CHAPTER ONE

Introduction and Summary

Agricultural (or "green") biotechnology, the most cutting-edge contemporary technology in food production, faces an uncertain future. Will it follow the example of nuclear energy, which turned out to be one of the most unpopular and uneconomical innovations in history? Or will it revolutionize food production around the world? Are prevailing public and private sector strategies for coping with the most important political, economic, and societal challenges to agri-biotechnology effective in terms of creating a long-term global market for the technology? What policies could be adopted to shape the evolution of the technology in ways that benefit humanity and the environment?

In this book I argue that global *regulatory polarization* and *trade conflicts* have exacerbated already existing domestic controversies over agricultural biotechnology and have thrown the latter into a deep crisis.

Regulatory polarization has emerged as European Union (EU) countries have imposed severe regulatory constraints on agri-biotechnology, whereas the United States has opened its market to most agri-biotech applications. Other countries have either aligned with one or the other of the world's two largest economies, or they have been struggling to find some middle ground.

The analysis in this book shows that regulatory polarization has been driven by differences across countries in public opinion, interest group politics, and institutional structures. It also shows that regulatory polarization has created strong tensions in the world trading system. International conflicts over regulatory differences, which tend to act as non-tariff barriers to trade, have been intensifying since the first genetically engineered (GE) crops appeared on international markets in 1996.

The largest part of the book concentrates on: describing *how* regulatory polarization has emerged (chapter 3); explaining *why* it has emerged (chapters 4 and 5); and assessing the likelihood of escalation of international trade tensions over regulatory differences (chapter 6).

In light of this analysis I conclude that prevailing public and private sector policies do not add up to an effective strategy for mitigating or overcoming regulatory polarization, diffusing trade tensions, and creating a long-term global market for the technology. The dominant public

sector policies include: establishing ever more complex and stringent regulations that are increasingly divorced from scientific evidence and insufficiently backed by robust institutional structures for implementation (this is largely the European Union's strategy for increasing public acceptance of green biotechnology); threats of escalating trade disputes over differing regulations to force open foreign markets for the technology (a strategy favored by parts of the US government, the US biotech industry, and US farmers). The dominant private sector policies include: educating consumers about the benefits and (low) risks of the technology; highlighting consumer benefits of future GE products; ad hoc efforts to accommodate consumer demand for non-GE products through market-driven product differentiation (crop segregation and labeling); lobbying the US government to force open foreign markets via trade disputes.

Continuing regulatory polarization and trade conflict darken agri-biotechnology's prospects for three reasons.

First, regulatory polarization locks in or even increases fragmentation of international agricultural markets, and it implies reduced market access for agri-biotechnology and its products. It thus reduces scale economies and returns on investment into the technology. And it discourages further private sector investment in a new sector that could otherwise grow into a market worth several hundred billion dollars. Because of uncertainties about market access for GE products, it also exerts a chilling effect on adoption of the technology by farmers around the world.

Second, as I will show in chapter 6, trade conflicts over differing agri-biotech regulations are very difficult to solve, particularly within the World Trade Organization (WTO). Thus, they threaten to tax international institutions and impact negatively on efforts to liberalize global trade in agricultural goods and services. They exacerbate problems of global market fragmentation and uncertainties about market access caused by regulatory polarization. And they amplify already existing domestic controversies over the technology. All this, again, impacts negatively on investment, research and development, and adoption of the technology.

Third, regulatory polarization and trade conflict slow down public sector support for agri-biotechnology. This concerns in particular support by richer nations for developing countries where the technology might be needed most for increasing agricultural productivity. EU countries, Japan, and other agri-biotech adverse states have been highly reluctant to include biotechnology in their development assistance programs. So have non-governmental organizations (NGOs). Moreover, many developing countries have refused help of this nature for fear of losing agricultural export opportunities in biotech adverse markets. This situation

creates a "legitimacy trap." Agri-biotech proponents have made "feeding the poor" one of their key selling points. Continuing emphasis of this legitimating argument, but failure to deliver on this account, could undermine the legitimacy of the technology in both rich and poor countries.

The book ends with suggestions for policy reforms that could help to avoid the seemingly unavoidable trajectory that leads from regulatory polarization to trade conflict to stagnation or decline of agri-biotechnology (chapter 7). These suggestions focus on establishing strong regulatory authorities backed by robust liability laws, market-driven product differentiation based on mandatory labeling of GE products, and support for developing countries.

The genie is out of the bottle. Food biotechnology and its applications are with us, and the technology is developing rapidly. Based on current knowledge about the benefits and risks of agri-biotechnology, neither blanket bans nor libertarian solutions appear warranted. As with many other new technologies, complex trade-offs between public safety concerns and private economic freedom have to be found. Whether one supports or opposes food biotechnology, the starting point for politically stable and economically and ecologically sensible trade-offs must be a sophisticated understanding of where we stand, how we got here, where we are likely to go, and what the pressures towards particular futures are. If this book can help both supporters and critics of agri-biotechnology in this process I will have achieved more than I could hope for.

Finally, I have tried to present conceptual (or theoretical) arguments and the associated evidence in a way that makes the book accessible to non-social scientists and non-experts in biotech issues. I am confident, however, that social scientists and biotech experts will also find much theoretical and empirical food for thought.

Technological Revolution

Breathtaking innovation in biotechnology has brought humankind to the doorstep of a third "green revolution" within less than a century. The first green revolution, which began in the 1930s, was initiated by three developments: large-scale application of Gregor Mendel's work, carried out in the 19th century, on inheritance in plant breeding; discovery of inexpensive methods for the production of nitrogen fertilizer; and development of high yield hybrid corn. Rapid yield increases throughout the 1970s in corn and other temperate-climate crops were, in addition, obtained through increasingly effective fertilizers, pesticides, crop species, machinery, and farm management. The average farmer in modern agriculture is thus able to feed up to 30 non-farmers.

The second green revolution, which took place in the 1960s and 1970s, carried the same technologies to the developing world and crops grown in the tropics (notably, rice).

The third green revolution, which is still at an early stage, was born in the 1970s[1] and commercialized in the 1990s. It has been led by agricultural biotechnology.[2] According to the proponents of this technology, it will result in another massive increase in productivity, with a predicted feeding ability far beyond 1:30. It is also expected to provide qualitative improvements in the food supply (e.g., healthier food).

Controversy

The advent of agricultural biotechnology sparked a worldwide public controversy of breadth and intensity unseen since the peak of the anti-nuclear energy movement in the 1970s and 1980s. The controversy over green biotechnology forms part of wider ranging societal controversies over various applications of biotechnology, notably, cloning and other biotech-related reproductive technologies, stem-cell research, xenotransplantation, transgenic animals, and genetic testing. Debates over such biotech applications also tie in with more general issues, such as world trade and globalization, intellectual property rights and the patenting of life forms, the future of agriculture, poverty and hunger, and the role of science in society.[3] All of these issues involve clashes between natural science paradigms and political measures designed to cope with uncertainty and ethics. They also involve disputes over how to balance economic competitiveness and politically legitimate and viable regulatory systems for new technologies.

Most analysts regard 1996–97 as the watershed years in the controversy over green biotechnology. In those years, the first agri-biotech mass commodities appeared on international markets: Roundup Ready soybeans and Bt corn. At the same time, the first successful cloning of an animal (Dolly, a sheep) from an adult cell took place at the Roslin Institute in Scotland. Ever since, regulatory authorities around the world have been struggling with the issue. Media coverage has exploded. NGO campaigns and consumer revolts have become part of the political landscape of many countries. International trade tensions over differences across countries in agri-biotech regulation have built up. And the concept of the modern life sciences firm that integrates agrochemicals, crop sciences, pharmaceuticals, and health and food products has experienced a profound crisis.[4]

The proponents of the technology claim that it will, in the medium to long term, help in reducing hunger, public health problems, and environ-

mental stress. It will, in their view, result in cheaper and better food and it is necessary to prevent massive food shortages and environmental degradation as the world's population approaches 9–10 billion in 2050. Consumer benefits are said to include food with less organic contaminants and microorganisms, less pesticide residues, more vitamin A and other vitamins, higher iron and protein content, less cholesterol, longer shelf-life, and better keeping quality. Future products are expected to contain more micronutrients, less toxins, edible vaccines, and less allergens. Environmental benefits are said to include increased yields, which reduces the need to convert forests and habitat into farmland, reduced use of insecticides, herbicides, and nitrogen fertilizers, improved water quality and biodiversity, and soil conservation. Benefits to farmers purportedly include higher and more stable yields, more cost efficient and convenient pest control, reduced fertilizer cost, and higher profits.[5]

The critics of agricultural biotechnology maintain that the medium- to long-term health and environmental risks of GE (or transgenic) organisms are poorly understood, and that the technology promotes excessive corporate power through patenting of the food chain. They also invoke a range of ethical concerns, arguing, for example, that the technology involves "tampering with nature."

Stakes

Whether consumer health, the environment, and the hungry will, in the long term, benefit or suffer from agricultural biotechnology remains open and contested. If the proponents' predictions materialized at some point in the future, humanity and the environment would benefit enormously. However, the public health, environmental, and commercial risks could also be considerable. Some readers may recall the prediction by Admiral Lewis Strauss, the head of the US Atomic Energy Commission, who claimed in the 1950s that nuclear power would eventually be too cheap to meter.[6] Nuclear power turned out to be one of the most uneconomical and unpopular technological innovations in human history. It has not collapsed entirely. But it has never reached the adoption rate and market share that its proponents originally predicted.

Will green biotechnology suffer the same fate? We will probably know in 10–20 years from now. In the meantime, a better understanding of the political, economic, and societal determinants of the future of green biotechnology can help stakeholders to make well-informed predictions. It can contribute to more accurate assessments of public and private sector strategies for coping with challenges to agri-biotechnology. And it can be helpful in devising policy solutions that promote applications of

agri-biotechnology that benefit both rich and poor inhabitants of our planet in ecological, human health, and economic terms.

For proponents and opponents of green biotechnology, the public health, environmental, and ethical stakes are obviously large. So are the more narrow economic stakes for biotech firms, farmers, food processors, and retailers.

As of 2002, the world market for transgenic crops and GE food products and ingredients was estimated at around 17 billion USD. It consisted largely of insect-resistant corn and cotton and herbicide-tolerant soybeans. By 2006, this market, in which soybeans and cotton will still hold the lion's share, is predicted to reach over 20 billion USD. The potential market for ''white biotechnology'', i.e., the use of GE plants for the production of vaccines, renewable sources of energy (e.g. ethanol), biodegradable plastics, and other goods could be much larger, possibly up to 100–500 billion USD per year by 2020.[7] The area planted to GE crops stood at over 58 million hectares (145 million acres) in 2002 and is likely to grow further.[8] Investment in agri-biotech research and development is difficult to estimate, but runs into billions of USD per year. Input suppliers (agri-biotech firms), GE crop farmers, as well as food processors and retailers that support agri-biotechnology have a lot to lose if the tide turns against this technology. Finally, billions of dollars in exports of GE crops or processed foods that contain GE organisms are also at stake.

Challenges on the Demand and Supply Side

In chapter 2 I claim that, despite ongoing scientific innovation and persistent emphasis by the technology's proponents of large upcoming benefits, agricultural biotechnology is facing a profound crisis. To support this claim I discuss the most relevant demand (i.e., consumer) and supply (i.e., producer) issues[9] in agri-biotechnology. This analysis provides the starting point for describing and explaining regulatory responses and international trade tensions that exacerbate the current crisis. Chapter 2 also equips readers less familiar with agri-biotech issues with some background knowledge that will facilitate reading of subsequent chapters.

On the demand side, consumers have so far not benefited significantly from GE crops and it is still open whether they will, on average, do so in future. Nelson et al. (1999), for example, have calculated that full adoption of GE corn and GE soy around the world would (compared to no adoption anywhere) result in no more than a 4.9 percent price reduction (and less than a 2 percent increase in output) for corn and a 1.7 percent price reduction (and 0.5 percent increase in output) for soybeans. Other agri-biotech applications may produce more impressive results in terms of more and cheaper

food, but we simply do not know at this stage. Moreover, because virtually all agri-biotech applications currently on the market focus on agronomic (or input) traits, GE products have not benefited consumers in terms of superior product quality (e.g., healthier food). Again, future products may provide such benefits. But whether and when such products will appear on mass consumer markets is still guesswork. These problems on the demand side (small consumer benefits) have been exacerbated by public controversies over health, environmental, and economic effects of the technology, as well as opposition on ethical grounds.

On the supply side, according to proponents of agri-biotechnology, increasing GE crop acreage testifies to the success of the technology. The same holds for the growing number of countries that engage in research and development in this area.[10] In chapter 2 I conclude that such arguments mask fundamental problems on the supply side of agri-biotechnology. Technology adoption is limited primarily to the United States, Argentina, and Canada. The farm-level benefits of the technology remain disputed. At this stage, the available evidence shows that some farmers have indeed benefited from GE crops. But it does not support the more general claim by the proponents that the average farmer growing GE crops between 1996 and 2002 has benefited substantially, particularly when one considers not only narrow agronomic benefits (e.g., yields) but also farm profits.[11] Future GE crops may result in much higher yields, lower pest-control costs, and higher profits for farmers. So far, this remains no more than an optimistic scenario based on some encouraging evidence from field trials with a wide range of GE crops. Thus far, farm-level adoption of GE crops seems to have been driven by factors other than profitability, for example, marketing strategies of biotech firms, structures of grain-handling systems, and convenience effects in farm management. Whether current adoption rates can be sustained is questionable, particularly if problems on the demand side also persist.

Regulatory polarization and international trade tensions over differences in regulation across countries have added considerably to these problems. Regulatory differences are described in chapter 3 and explained in chapters 4 and 5. International trade implications are examined in chapter 6.

Regulatory Polarization

In the mid-1980s, the biotechnology policies of West European countries, the United States, and other countries were similar. At the end of the 1980s, they began to diverge. Since 1990, the European Union and its member states have moved towards ever more stringent approval and

labeling standards, with strong emphasis on the *precautionary principle*.[12] As a consequence, very few agricultural biotech applications have been approved for commercialization in the European Union, commercial planting of GE crops is almost non-existent in EU countries, and the number of field trials is far lower than in the United States. The number of labeled GE foods on the EU market has approached zero as food processors and retailers have chosen to avoid them rather than label GE foods. The EU market for GE food products has shrunk to GE enzymes, food ingredients and animal feed not subject to mandatory labeling.

In stark contrast, US policy-makers have embraced agricultural biotechnology. They have taken the position that agri-biotechnology is simply a new and innovative food and feed production technology that does not per se make produced food and feed less safe than their conventional counterparts. The US Food and Drug Administration (FDA), the Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) have, through relatively informal notification procedures and with very little governmental pre-market risk assessments, approved most industry requests for field testing and commercialization of GE products. Producers may voluntarily label GE foods but are not obliged to do so. More than 50 GE crop varieties are on the US market. Many more GE varieties have been authorized for field testing. GE crop acreage increased dramatically between 1996 and 2002. And GE ingredients can be found in thousands of processed food products.

These differences between the European Union and the United States are at the heart of a trend I call regulatory polarization: an increasing gap is developing between agri-biotech promoting and agri-biotech restricting countries, both in terms of approval and labeling regulation and at the market level. The hard core of the pro-agri-biotech world clusters around the United States and includes in particular Argentina and Canada. The agri-biotech restricting part of the world clusters around the European Union and also includes a range of non-EU states, such as Norway, Switzerland, and many Central and Eastern European countries.

Many other nations (e.g., Australia, Brazil, China, India, Japan, Mexico, Russia, and South Africa) have moved towards stricter approval procedures. And many of these countries (e.g., Australia, China, Japan, South Korea, Russia) have adopted mandatory labeling requirements for GE food. While these regulations differ very much in terms of their stringency, on average they position these countries somewhere in between the European Union and the United States.

Developing countries in particular have been struggling to make sense of scientific and political controversies about risks and benefits of the technology. Disputes in 2002 over US food aid to sub-Saharan Africa

that included GE crops are only the tip of the iceberg: for many developing countries establishing regulatory systems that are effective, cost efficient, affordable, and do not antagonize the United States or the European Union amounts to squaring a circle.

These "tectonic shifts" in the world's landscape of agri-biotech regulation have thus far not generated much pressure for reform of US approval and labeling standards (nor those of Argentina and Canada). But they have influenced markets. Most analysts note a chilling effect on GE corn and GE soybean cultivation in the United States and other GE crop producing countries. The exception, GE cotton, is a non-food product. Regulatory polarization has contributed substantially to delaying commercialization of new GE crops, most notably, GE wheat and rice. Moreover, it has all but promoted public funding of agri-biotech R&D in developing countries where the technology might be most beneficial. The increasing regulatory divide is also affecting global agricultural trade.

Explaining Regulatory Polarization

Conventional wisdom tends to account for differences between countries in agri-biotech regulation with arguments about differences in "regulatory culture." The following text exemplifies this type of explanation in somewhat poetic form:

> *The Risk of Nations*
> In the US products are safe until proven risky
> In France products are risky until proven safe
> In the UK products are risky even when proven safe
> In India products are safe even when proven risky
> In Switzerland products are risky especially after they have been proven safe
> In Kenya products are safe especially after they have been proven risky
> In Canada products are neither safe nor risky
> In Brazil products are both safe and risky
> In Ethiopia products are risky even if they have not been developed
>
> *Source*: anonymous contributor to www.agbioworld.org.

Arguments such as the above probably contain a grain of truth, but are dangerously close to stereotypes. Most social science work has thus combined arguments about national regulatory styles (or culture) with empirical research on institutional structures, the media, consumer perceptions, and NGO and industry behavior.[13] The explanation of regulatory polarization offered in chapters 4 and 5 builds on this work, but casts it

into a more systematic and parsimonious framework. It also takes into account driving forces not or inadequately examined in previous research. And it shows that some of the most popular explanations of transatlantic differences in agri-biotech regulation (notably, technophobia and protectionist interests as driving forces of stricter EU regulations) are wrong.

I explain differences in regulatory outcomes across jurisdictions in terms of consumer perceptions, activity of NGOs, interests and behavior of biotech firms, farmers, processors and retailers, and institutional characteristics of the political systems concerned. The analysis illuminates market processes as well as domestic and international political processes. It focuses on the European Union and the United States because these two political units exhibit the most striking variation in regulatory outcomes, and because EU and US behavior in this policy area has a strong effect on what other countries do.

The explanation combines two theoretical perspectives. The first views regulation as the result of a struggle for political and market influence among different interest groups within the European Union and the United States; that is, among input suppliers (agri-biotech firms), farmers, processors and retailers, and consumer and environmental groups. This explanation sheds light on why these groups have different preferences, and on when and why particular interests prevail in the policy-making process. The second perspective explores the effect of interactions among different jurisdictions (EU countries, US states) in federalist political systems (the European Union, the United States).

While the former explanation focuses on societal influences that operate from the individual or firm level upward (bottom up perspective), the latter concentrates on the effects of system-wide political structures and institutions (top down perspective). In the European Union, both processes have worked in ways that have driven agri-biotech regulation towards greater stringency. In the United States, they have worked in ways that have sustained agri-biotech promoting regulation.

Interest Group Perspective

Conventional politico-economic theories of regulation claim that environmental and consumer groups, because of their large and heterogeneous membership, experience greater problems than producers (industry) in mobilizing supporters and influencing public policy. The analysis in chapter 4 shows, however, that the *collective action capacity* of environmental and consumer interests has varied substantially between the European Union and the United States. This variation can be traced back to differences in public perceptions of agricultural biotechnology, consumer trust in regulatory authorities, and institutional settings.

Due to greater public outrage, defined in terms of more negative consumer perceptions of agri-biotechnology and lower public trust in regulatory agencies, the collective action capacity of agri-biotech adverse European environmental and consumer groups has been higher than the capacity of their US counterparts. Transatlantic differences in the extent and nature of agri-biotech campaigns by NGOs reflect this variation in collective action capacity. Agri-biotech adverse groups in Europe have thus been more successful in *shaping markets* for the technology than agri-biotech adverse groups in the United States. Public outrage in combination with more institutional access due to multilevel and decentralized policy-making[14] has also enabled agri-biotech adverse interests in Europe to exert more *influence on agri-biotech policy-making*. In the United States, low public outrage and a centralized regulatory system for agri-biotechnology have acted against agri-biotech adverse interests.

The collective action capacity of pro-agri-biotech producers has also varied substantially between the European Union and the United States. In Europe, public outrage and NGO campaigns have driven a wedge between biotech firms on the one hand and food processors, retailers, and farmers on the other hand. Thus, they have reduced the collective action capacity of pro-biotech interests. Interestingly, the pro-biotech coalition in Europe has not been crippled by protectionist "piggy-backing" by some producers (notably, farmers).[15] The latter argument figures most prominently in the economic theory of regulation and in US attacks on EU agri-biotech regulation. It has been weakened because those firms most vulnerable to market pressure spearheaded by NGOs, notably, food processors and retailers, have been pushed towards support for stricter regulation. In contrast, in the United States a cohesive and well-organized pro-biotech producer coalition has prevailed due to lower public outrage and weaker campaigns by agri-biotech adverse NGOs. Differences in industrial structure (particularly, higher concentration, both in economic and organizational terms, of the retail sector in the European Union than in the United States) and associated rigidities also play a role in explaining why the pro-agri-biotech producer coalition has been much weaker in the European Union than in the United States.

Regulation in Federalist Systems

The interest group explanation does not account for differences in interests and policies of individual EU countries and US states and their implications for variation of policies at the EU and US level. Chapter 5 fills the gap. It regards EU and US agri-biotech policies as outcomes of interactions between political subunits (member states in the European Union, states in the United States) within a larger (federal) political system where

these subunits can act autonomously to varying degrees. The explanation concentrates on whether political subunits within the larger political system can, by unilaterally installing stricter or laxer regulation of agricultural biotechnology, push the stringency of system-wide regulations up or down. The analysis of agri-biotech policy-making in the European Union and the United States shows that in the European Union we observe a substantial "ratcheting-up" effect, whereas "centralized laxity" has prevailed in the United States.

EU countries are bound by supranational rules that guarantee the free flow of agricultural goods within the European Union's internal market. But they maintain considerable national autonomy in closely related policy areas, such as environmental and public health regulation. For example: in many areas they have safeguarded the right to establish regulation that is stricter than minimum standards set by the European Union or that deviates from the principle of mutual recognition.[16] These conditions also apply to agri-biotechnology.

When the forces described and explained by the interest group perspective began to drive up the stringency of regulation in more risk-averse EU countries, the more agri-biotech friendly nations as well as the EU Commission faced a dilemma: how to satisfy demands, in some countries, for stricter agri-biotech regulation and, at the same time, safeguard the European Union's internal market? Variation across countries in approval and labeling standards for GE products threatened to disrupt agricultural trade in the European Union. In view of strong public support for strict agri-biotech regulation in around half of the European Union's member countries, downward harmonization to levels acceptable to pro-agri-biotech countries was impossible. Pro-agri-biotech countries in the European Union have thus regularly caved into the demands of agri-biotech adverse countries. They have done so because, in their view, the costs of market disruptions are higher than the costs of restrictive agri-biotech regulation. In this "ratcheting up" process agri-biotech adverse countries have, step by step, moved towards more stringent regulations and have dragged EU-wide regulations upward in this process. The supranational bodies of the European Union (Commission, European Court of Justice) have so far not resisted this development.

Agri-biotech regulation is more centralized in the United States than in the European Union, both in terms of political levels and institutions involved. It is largely in the hands of two independent federal agencies and one federal ministry (FDA, EPA, USDA). What might appear like a paradox in the EU case—that a fragmentation of decision-making authority produces upward harmonization and not simply paralysis—does not come into play in the United States to the extent it does in the European Union. Bottom up pressure for stricter regulation has in some

cases led to diverging policy preferences among US states. However, due to institutional and legal constraints described in chapter 5, the options of US states for stricter unilateral regulation of agricultural biotechnology are much more limited than the options of individual EU countries. Even if public pressure for stricter agri-biotech regulation grew in some US states, and if these states imposed some restrictions that were upheld by the courts, a "ratcheting up" trend would emerge much more slowly in the United States than in the European Union. The most likely scenario is that some large US states introduce restrictions (e.g., mandatory labeling of GE food), and that these restrictions have negative effects on other states' agricultural exports. Farmers in the latter states, perhaps followed by their governments, would thus have an incentive to meet the higher standards in their export markets. Eventually, this "trading up"[17] effect might spread throughout the United States and motivate federal agencies to tighten regulations. But we are still far away from this scenario. In other words, as of now, relatively positive public perceptions of agri-biotechnology and weak NGO campaigns are primarily responsible for lax agri-biotech regulation in the United States. However, federal processes in the United States constitute an additional barrier against stricter regulation should bottom up pressure increase in future.

Will Regulatory Polarization Persist?

The analysis in chapters 4 and 5 shows that a combination of interest group dynamics and particular characteristics of regulatory federalism in the European Union has increased regulatory restrictions on agricultural biotechnology in the European Union. These forces are much weaker in the United States, which accounts for persistent regulatory laxity there. The analysis also suggests that both political systems will remain on their respective trajectory for the next few years.

A reversal of the European Union's policy is unlikely because of low public acceptance of GE food, low trust in regulators, pressure by NGOs, growing opposition to GE crops among farmers, strong incentives for processors and retailers to stay away or withdraw from the market for labeled GE foods, and institutional inertia in EU policy-making. The dominance of agri-biotech adverse interests in the European Union is bolstered by the characteristics of regulatory federalism in the European Union. Decision-making structures in the European Union allow agri-biotech adverse minorities to block efforts to relax existing standards. In addition, a combination of multilevel and decentralized decision-making, substantial regulatory autonomy of EU countries, and concerns about safeguarding the European Union's internal market encourage a "ratcheting up" of regulations rather than downward harmonization.

If one accepts the conclusion that the European Union will not move towards the US model of centralized laxity, will US policy move towards the EU model? The evidence presented in chapters 4 and 5 suggests it will not. Somewhat increased public concern over GE food since the late 1990s, and the StarLink controversy in particular, have produced some cracks in the pro-agri-biotech coalition. But these cracks have thus far been much too small to pose a serious threat to the cohesion of this coalition. For example, conflicts between US farmers and biotech firms in view of precarious export opportunities for GE crops have been reduced through increased government subsidies for US farmers. In addition to low interest group (''bottom up'') pressure for stricter agri-biotech regulation, the characteristics of US regulatory federalism act against more restrictive agri-biotech policies. The analysis in chapter 5 shows that, even in the unlikely event that consumer pressure for tighter rules grew, heavily constrained regulatory autonomy of US states in agri-biotech matters combined with centralized decision-making at the federal level would slow down any ''contagion'' effect that may emanate from individual US states trying to impose more restrictive policies.

Whether regulatory polarization will persist depends not only on the domestic processes just discussed. It also depends on developments at the international level.

First, in the long run the evolution of the world's regulatory landscape for agri-biotechnology will also be shaped by the policies of countries other than the European Union and the United States. If most of these other countries moved towards the EU model, this would create pressure for stricter regulation in the United States. Pressure for a relaxation of regulation in the European Union would mount if most other countries moved towards the US model. For the time being, the world's two largest economies are clearly the principal drivers of worldwide regulatory activity. Their policy choices visibly limit the options of other countries, particularly those that are economically dependent on the European Union, the United States, or both. Switzerland, Norway, and Central and Eastern European countries have thus aligned with the European Union, Canada with the United States. Other countries, which are less dependent on EU or US markets, for example, China, Brazil, India, Japan, and Russia, have adopted regulations whose stringency lies somewhere between the EU and the US models. Agri-biotech policy in these countries is very recent and very much in flux. Both the European Union and the United States are currently battling for influence on the regulatory policies of these countries by trying to entice, coerce, or cajole them into one or the other policy. The acrimonious dispute over GE food aid deliveries to sub-Saharan Africa in 2002 exemplifies this volatile and conflictual situation.

Whether other countries will eventually move towards the EU or the US model of agri-biotech regulation remains open.

Second, whether regulatory polarization will persist depends also on how trade tensions associated with regulatory polarization are played out in regional and global trading systems. In principle, three scenarios are possible. Transatlantic (perhaps even worldwide) convergence of agri-biotech regulations could develop in two ways: through voluntary negotiations and international agreements that harmonize regulations (harmonization may occur at higher or lower levels of stringency); or through coercion exercised via international dispute settlement mechanisms (notably, those of the WTO system). Chapter 6 concentrates on these two possibilities. Alternatively, problems associated with regulatory polarization could, to some extent, be sorted out in global markets. For example, food industries could adapt to heterogeneous consumer preferences and offer an increasing range of GE and non-GE products. I will explore this option in chapters 6 and 7. This market-based approach would not reduce regulatory polarization in a direct fashion. But it could help in mitigating some of the negative consequences of polarization mentioned at the outset of this chapter.

International Trade Implications

In an increasingly integrated world economy, the effects of national and regional agri-biotech regulations reach far beyond the countries adopting them. In particular, differences in biotech approval and labeling standards affect international trade flows and may result in conflict within regional and global trading systems. In chapter 6 I argue that regulatory polarization has put the world's two biggest economies, the European Union and the United States, on a collision course.

I then concentrate on cooperative and unilateral strategies for reducing regulatory polarization, with an emphasis on assessing the likelihood and consequences of a full blown dispute over agri-biotechnology in the WTO. The principal proposition in this chapter is that escalation of existing trade tensions is more likely if: (a) economic losses due to the European Union's agri-biotech restrictions are large and concentrated on politically influential economic actors in the United States; (b) non-coercive policy measures for solving the problem are ineffective; (c) the prospects for the United States to win a legal case in the WTO are good and the European Union is likely to make concessions before a WTO verdict or after a "guilty" verdict. The evidence for the first two conditions points to escalation. The evidence for the third condition is ambiguous.

The assessment of distributional consequences of regulatory polarization

focuses on export revenue losses and implications for aggregate EU and US welfare. It suggests that, in aggregate welfare terms, the costs of regulatory polarization may be falling primarily on the European Union, and only to a smaller extent on the United States. Costs to the United States, however, tend to fall on a small, well-organized and funded, and politically influential group of economic actors, primarily biotech firms and export-oriented farmers. Their losses currently amount to several hundred million USD per year. But these losses could rise to several billion USD per year if the European Union tightened its regulations further and other countries followed the EU model. These economic losers of EU regulation have a powerful incentive to push the US government towards coercive measures to pry open European Union and other markets for American GE products. Studies on protectionism and trade disputes in other policy areas show that such conditions tend to promote escalation.

The analysis of non-coercive strategies for coping with growing trade tensions (notably, mutual recognition, compensation, harmonization, and unilateral regulatory or market adjustment in the United States) shows that none of these conventional policies is likely to be effective in reducing regulatory polarization and trade tensions. Mutual recognition is unacceptable to the European Union and the United States because it would undermine the legitimacy of both sides' respective policy. Compensation would founder on political legitimacy and financial grounds. All international harmonization efforts are deadlocked for the same reasons that have led to regulatory polarization. The same holds for unilateral regulatory adjustment in the United States. Unilateral market adjustment in the United States has helped in mitigating trade tensions but cannot solve the problem by itself.

The evidence on the third condition is inconclusive. On the one hand, I show that for legal and strategic/political reasons the WTO is likely to uphold the European Union's strict regulations should the United States set the WTO's dispute settlement procedure in motion. In particular, upholding is more likely if: (1) legal rules do not provide clear-cut guidance as to whether the defendant's regulations are legitimate (lawful) or not; (2) the defendant is economically powerful and is unlikely to comply with an adverse verdict; (3) the defendant is, explicitly or implicitly, supported by other influential WTO countries; (4) important negotiations on extending trade liberalization in the WTO are under way; (5) a recent and comparable case ended with substantial political backlash. The evidence on all five points suggests that we should not expect the US government to escalate the conflict because the United States would not win the legal case.

On the other hand, we know from other trade conflicts that governments sometimes escalate trade disputes in which the probability of

winning the case is low. There are several reasons why governments may do so. Potential plaintiffs may conclude that winning domestic political support from crucial constituencies by escalating a trade dispute is more important than actually winning the case. Such action promises short-term gains, whereas WTO proceedings often take years and adverse outcomes occur at some point in the future. Moreover, potential plaintiffs usually do not face much domestic opposition to escalation because the costs of escalation (e.g., punitive economic measures and countermeasures, disruption of further trade talks) are often dispersed over the entire economy or a large part thereof.

By and large, the analysis in chapter 6 suggests that the likelihood of escalation of transatlantic trade tensions over agricultural biotechnology is high. Such escalation would impose an almost unmanageable task on the WTO and could disrupt efforts to liberalize world agricultural trade. It could easily develop into a cycle of punitive economic measures and countermeasures that could cost biotech firms, farmers, consumers, and taxpayers on both sides of the Atlantic billions of dollars. Moreover, as discussed in the next section, it would add further to the crisis agricultural biotechnology already finds itself in.

In other words, while voluntary harmonization, mutual recognition, compensation, and unilateral regulatory adjustment in the United States will be next to impossible in the next few years, the likelihood of coercive efforts via the WTO is growing rapidly. The assessment in chapter 6 shows, however, that escalation is a no-win and probably even counter-productive strategy. If one accepts these findings, market-based solutions, in forms to be discussed in chapter 7, may turn out to be the most effective strategy for coping with regulatory polarization and trade tensions.

In mid-May 2003, when this book went to press, the United States formally carried the dispute into the WTO by requesting consultations. Its request was supported by Argentina and Canada. WTO rules call for consultations as a first step in order to give plaintiffs and defendants a chance to solve the problem cooperatively. If a dispute cannot be settled through consultations within 60 days the plaintiff can forward the case to a dispute settlement panel. This process, including possible appeals against a panel ruling, normally takes 10–18 months, possibly longer if the WTO needs to decide on punitive measures and appeals against such measures—provided the defendant is found guilty. In other words, if neither the United States nor the European Union backs down, final WTO decisions on whether the European Union's regulations are compatible with WTO rules will probably be made in late 2004 or early 2005. The analysis in this book suggests that the dispute is likely to escalate all the way to formal WTO rulings, and that those rulings will not resolve the problem.

Crisis

It is unlikely that regulatory polarization, escalating trade tensions, and the underlying societal controversies will lead to a collapse and disappearance of green biotechnology. But they have thrown this technology into a profound crisis. As noted by the *Economist* already in 2000,[18] "Environmentalist hate the idea, consumers don't seem to care for it, farmers are increasingly diffident, and the companies that develop it are either imploding or off-loading their GMO subsidiaries as fast as they can find anyone to buy them."

In this market and regulatory setting, research, development, and adoption of the technology will remain far behind what would otherwise be feasible and perhaps sensible from technological, economic, environmental, public health, and humanitarian viewpoints. These circumstances deter private investment in agri-biotech R&D, not only in Europe and countries with similar restrictions, but also in the United States. They have clearly increased commercial risks for biotech firms, farmers, and food processors and retailers because of greater uncertainty over export markets and fear of "spillovers" of consumer revolt and regulatory restrictions from agri-biotech adverse to agri-biotech promoting countries. Leading agri-biotech firms have invested heavily in the technology, but have become hesitant to direct more investment into this area.

Regulatory polarization, escalating trade tensions, and continuing societal controversy over agricultural biotechnology also deter public and NGO support for agri-biotech R&D in developing countries where the technology could potentially contribute most to improved living conditions. For public relations reasons and to raise political support for agri-biotechnology, some biotech firms have provided free access to patented GE crops to some developing countries. But such gifts are ad hoc and selective. Commercial incentives of input suppliers are and will remain biased towards OECD markets, where purchasing power is much higher. Intensified ties between private sector and university-based R&D, particularly in the United States but also in Europe, have reinforced that trend.

Government and NGO support is unlikely to fill the gap. In Europe and elsewhere, governments and NGOs are highly reluctant to sponsor agri-biotech R&D in developing countries, primarily because of the anticipated political backlash. Many developing countries, for their part, are reluctant to accept help in this area for several reasons. The first generation of GE crops has not provided consumer benefits (in price or quality) and current farm-level economics of existing agri-biotech applications are, on average, disputed. Moreover, many developing countries fear export revenue losses should the number and size of agri-biotech adverse markets continue to grow. In particular, financial, technical, and admin-

istrative problems in operating a reliable system of segregation, identity preservation, and labeling are likely to deter many developing countries from adopting the technology. As noted above, these conditions create a *legitimacy trap* for agri-biotechnology. While pro-biotech circles are persistently using "feeding the poor" arguments to bolster the usefulness and legitimacy of agri-biotechnology, economic, societal and regulatory constraints are hampering development and marketing of such agri-biotech applications. The industry's inability to deliver on its promises, in turn, negatively affects the legitimacy of the technology.

Policy Reforms

What could public and private sector stakeholders do to overcome the current doldrums and equip agri-biotechnology with a fair chance to prove its economic, environmental, public health, and humanitarian benefits in the long run?

In chapter 7 I start out by arguing that most alternatives to the proposed regulatory reforms, which are frequently advocated by pro-agri-biotech circles, are neither feasible from a political viewpoint (e.g., a substantial relaxation of the European Union's agri-biotech rules), nor would they create and sustain long-term consumer confidence in agricultural GE products. Notably, no convincing empirical evidence exists to support the widely held view among agri-biotech supporters that pouring millions of dollars into public relations campaigns will produce more knowledgeable consumers who are more supportive of the technology. Moreover, US efforts to pry open foreign markets via trade disputes in the WTO are very unlikely to produce the results that agri-biotech proponents are hoping for.

I propose instead that policy reforms should focus on three elements: strengthening regulatory authorities and liability laws, supporting market-driven product differentiation, and supporting developing countries.

These policy reforms would initially impose some additional costs on producers and consumers. They may, at first sight, also look particularly unattractive to those who advocate regulatory decisions based exclusively on existing scientific evidence for health and environmental risks. Indeed, scientists have thus far not been able to demonstrate that agricultural GE products currently on the market pose public health risks—there is more scientific uncertainty as to the environmental implications of agri-biotechnology. However, I will argue that, whatever the "real" risks are, the proposed reforms are the price to pay for long-term consumer confidence and sustained investment in the technology. The cost of persistent regulatory polarization, trade tensions, and turmoil in global markets for agri-biotech

products—the most likely scenario in the absence of regulatory reforms along the lines suggested in chapter 7—could be much higher.

First, all jurisdictions producing and/or importing GE crops, food or feed, above all the European Union, should establish powerful, politically independent, and science-oriented regulatory authorities. I will argue that the European Union in particular finds itself in a trilemma that involves trade-offs between decentralized and multilevel regulation, food safety, and market concentration. The analysis of this trilemma shows that moving from decentralized, network-like regulation to more centralized forms of governance in food safety would be the most effective option for increasing consumer confidence.

In the absence of such reform, ever more complex and costly agri-biotech regulation that lacks a solid scientific justification is likely to produce a vicious circle involving complex regulation followed by implementation failures, further decline of public trust in food safety and regulators, even more complex regulation in response, increasing market concentration as firms try to cope with food safety problems through vertical integration and self-regulation, and so on.

The strengthening of regulatory authorities should be combined with a tightening of liability laws. Stronger regulatory authorities and stronger liability laws would go a long way towards enhancing public support for agri-biotechnology. The former in particular would also act against excessive market concentration in the food sector.

Second, public and private sector stakeholders should support market-driven product differentiation, that is, the establishment of national and international markets where GE and non-GE products can be safely and reliably traded. This necessitates that all countries cultivating GE crops and/or importing such crops or products implement strict and science-based risk assessment and approval procedures. It also necessitates efficient systems of identity preservation (IP) and labeling.

To reduce short-term disincentives among GE crop farmers, food processors, and retailers, the startup costs of IP and labeling systems could be subsidized by governments. Governments could also support market-driven product differentiation by setting tolerance levels, promoting certification and verification procedures for non-GE products, and providing detailed information on planting, yields, and prices of GE products and their conventional counterparts, thus enabling farmers to make better informed choices. To facilitate international trade in GE products, the European Union and the United States should move towards joint standards for risk assessment, approval, labeling, testing, IP, and liability that could then be implemented also in other countries.

Under conditions of market-driven product differentiation GE foods can only survive if they offer compelling consumer benefits (e.g., in terms of

quality and/or price). Biotech firms, cultivators, food processors, and retailers should thus concentrate on food products that offer such benefits (unlike first generation GE crops). To improve the general legitimacy of the technology, in both rich and poor countries, genetic improvement of agronomic traits should concentrate primarily on varieties that are particularly useful also to developing countries. To facilitate the setting up and operation of differentiated markets, biotech and food firms should avoid marketing of GE products that can spread quickly throughout the food chain and/or have a high potential for cross-pollination or outcrossing.

Third, international funding and technical support will be required to set up effective regulatory systems in developing countries, including also biosafety measures for R&D. Biotech accidents in developing countries could have disastrous implications for the technology in rich and poor countries. In addition, weak regulation in developing countries could hamper those countries' agricultural export opportunities in markets subject to stricter and more effective agri-biotech rules.

Governments, biotech firms, and international scientific associations should set up and fund an independent international organization. This organization should provide financial and technical assistance for regulatory efforts in developing countries, conduct research into health and environmental issues associated with agricultural biotechnology, and fund and supervise agri-biotech R&D in developing countries in areas where private investment is not forthcoming or patents hamper technology transfers.

Even if the international community, and in particular the world's largest economies, can find a regulatory modus vivendi within the next few years we are likely to see perhaps five to ten more years of controversy and heterogeneous ad hoc responses by policy-makers around the world. If the policy reforms recommended in this book were implemented it seems more likely that the storm would eventually settle. We may then find a variety of agricultural GE products competing in the market with conventional or organic counterparts. Consumers would be more confident in the safety of the food supply and would be able to exercise informed choices based on whatever criteria they deem important. Farmers, processors, retailers, and biotech firms would experience less uncertainty on the demand side. They would be able to capture premiums with GE products deemed beneficial by consumers, and to direct longer-term investment to products and business areas where consumer demand is most promising. Residual risks to public health and the environment would be under effective government control and, should prevention fail, would be covered by robust liability laws.