliver appropriate outcomes in the local system. In the absence of trade, this could be optimal.

Problems can and will emerge where trade can and should exist (based on comparative advantages). Different rules, which can be locally optimal, may erect barriers to trade, which—all other things being equal—will often generate economic rents that can be exploited. Rent-seeking has been demonstrated by Bhagwati (1982), Laband and Sophocleus (1988), and others to create major distortions in an economy and dissipate non-trivial parts of an economy in wasteful activities or to contribute to a culture of cronyism and corruption.

Development of Expertise in Specialized Institutions

One alternative to having every nation state work independently to develop its own rules and systems is to do that work collectively in the context of one of the many specialized international science or regulatory agencies. This effort could come without any reference to national policies and rules, but in most cases there is an effort to build upon national competence to develop new, purpose-built international rules and structures to manage safety and trade.

This work tends to be most successful when the action arena is narrowly controlled, with participants drawn from a narrow range of epistemic communities. In that way, the process is able to effectively exogenize many of the views and perspectives that would make it difficult to reach consensus.

There are a wide range of efforts that have done just this. The OECD, for example, has taken the initiative to develop Consensus Documents that comprise technical information for use during the regulatory assessment of products of biotechnology and are mutually recognized among OECD Member countries. To date, 54 Consensus Documents have been developed; in 2013, 44 remained current and operational. They focus on the

biology of organisms (in 2013, there were 15 for plants, 12 for trees, and a number for micro-organisms), introduced novel traits (in 2013, they related to the five most common introduced traits), and various facilitating norms. Meanwhile, industry standards (either brands or collective criteria as encompassed in International Standards Organization [ISO] or Hazard Analysis and Critical Control Points [HACCP] systems) can also provide a starting point for international standards. Standards from Codex, the OIE, and the IPPC have at times been used to build up a basic agreed text of acceptable measures. The usual process is for bilateral talks between major producer and consumer nations to arrive at a common standard, which is then put forward as an international standard for harmonization.

While practical, this ‘patchwork’ approach (which defers to specialization) presents certain problems. Some issues are not immediately taken up by any institution (take, for example, socio-economic considerations). Moreover, it is never clear what to do when there is inadequate data; one of the biggest challenges of current science-based processes is that there is often a lack of scientific data upon which to base new standards. Moreover, there is simply no objective way to decide how to deal with scientific uncertainty about the long-term effects on human health or the environment.

Industry-based Management

One response to slow development of national and international rules has been for the companies or parts of the biotechnology industry to implement self-regulation to maintain market access. There are a number of cases where parts of the agri-food industry have developed systems to deliver products with higher standards than domestic or even international minimum standards. The red meats industry in Australia (Spriggs & Isaac, 2001); the canola industry in Canada (Gray, Malla, & Phillips, 2006; Phillips & Smyth, 2004); retailers and processors in the EU, North America, and Asia (Phillips & McNeill, 2002); and the corn industry in the United States have all adopted private standards at one time or another in the recent past. Over time, private standards—supplemented by HACCP protocols or ISO ratings (particularly 9000 and 14000 series)—could supplement or replace public regulation. In order to address market demands, new physical and organizational infrastructure to achieve separability and traceability may be required. Already, the ISO has developed new eco-labeling standards (ISO 14020 and ISO 14024) and has presented industry with the opportunity to use

the standards as a way to avoid environmental challenges to their products introduced into domestic or foreign markets.

This approach is underdeveloped at present but represents an interesting possibility for industry to avoid regulation by developing its own standards that will ensure regulatory and market acceptance of their products. A major advantage is that such an approach would not require industry to bite off large chunks of the regulatory apple. Instead, problems can be resolved in bite-sized pieces as problems and opportunities are identified.

Intergovernmental Negotiation

In the past, once nations have structured their own internal systems (as discussed above) and have begun to trade, there has been a tendency of either industry or governments to seek ways to ‘level the playing field’ in the international marketplace. Perhaps it is time to go back into the past and adopt pre-existing approaches to this new technology. A number of negotiation approaches have been used successfully in the past. The main action arena in the past has been the GATT/WTO, which at its root has a few core principles that drive all of the activities. Essentially, the trade system establishes a number of overarching principles by which all specific measures and commitments are managed. The most-favored-nation (MFN) principle (Article 1 in GATT, Article 2 in the General Agreement on Trade in Services [GATS], and Article 4 in Trade-Related Aspects of Intellectual Property Rights [TRIPS]) establishes that countries cannot normally discriminate between their trading partners—any concessions granted to one Member (such as a lower customs duty rate for one of their products) must be provided to all WTO members (Article 3 of GATT, Article 17 of GATS, and Article 3 of TRIPS). Other important principles include the ‘like products’ provision, whereby similar products should be treated the same, and the pervasive commitment to transparency in all trade-related measures.

In the early rounds of GATT negotiations, the process was predominantly one of reciprocal negotiating related to key issues and key markets. A country made bids and offers with key traders to liberalize specific areas; once bilateral agreements were set, they were multilateralized through the MFN principle. In this way, the negotiations focused on those trade issues that had the greatest commercial importance. This strategy would entail those countries producing and exporting the bulk of the GM crops (the United States, Brazil,

Argentina, and Canada) engaging in narrowly-based negotiations with the key importers (the EU and Japan) related to a handful of GM crops—soybeans, corn, cotton, and canola. The strong reciprocity of interests in continued international trade in those products among those countries would improve the likelihood of success.

When the number of GATT Members expanded, a second negotiating approach was added. Instead of simply negotiating for each issue, tariff, or product, negotiating groups would adopt formulae for dealing with a wide range of measures. One approach, first adopted in the Kennedy Round (1963-1967) was to negotiate a formula for cutting tariffs (called the Swiss formula) whereby tariffs were bundled into four bands, and higher cuts were assessed for higher tariffs (Reinert, Rajan, Glass, & Davis, 2009). The Uruguay Round of negotiations introduced and implemented two new approaches. First, they created a practical system to convert non-tariff measures (such as quotas) into tariffs. Then they adopted a traffic-light analogy to rank policies in the agri-food talks. Green-box domestic or trade policies were deemed to be minimally trade distorting and excluded from domestic support reduction commitments (this generally included policies dealing with research, extension, inspection, and grading; environmental or conservation programs; disaster relief; crop insurance; domestic food assistance; food security stocks; structural adjustment programs; direct payments not linked to production; and export market promotion). Amber-box policies such as market price support, payments related to current production, or prices and input subsidies were subject to careful review and binding reduction over time. Blue-box policies (e.g., acceptable, but temporary, or transition policies such as payments under production-limiting programs that with further reforms could turn Green) were bound and targeted for transition. Red-box policies were prohibited and were to be immediately withdrawn.

Each of these previous attempts to innovate new negotiating processes has been the result of shifting action arenas, adding new actors with new interests, and occasionally by forcefully interjecting new norms and concepts. The shift from the bid-and-ask system to formulas and analogies came when membership in the GATT swelled from a dozen or so members to more than 60 in 1963; the WTO had 159 members in 2013. The relatively closed shop of lawyers and trade diplomats was not the source of inspiration—rather, economists versed in mathematics and algebra showed how the insurmountable details could be agglomerated into

formula and then negotiated without explicit reference to specific measures, except as they involved exceptions. Similarly, the stop-light analogy came from a request to the scholarly academic community to offer suggestions on how to deal with the perennially thorny question of agri-food policy. The increasing globalization of the scholarly community—especially the introgression of mathematics and algebra as the common language and conceptual reasoning—provided the ultimate base for this breakthrough.

One risk of relying on issues-based negotiations is that they often focus on older issues and not on contemporary concerns. Furthermore, this approach can often isolate many of the recently mobilized developing nations and actors, which simply puts pressure on other forums.

Reference to ‘Eminent Persons’

In some cases there is a strong tendency to punt the ball to individuals or groups of ‘eminent persons’ to see if their knowledge and authority can develop something new and interject it into the policy dialogue. In the context of GM foods, the policy dialogue has been mostly a punting game, with few tries or even field goals. There have been two somewhat distinct approaches. Most governments have created or commissioned experts or epistemic groups to offer advice, while an increasing number have engaged in a range of ‘democratic engagement’ processes that seek to democratize the dialogue and engage a pluralist range of values, interests, and beliefs.

From the beginnings at the Asilomar Conference in 1975, where an informal group of industry, academic, and government scientists established a self-defined moratorium for genetic engineering, governments have looked to eminent persons or groups to help them clarify the knowledge base, frame the issues, scope out options, and provide advice on choices. Most governments have used formal or informal advisory councils, royal commissions, royal societies, academies, and other advisory commissions to examine and pontificate on some aspect of GM foods. The shelves are full of these reports. In most cases expert groups have provided expert advice, which is then often adapted and adopted into the regulatory and governance system. While quite valuable at times, few if any of these reports have offered much more than incremental, iterative advice on how to sustain, enhance, or extend the largely modernist, science-informed system.

The second approach has been to expand the scope of dialogue to include those without epistemic expertise. This has been done in two ways. First, some governments have reformulated their advisory structures to engage new actors. In Canada, for instance, the Government of Canada replaced its expert National Biotechnology Advisory Committee in 1999 with the more pluralist Canadian Biotechnology Advisory Committee, while in New Zealand a Royal Commission of Inquiry on Genetic Modification in 2001 engaged a mix of participants. The other approach has been to use a range of purpose-built processes to engage new actors. This effort was pioneered in the United States, where the National Institute of Health (NIH) brought together medical experts to assess the safety and efficacy of medical technologies and then was transformed by the Danish Board of Technology from an experts-only model into a mediated process that engages both experts and citizens (Einsiedel & Eastlick, 2000). A range of new models has emerged and been used to elicit new perspectives, including consensus conferences (e.g., in Canada and Denmark), ‘citizens’ juries (e.g., in France), focus groups, and public consultations (such as the UK GM Nation process in 2003; Wilsden & Willis, 2004). In most cases, the advice from both the advisory groups and the processes are acknowledged but are adopted and adapted in only rare circumstances. Most of the advice from these processes tends to be more nebulous and less specific, so it is harder to translate into policy and practice (Phillips, 2012). Those instances of clear concordance between the advice and government action—such as France’s proposed moratorium on GM food in 1999 following the report of a citizens’ jury that concluded GM foods were not desired—are usually examples of convergence of interests rather than true influence. The challenge is that democratic engagement action arenas are seldom, if ever, defined as authoritative venues for decision-making; instead, they are side shows that are used to amplify prior positions or to ignore if incompatible.

Disputes and Case Law

In absence of any action in any of the other action arenas, the binding dispute settlement mechanism (DSM) in the WTO offers one venue for states to engage in pushing the rules. The processes for handling trade disputes are, for the most part, in place at the WTO. The benefit of this approach for countries exporting GM crops is that it does not require further negotiations and is most likely to deliver pro-trade, science-informed,

and rules-based decisions. The decisions related to the SPS and TBT agreements noted earlier, combined with a recent DSM opinion related to the EU moratorium on GM food, have affirmed that the WTO will respond to cases when they are engaged, but that their decisions will be relatively narrow and focused on resolving the case at hand rather than broadly interpreting the treaty and its principles (WTO, 2008).

The case-by-case approach has some very serious drawbacks. Coverage of issues affecting biotechnology depends on cases actually being brought before the tribunals in question. The IPPC tribunal has heard no cases. WTO panels have heard cases on health and food safety issues but so far have not shown that they are equipped to deal with other thorny questions, such as how to balance environmental and socio-economic issues with trade concerns.

A number of other features, some practical and some systemic, make this approach problematic. First, there is the long-standing problem of unequal resources between developed and developing countries to bring a case (or several of them) before the WTO. Second, depending on the issues that member states would want to take forward to the dispute settlement system, it would take years to fully develop a body of law sufficient to regulate trade in GM products. Finally, even when decisions are clear and complete, states do not always comply with the WTO’s binding decisions (e.g., the EU has not complied with the panel ruling on the beef hormones case). At the end of the day, a losing party can side-step the consequences of a negative decision by paying compensation to the successful party. If such compensation is not forthcoming, the successful party can obtain an authorized suspension of trade benefits towards the losing party and enact trade sanctions. In the end, however, the importing country’s trade is not enhanced. Given the complexity and strongly held beliefs related to these cases, non-compliance is very possible, which could over time undermine the entire WTO system.

More fundamentally, the case-by-case approach can be attacked in that it is science-based, and there is currently no institution that can develop a concurrent case-law approach to deal with the outstanding socio-economic issues.

Parallel or Convergent Paths

We are now faced with the scenario where we have two parallel, or possibly still divergent, regulatory paths. The science-based or modernist path is led by the Americas and to a lesser extent the Austral-Asian region. The

socio-economic consideration or postmodern path is led by Europe and, through post-colonial connections, Africa. The postmodern path is not fundamentally about the safety of GM food consumption. If it were, no European would travel to North America, as this would require them to eat the food in North America. This is confirmed by a report to the European Commission (2011, p. 8) on socio-economic implications of GM crop production, which asserted that “[r]esponses given by consumers when prompted by questionnaires about GM-food are not a reliable guide to what they do when shopping in grocery stores. Europeans buy GM-foods when they are physically present on the shelves.”

Given that food and health safety are not the major concerns of postmodernists, the driver then has to be politics. It is not the political agenda of most average citizens/consumers, but the political agenda of narrow, focused special interest groups. These interest groups have entrenched interests with strong political agendas. Therefore, the question that dominates this topic is: can the world continue with two competing, parallel regulatory and trade paths, or will convergence occur?

It is conceivable that a dual regulatory approach could function for the next 10 to 20 years without creating substantial problems. The Americas and the Austral-Asian countries will continue to move forward with the commercialization of innovative agricultural technologies, and the European-African alliance will continue to fall further behind in terms of technological advancement. However, at some point the loss of one-half of the potential market for new products will begin to have an impact on investment decisions and a solution will need to be found. That is, states and firms will seek to reduce the investment uncertainty and increase the regulatory transparency of socio-economic considerations so that the polarized world can be replaced by an international regulatory system that provides consistent decisions.

The challenge of embedding socio-economic considerations in risk regulation is their potential for nefarious use. All too often, socio-economic considerations are used by governments to mask third-party protection or to prevent the import of competing products from other countries. Examples of socio-economic considerations can include, but are not limited to, food security, benefits to society, indigenous knowledge, impacts on biodiversity, health impacts, environmental impacts, market access, consumer choice, labor impacts, intellectual property rights, ethical implications, and religious/cultural implications.

It is theoretically conceivable that some of the above list could be methodologically incorporated into a sci-

ence-based regulatory framework (see Ludlow, Smyth, & Falck-Zepeda, forthcoming). Of course, this would add cost to the regulatory process in terms of research investment and time required for regulatory approval (Phillips McDougall [2011] show that the pathway and cost-to-market have already increased). However, the fundamental challenge that will still remain is how to deal with those socio-economic considerations that cannot be incorporated into a science-based framework. Even if a mechanism could be developed to incorporate socio-economic considerations, the practical problem remains of how to prevent them from being captured by vested economic interests.

The central tendencies of states and markets are well known and understood, but the incorporation of ‘social voice’ is problematic. The problem is that social-based regulations have no process for reconciling differences in the way science-based regulation does. With the strong political focus of advocates for socio-economic considerations, it is possible to distinguish between three foundational types of civil authorities, depending on their underlying objectives—some are strongly values-driven, a second group are fundamentally interests-based, and a third class are primarily focused on enforcing epistemological norms (Phillips, 2007). What ends up often happening is that decisions become political. The regulatory system is opened up to all kinds of manipulation, depending on which party is in power at any given point in time. Removing politics from international regulation and trade was the driving reason behind the establishment of the GATT and now the whole discussion about the inclusion of SEC is driving the world back to the environment that it sought to escape 65 years ago with the establishment of rules-based institutions such as General Agreement on Tariffs and Trade (Kerr, 2000). Without science-informed decision-making as a basis for regulatory choice, the politicization of the process will naturally lead to manipulation of the system and deterioration in the international trade of agriculture products.

Conclusions

A number of observations can be made about the present dual nature of the regulatory framework for biotechnology-derived products.

Biotechnology, especially the area of GM foods, offers a real-time experimental space where the modernist and postmodernist systems are seeking accord. The battle is engaged, the action arenas mostly defined and the actors are mobilized. New norms, processes, and

institutions are emerging, while at the same time, industry is pushing ahead with adoption. Seventeen years following initial commercialization, GM foods are widely produced on every continent and widely traded in more than half of international commerce. James (2013) concludes that GM technologies have been the fastest and most extensively adopted new agri-food innovation in the history of agriculture. Nevertheless, tensions remain. Some important actors remain disconnected from any authoritative action arena, and there are real and significant gaps in our knowledge systems. In many areas, arguments continue over the norms that should drive our system and the connections that can and should drive decision-making are in many cases tenuous or ineffective, in that the US and some other key countries are not members of all of the institutions.

We conclude that the complexity of the various issues makes it very unlikely for any comprehensive approach to the regulation of biotechnology. Such an approach is also probably undesirable, as comprehensive negotiations often lead to 'horse-trading' that produces anomalies and inconsistencies (Kerr [2003] notes, for example, the inconsistency of having intellectual property protection within the WTO). Furthermore, it is not clear whether there is any institution ready to accept this gargantuan task. The OECD is facilitating dialogue and collecting data but suffers from a limited membership. The WTO has its hands full with other trade issues. The Cartagena Protocol on Biosafety has focused on environmental issues and will be fully occupied for the foreseeable future establishing a framework for balancing international environment interests without overly distorting international trade. Furthermore, consumer concerns and continuing anxiety surrounding GM products coupled with the atmosphere of protest against large organizations demonstrate that comprehensive negotiations will be very difficult to sell to consumer and activist groups.

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