Risk and Reward:

U.S.-EU Regulatory Cooperation on Food Safety and the Environment

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Policy Paper

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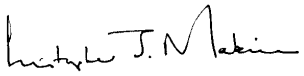
Foreword

In a previous report in April 2001, *Changing Terms of Trade: Managing the New Transatlantic Economy,* an Atlantic Council working group noted that as transatlantic economic issues increasingly revolved around matters previously regarded as 'domestic,' representatives of domestic interests, including civil society groups, were ever more engaged in the transatlantic policy dialogue. Among many other recommendations, the working group called for the creation of new mechanisms for managing the different attitudes on the two sides of the Atlantic towards public risk and the role of the state. More specifically, the working group recommended that the United States should press for greater clarity on the definition and use of the precautionary principle and called for the establishment of nongovernmental task forces to examine specific issues, such as biotechnology, internet commerce and other regulatory issues that could cause transatlantic frictions.

This report represents the Council's own response to this recommendation, in the form of the results of a new working group established to address U.S.-EU regulatory policy differences relating to food safety and the environment. The group's task was to examine current transatlantic tensions arising out of several areas of domestic regulation on issues surrounding food safety and environmental protection, with particular consideration given to the difference in approaches to managing risk. The working group had a broad membership, with representatives from industry, governments, environmental agencies, civil society groups, think tanks and universities. We hope their recommendations will be of use to policy-makers and other interested parties on both sides of the Atlantic.

The conclusions of this report reflect a consensus of the individual views of the working group members, and do not necessarily represent those of any organization. While not every participant may agree with every recommendation made, all have agreed that the report captures the key points that were discussed. Individual dissenting viewpoints are included in the annex to this report. In addition, the report benefited from the participation of several government representatives and others who, for professional reasons, cannot be formally associated with a report of this kind. These individuals are listed as 'observers,' but bear no responsibility for the final form of the report or its recommendations.

The Atlantic Council would like to thank all those who made this report possible. Particular thanks are due to the working group's co-chairmen, David L. Aaron and C. Boyden Gray, for ably guiding the discussions and shaping the direction of the group's work. The working group also benefited from presentations on particular topics by Michelle Egan of American University; Carol Tucker Foreman of Consumer Federation of America; Antoine van der Haegen of the Delegation of the European Commission; Robbin Johnson of Cargill; Hans Klemm of the Department of State; Charles Ludolph of Stonebridge International; Peter Morici of the University of Maryland; William Nitze of Gemstar Group; David Stirpe of the Alliance for Responsible Atmospheric Policy; and Brooks Yeager of World Wildlife Fund. Although they are not responsible for the contents of this report, their comments made a great contribution to the discussions. Finally, we are grateful to our sponsors, the German Marshall Fund of the United States, The Dow Chemical Company, and Cargill. While they bear no responsibility for its recommendations, their support was essential to the production of this report.



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Risk and Reward:

U.S.-EU Regulatory Cooperation on Food Safety and the Environment

Executive Summary

Transatlantic Relations and Regulatory Policy

Environmental protection and food safety have been among the most volatile issues in the U.S.-European relationship. While they are now overshadowed somewhat by the transatlantic debate over Iraq and other political and military matters, tensions over environment and food safety are just below the surface, and — if not addressed — will have enduring corrosive and divisive effects. Indeed, the recent acrimony over these issues has contributed to concern about an erosion of shared transatlantic values and a deterioration in U.S.-European relations generally. Moreover, as recently demonstrated at the Johannesburg UN summit on sustainable development, the failure of the United States and Europe to work together on these issues does not have only bilateral consequences. It represents a significant lost opportunity to provide leadership in addressing environment and food safety on a global level. The United States and Europe have both been leaders in these areas — a fact that is too often overlooked in the current debate. Unless they now find a way to reconcile their different perspectives and approaches, the United States and the European Union will miss real opportunities to work together in addressing global environmental and public health issues.

In recent years, U.S.-EU trade disputes have focused increasingly on differences in regulation, rather than the traditional barriers of tariffs or subsidies. Regulatory requirements established primarily with domestic concerns and politics in mind can affect the free flow of international commerce. Such regulatory differences have contributed to U.S.-EU disputes over a range of food and environmental issues, including beef hormones, genetically modified foods and feed, ozone depleting chemicals, and aircraft engines. As the U.S. and European economies become ever more intimately linked, such regulation-based disputes are likely to increase in number and frequency, and because regulatory issues are intrinsically linked to domestic politics, these matters are likely to be sensitive and difficult to resolve. Their impact will go beyond trade policy, contributing to concerns about a rise in tensions in the transatlantic relationship overall.

The effect of these disputes reaches beyond the United States and the European Union, as standards established through U.S. and EU regulations often become de facto international standards. The outcome of U.S. and EU discussions will establish the pattern for how governments around the world

deal with these new technologies and products, and will be key to the development of global regulations and markets.

A key element dividing the United States and Europe has been their distinct views of precaution. Although both acknowledge the general need for precaution, especially when dealing with new technologies that might affect human health or environmental protection, they differ considerably over the desirability of a formal "precautionary principle" and its application to broader policy areas. The EU has sought to expand the application of the precautionary principle. The U.S. government has maintained that an internationally agreed precautionary principle is not appropriate for widespread application. The United States also maintains that existing rules already acknowledge the right of governments to exercise precaution.

Efforts to resolve these regulatory disputes have so far met with mixed success. Use of the WTO dispute resolution procedure has been criticized by some who believe that process ignores environmental considerations, but recent rulings indicate that the WTO will allow trade restrictions based on environmental concerns under certain circumstances. However, securing compliance on such politically sensitive issues can sometimes be problematic. As a result, the U.S. and EU trade policy communities have recently given greater emphasis to bilateral negotiation and mediation as a more desirable way to reduce regulatory disputes, while reserving the right to pursue remedies through the WTO if consultations fail.

GMOs and Food Safety: A Lesson in Consumer Attitudes and Regulatory Policy

Developments in biotechnology in the areas of food and agriculture have presented the transatlantic relationship with one of its most difficult challenges, and future innovations in biotechnology are likely to test the relationship even more severely. In the United States, agricultural biotechnology, including genetically modified foods and feed, has for the most part been accepted as part of the normal process of technological innovation in both farming and the food industry. In Europe, however, a string of food safety scandals has damaged public confidence in food safety institutions. Although none involved GMOs, these episodes made the public (and the politicians), extremely wary of such new technology. Thus, in seeking to bridge transatlantic differences, a key issue will be consumer confidence. Effective risk assessment and risk management will be essential, and ways must be developed to provide consumers with the information and choice they desire. U.S.-EU differences over GMOs have also affected the international agricultural market as both Washington and Brussels have sought to convince other governments of the merit of their respective positions. This is not simply a matter of markets, however, as was demonstrated by the recent reluctance of some African governments to accept GM food aid, despite a looming famine.

Conclusions

- Consumer confidence is the most important determinant of any future market for agricultural biotechnology. Central to this will be restoring the credibility of European food safety institutions.

- A credible scientific risk assessment process is essential as we proceed with the development of agricultural biotechnology products, including GMOs.

- Some form of labeling and "traceability" may be useful in providing consumers with information and choice. But such mechanisms must not effectively close the market to safe products and must be implemented in a workable and verifiable way.

- The continuing U.S.-EU dispute over GMOs threatens to evolve into a global rivalry over the use of agricultural biotechnology. How the United States and the European Union will resolve this dispute — or fail to resolve it — will have significant implications for future trade in biotechnology.

Recommendations

- The United States should encourage European efforts to restore public confidence in food safety institutions, and should thus be as supportive as possible of the new European Food Safety Authority. Exchanges between the FDA and the EFSA should be established in order to facilitate sharing of perspectives and best practices, with the goal of enhancing the risk assessment capabilities of both institutions. The United States should also continue to stress the central role of the Codex Alimentarius as the primary body for establishing food safety standards internationally.

- Whenever possible, the United States and the EU should move toward a more collaborative risk assessment process, especially in relation to GM products. The establishment of the EFSA may offer opportunities in this area, as may the current push for increased scientific cooperation under the New Transatlantic Agenda (NTA). It might be especially useful to consider whether a scientific risk assessment procedure that falls between the current GRAS ("generally regarded as safe") and food additives procedures would be useful. The end goal of this scientific collaboration should be to establish a foundation for a transatlantic mutual recognition agreement on agricultural biotechnology products.

- Since some form of labeling and product tracing is probably inevitable in some countries, the United States and the European Union should focus their efforts on ensuring that such a scheme is workable and not misleading while providing consumers with sufficient choice. Labeling that allows the easy identification of GM-free products and the development of a market in those goods is most likely to provide consumers with the widest choice. Any such scheme must be enforceable through testing or certification. This may make it desirable for the

U.S. government to establish a certification regime for GMOs, after conducting a survey of existing certification practices to see which might serve as an appropriate model.

- If the EU passes a labeling and traceability measure with requirements that are essentially unworkable, the United States should give serious consideration to starting the process of pursuing a case through the WTO dispute resolution mechanism. That case should not challenge the EU's obligation to establish a certain level of safety for its citizens, but should be focused on the workability of any such scheme and ensuring that it is nondiscriminatory.

Protecting the Environment: Transatlantic Conflict and Cooperation

Both the United States and the European Union (including the member states) have adopted many laws and regulations designed to protect their environments. Indeed, they have been in the forefront internationally in developing such rules. However, the different regulatory approaches behind these rules have led to disputes. Although disagreements to date have been limited in both number and scope, some have been especially persistent. Given the importance of environmental protection to both the European and U.S. publics, the political sensitivity of these disagreements is likely to increase, leading to greater transatlantic tensions in the future. Moreover, these regulatory issues have a significant international dimension, as the standards and practices that develop out of the two dominant markets will inevitably affect those adopted by multilateral standard-setting bodies and international corporations.

The disagreement over the Kyoto Protocol on climate change is only the most visible example of transatlantic conflict over the environment. Other, lower profile cases — over hushkits for airplanes, electronic waste recycling, persistent organic pollutants, and ozone-depleting substances — have also generated serious tensions. These cases proved to be particularly complex because of the multitude of actors involved, most with primarily domestic orientations and agendas, and because of the impact of continually changing technologies. Finally, while the United States and the EU often agree in their assessment of the risk, they sometimes use incompatible mechanisms to manage that risk and approach implementation and enforcement very differently.

Conclusions

- Although both the United States and the EU share the basic goal of environmental protection, they have pursued this objective through the development of distinct, and sometimes conflicting, regulations and standards. These regulatory differences have the potential to become another acrimonious area of transatlantic relations in the future.

- Efforts to reconcile U.S. and EU regulatory regimes have been hampered by several factors, including: the involvement of multiple actors with multiple agendas; the impact of constant technological innovation; the divergent views of technical standards and of cost-benefit analysis; and differing emphases on implementation and enforcement.

- Transatlantic differences over environmental matters should not be treated either as a mere technical question or a simple trade dispute. They reflect very divergent political choices, with the key differences being over risk management, rather than risk assessment.

- Avoiding an enhanced level of transatlantic tension over this issue will require greater U.S. engagement in creating sound policy on environmental protection, and more willingness by both to seek out opportunities to share perspectives and develop a more collaborative approach.

Recommendations

- The United States and the EU should reaffirm their common commitment to environmental protection. On the U.S. side, this will require greater engagement and leadership, especially from the White House and Congress. An interagency group on international aspects of environmental protection would help give this issue a higher profile across the government. The commitment of the United States and the EU could also be demonstrated by a joint statement on environmental protection and its compatibility with international trade, to be issued at the next U.S.-EU summit in the spring of 2003.

- Although risk assessment has not been the major point of difference over environmental issues, encouraging more collaborative assessments, perhaps through the NTA scientific cooperation agreements, can help build a stronger foundation for U.S.-EU understanding and cooperation in this area. Exchanges between appropriate U.S. and EU agencies could be extremely useful in fostering the sharing of perspectives and development of cooperative activities and should be mandated and funded by Congress. Among the long-term aims might be the joint development of standards for environmental technologies that are compatible with international trading obligations and the design of appropriate mutual recognition agreements.

- Collaboration in risk management will be essential in avoiding future tensions and could begin with a comparison of best practices, both in environmental protection and in regulatory policy. Such a comparison could be undertaken by industry and NGOs, as well as by U.S. and EU agencies, and could be valuable in identifying specific mechanisms that contribute to environmental protection while not creating barriers to commerce.

- U.S. government and industry must re-engage on the issue of standards, particularly within the international standards setting bodies. This should not be treated as an area of mere technical discussion, but as an issue in which U.S. leadership (from both the government and private sector) will be key in ensuring that the results are compatible with both protecting the environment and the obligations of international commerce. Establishing new congressional reporting requirements on the status of international standards and the actions of U.S. agencies could provide the necessary stimulus. But this is not simply a government responsibility — U.S. corporations should also be prepared to take on the necessary leadership roles in private-sector bodies.

Reconciling Regulatory Regimes

The United States and the European Union face the challenge of reconciling their regulatory regimes to attain two distinct — but not necessarily conflicting — goals: to protect the environment and consumers, and to fulfill the obligations of the international trading system. We are now at a fork in the road. If U.S. and EU regulatory policy continues to be made without adequate regard for its international impact, future regulatory issues could easily erupt into yet another series of difficult and persistent transatlantic disputes. But if Washington and Brussels begin to exercise leadership on this issue, they could foster the development of new strategies for reconciling distinctive regulatory systems. A first step has been made with the agreement on Guidelines for Regulatory Cooperation and Transparency. Further steps, such as negotiating a "time-out" provision that would require each government to stop the legislative process for consultations, could also be helpful. Over the long term, constructing a more collaborative approach could be much more effective in protecting citizens and the environment than continuing a pattern of rivalry and disputes. The following general principles, drawn from the cases discussed in this report, could help guide that process.

Public confidence in regulatory and enforcement authorities will be critical to building transatlantic agreement.

The regulatory process should be as transparent as possible, both for the public and for other governments.

Government agencies and legislatures should pay greater attention to the international implications of the regulatory process.

Risk assessment should be an increasingly collaborative undertaking, both on food and environmental issues.

There is a place for precaution, but it should be exercised in the context of specific cases and should be provisional, pending continuing scientific assessment.

Risk management is central to any regulatory system and should be developed in a way that allows reasonable flexibility in achieving performance objectives and that takes into account the costs and benefits of different approaches.

Regulations should include adequate provisions for uniform implementation and enforcement.

International institutions remain a key element in the reconciliation of these regulatory regimes.

Overcoming the current regulatory differences between the United States and the EU will not be an easy task. There will not be one single step that by itself will make this endeavor a success; instead it will be a lengthy process involving changes in attitudes and procedures across many agencies and institutions. But neither the United States nor the European Union can afford any longer to write regulations on food safety and environmental protection in domestic isolation, only later to be forced to defend those

rules in the international arena. As the transatlantic economies integrate, so must the regulatory processes that affect so much of the economic exchange across the Atlantic. By taking advantage of opportunities for greater consultation and eventually collaboration, the United States and the EU will reduce the chance that regulatory policy will lead to a series of difficult confrontations. Instead they will be able to focus on working together in creating regulatory regimes that effectively protect consumers and the environment.

Risk and Reward:

U.S.-EU Regulatory Cooperation on Food Safety and the Environment

Overview

In recent years, environmental protection and food safety have been among the most volatile issues in the U.S.-European relationship. While they are now overshadowed somewhat by the transatlantic debate over Iraq and other political and military matters, tensions over environment and food safety are just below the surface, and — if not addressed — will have enduring corrosive and divisive effects. Indeed, the current acrimony over these issues has contributed to concern about an erosion of shared transatlantic values and a deterioration in U.S.-European relations generally. Moreover, as recently demonstrated at the Johannesburg UN summit on sustainable development, the failure of the United States and Europe to work together on these issues does not just have bilateral consequences. It represents a significant lost opportunity to provide leadership in addressing environment and food safety on a global level. The United States and Europe have both been leaders in these areas — a fact that is overlooked far too often in the current debate. The impact of their current differences has been felt most concretely in the transatlantic trade arena, in a series of persistent disputes. But these differences represent far more than just another transatlantic trading issue. Unless they now find a way to reconcile their different perspectives and approaches, the United States and the European Union will miss real opportunities to work together in addressing global environmental and public health issues.

In coping with these disagreements, the United States and the European Union face two alternative paths. Although the differences are primarily not about whether consumers and the environment should be protected, but how to achieve those goals, they are still significant. Because of public concerns, especially in Europe, they have become politically sensitive and thus difficult to resolve. Without a change in approach, the issues of environmental protection and food safety are likely to become even more prominent and divisive in transatlantic relations. The alternative is for the United States and the European Union (and its member states) to reaffirm their shared commitment in these areas and then find specific ways they can work together in identifying and managing the risks faced by their citizens and environments. This strategy will not resolve all transatlantic differences over the environment and food safety, even over the longer term. But it may lay the foundation for a revitalized partnership in these areas, one that can reconcile the need to protect citizens and the environment from undue risk with the rewards of an open international trading system.

Transatlantic Relations and Regulatory Policy

Environmental protection and food safety might seem to be purely domestic policy areas. But regulations to address these issues have had a growing impact on the transatlantic and international economies. U.S.-EU trade disputes focus increasingly on differences in regulation, rather than the traditional barriers of tariffs or subsidies. In effect, regulatory requirements established in the United States or the EU, primarily with domestic concerns and politics in mind, can affect the importation of products not produced or grown according to those requirements. It is certainly legitimate for governments to establish their own health or safety standards and to determine the level of risk that is acceptable in their societies. But the impact of those decisions goes far beyond national borders, especially in this age of globalization. In short, differences in regulatory requirements or in implementation of those requirements can significantly limit the flow of international trade. Thus, the reasoning behind such restrictions, and the conditions for their application, should be widely accepted as appropriate and legitimate. Clearly, no product, whether imported or not, should entail a safety threat to the consumer. At the other end of the spectrum, however, banning an import because some believe it is unsafe, despite an absence of scientific evidence to that effect, or designing regulations that discriminate against imports, are practices that are widely regarded as protectionist.

The complexities and sensitivities of these issues are amply demonstrated by the U.S.-EU disagreement over beef hormones. In 1996, the United States and Canada began World Trade Organization (WTO) consultations over the EU refusal to allow the importation of beef that had been injected with growth hormones. The EU claimed that its ban was justified on the grounds that hormone-injected meat could be harmful to the health of the consumer. The United States charged that the EU did not have an adequate scientific basis for that judgment. Eventually, the WTO found that because of the lack of a science-based risk assessment, the EU ban was contrary to international trade law. To date, however, the EU has refused to lift the ban and instead has accepted trade sanctions by the United States for lost sales. Although the United States does not regard this as a satisfactory or permanent solution, the politics of this issue in Europe make it very unlikely that either the ban, or U.S. sanctions, will be lifted anytime in the near future.

The beef hormones case, although it resulted in $117 million in retaliation by the United States, is only the tip of the proverbial iceberg. An EU moratorium on approval of new genetically modified organisms (GMOs) for import could result in much more acrimony and higher penalties if ever challenged in the WTO, as the United States has occasionally threatened. Pending European legislation on recycling, the use of ozone depleting chemicals and the production of greenhouse gases could also effectively limit imports of U.S. manufactures. Until a recent agreement, EU legislation on engine designs to mitigate aircraft noise pollution threatened to restrict the use of some U.S.-built aircraft in European skies, adversely affecting their value and the balance sheets of companies that owned them. For the most part, these disputes developed when legitimate government desires to protect citizens or the environment were pursued without sufficient regard for the impact of the resulting regulations in the international arena. Of course, trade disputes based on regulatory differences have not been limited to environment and food safety — privacy concerns and taxation of e-commerce are among the many other issues on which differing regulatory approaches have led to sharp words across the Atlantic.

In 2001, an Atlantic Council report on the overall U.S.-EU economic relationship highlighted the importance of these regulation-based disputes, noting both their complexity and the increasingly high stakes involved.[1] As a result, the working group on U.S.-EU Regulatory Policy, the Environment, and Food Safety was convened, under the co-chairmanship of David Aaron and C. Boyden Gray. Meeting from late 2001 to mid-2002, the group included representatives of industry, consumer groups, and environmental NGOs, as well as individuals with long experience in the policy decisions surrounding these issues.

On the surface, environmental and food safety issues do not seem closely connected, except for their ability to generate tension between the United States and Europe. In fact, at the core of these disputes are the efforts of both U.S. and European governments to manage risk in a technologically complex world in which globalization has eroded their ability to do so. In recent years, technological innovation has proceeded at a very rapid pace and brought many benefits to consumers. But in some cases, those benefits were accompanied by some seriously negative consequences. In other cases, the spread of new technologies — computers and mobile telephones, for example — has brought enormous efficiencies, but has also introduced new complications in areas such as the disposal of certain hazardous materials. For governments, these new technologies present a double challenge: how to identify the beneficial ones and encourage their use, while managing the risks, and sometimes even dangers, they may bring.

This balancing act was difficult enough in an age when national borders and economies could be tightly managed. But globalization has made it impossible for governments and their citizens to manage this challenge in isolation. This is particularly true of the United States and the European Union, whose relationship demonstrates the realities of globalization perhaps better than any other. U.S. and European corporations (and a growing number of genuinely transatlantic firms) seek markets for new products on both sides of the Atlantic. Information about those products and new technologies is quickly available to both U.S. and European consumers, although they may regard these innovations differently in terms their of desirability or their disadvantages. At the same time, U.S. and European governments seek to ensure that these new technologies are indeed safe for their citizens and environments, by writing regulations to safeguard against perceived potential consequences. But when these consequences are perceived differently on the two sides the Atlantic, and the resulting regulations are thus inconsistent with each other, the impact on transatlantic trade flows can be significant.

As the U.S. and European economies become ever more intimately linked through trade, mutual investment, and the general process of globalization, the impact of conflicting regulatory regimes will become even greater. Thus, regulation-based disputes are likely to increase in number and frequency during the next few years. Because regulatory issues are intrinsically linked to national preferences and domestic politics, disputes over these matters are likely to be sensitive, involving agencies and actors with strong domestic orientations and constituencies, which are less prone to consider compromise to meet their trade obligations or for the sake of transatlantic comity. Disputes concerning environmental protection and food safety tend to be especially volatile, as these matters are often of great public

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[1] *Changing Terms of Trade: Managing the New Transatlantic Economy*, Atlantic Council Policy Paper (Washington, DC: Atlantic Council of the United States) April 2001.

interest. As a result, the public profile of any dispute tends to be higher, the political stakes are greater, and the ability to compromise in the face of public pressure is reduced.

Although these disputes complicate the daily course of U.S.-EU interchange, particularly in the economic field, their potential impact on the transatlantic relationship over the longer term could be more serious and debilitating. The persistence of these disagreements will aggravate the tone of transatlantic economic discussions at a time when U.S.-EU partnership will be key in bringing the Doha Round of WTO negotiations to a successful conclusion. But what is particularly troublesome is the manner in which these disputes have been linked to a broader set of issues and to public concerns in a way that threatens to bring into question the sense of shared values that is at the core of transatlantic relations. U.S. challenges to EU environmental objectives and regulations, when linked to different U.S. and European responses to the issue of global climate change, have created in some European circles an image of the United States as callous about the environment. U.S. development of GMOs, when linked to food safety concerns in Europe, highlights and exacerbates some different attitudes about food and the credibility of government regulation. Thus, the impact of these disputes goes far beyond U.S.-EU economic relations. When joined with disagreements over the death penalty, the International Criminal Court and other similar issues, these environmental and food safety disputes raise the possibility that the U.S. and European publics may come to view each other as holding different beliefs on some core issues, which could undermine the traditional perception that the transatlantic partnership is based on a foundation of shared values.

The impact of these disputes also reaches beyond the United States and the European Union. Because these are the two largest markets in the world, the success or failure of new products and technologies in these markets often determines their availability in the global market. Moreover, standards established through U.S. and EU regulations often become the de facto international standards. In some cases, corporations simply adopt the most rigorous standard required to enter a significant market for all products, no matter their eventual destination. In other cases, the United States or the EU have sought to have their regulations accepted as the global norm, either through adoption by some international standard setting body or by convincing other countries to accept their approach.

Thus, current transatlantic differences over GMOs have expanded into a global effort by both sides to convince others, especially in the developing world, either to adopt the U.S. acceptance of this technology, which promises higher, cheaper crop yields, or to resist these products out of concern about the impact on the environment and access to the European market. Depending on the outcome of this campaign, GMO crops face three different futures: one in which products such as "Roundup-ready" soybeans and Bt-corn are widely grown around the world; a continuation of the current situation in which GMO products are grown only in certain countries but are available for trade, albeit in a limited fashion, and finally, one in which GMO production is limited to a few countries and only for domestic consumption. The impact of a restricted market on the development of future technologies is likely to be significant. The outcome of U.S. and EU discussions will establish the pattern for how governments around the world deal with these new technologies and products, and thus will be key to the development of global regulations and markets.

One of the most visible elements in the transatlantic debate over how to deal with the influx of new technologies and products, both domestically and in the international arena, has been the different ways in which the term "precaution" is used. Both sides acknowledge the need for precaution, especially when dealing with new technologies that might affect human health or environmental protection. But the United States and Europe differ considerably over the desirability of extending the application of an internationally agreed "precautionary principle" to more policy areas. Emerging out of international environmental law, and as noted in the 1992 Rio Declaration on the Environment and Development, that principle holds that the lack of scientific certainty regarding the harmfulness of a product should not be used to prevent a government from taking measures to protect the environment if there is a risk of serious or irreversible damage; that is, restrictions can be placed on a product if it is believed to cause serious environmental harm, even if the scientific evidence is incomplete. In early 2000, the United States and the EU signed the multilateral Biosafety Protocol, which contained language on precaution, stating that the lack of scientific certainty regarding potential adverse affects on biodiversity and human health should not prevent the importing party from taking a decision designed "to avoid or minimize such potential adverse effects."[2]

The EU has sought to expand the application of the precautionary principle beyond these environmental applications. For example, the Nice European Council called for greater acceptance of the principle in international fora, including the WTO, and for its extension into the areas of human health, as well as the environment.[3] The new EU General Food Law supports the use of the precautionary principle in those cases when a specific risk has been identified but scientific uncertainty still exists, although it is only to be applied on a provisional basis while further research is conducted.[4] The EU has sought to convince the international community to adopt a guidance that explains, in its view, the way precaution was intended to be applied under an international agreement on health risks. To date, EU efforts to attain international agreement on the use of the precautionary principle within such bodies as the Codex Alimentarius have been resisted in the WTO and Doha negotiations by developing countries and others.

The U.S. government, in contrast, has maintained that a general, internationally agreed, precautionary principle is not appropriate for widespread application. Instead, each product or technology should be evaluated on its own merit, with the balance between scientific uncertainty and the potential for benefit or harm considered on an individual basis. Such decisions should take into account the costs and benefits associated with alternatives and any response to scientific uncertainty should be proportionate to the likely danger. Moreover, the United States maintains that the existing international rules, such as the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), already

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2 The Biosafety Protocol established procedures for documenting the presence of GMOs in international shipments of bulk foods or animal feeds, and requires exporters to seek consent from the importing country before shipping certain living organisms containing GMOs that are intended to be released into the environment.

3 See "Council Resolution on the Precautionary Principle," Presidency Conclusions, Annex III, Nice European Council, December 7-10, 2000. Viewed at www.europa.eu.int.

4 "Regulation (EC) no 178/2002 of 28 January 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety." Official Journal of the European Communities, February 1, 2002.

adequately acknowledge the right of governments to exercise precaution. The European effort to extend the application of the precautionary principle, and the U.S. insistence that such precaution should be applied only in specific situations, has come to be an especially difficult element in U.S. and EU attempts to resolve these issues.[5]

As this discussion of precaution makes clear, transatlantic disputes over environmental and food safety issues do not occur in a vacuum. There is already a diverse array of international institutions that address some elements of these issues and that offer some mechanisms for resolving related disputes. The WTO's SPS regulates the imposition of trade restrictions designed to manage certain health risks (exposure of food to pests or disease, for example), while the World Health Organization's Codex Alimentarius commission seeks to harmonize food health standards. The Codex has seen an especially active dialogue about risk assessment and labeling as the EU has sought to gain greater international acceptance for its position. The WTO Agreement on Technical Barriers to Trade (TBT) addresses a wider array of domestic regulations that may affect imports, including, potentially, those rules intended to protect the environment. In accordance with the TBT, the WTO has been notified of national rules deviating from international standards for a range of environmental issues, including water quality, waste management, and energy efficiency.[6] Other specialized international agencies have also been brought into play, depending on the issue; for example, the International Civil Aviation Organization was key in reaching the current accommodation over aircraft noise. The OECD conducts extensive activities aimed at enhancing agreement among member states on biotechnology, but most of its findings are advisory in nature.

In many cases, when these disputes impinge on international trade, the WTO seems the natural forum for seeking a resolution. Although frequently criticized by environmentalists and others for giving priority to promoting unrestricted international commerce, the WTO has been more environmentally friendly than its critics assume. Under GATT Article XX, the WTO allows exceptions to normal trading rules for measures "necessary to protect human, animal or plant life or health" or "relating to the conservation of exhaustible resources." Recent decisions, especially in the so-called "Shrimp-Turtle" case, have indicated an increased willingness on the part of the WTO to consider environmental concerns in resolving trade disputes, perhaps more so when both parties are also signatories to a multilateral environmental agreement (MEA) that is specifically relevant to the case.[7] However, such exemptions can

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[5] For a presentation of recent transatlantic debates over the precautionary principle, see European Policy Centre Conference Report on "The U.S., Europe, Precaution and Risk Management: A Comparative Case Study Analysis of the Management of Risk in a Complex World," January 11-12, 2002 (published April 2002, viewed on April 23, 2002 at www.theepc.be).

[6] For a full discussion of SPS and TBT and their applicability, see Steve Charnovitz, "The Supervision of Health and Biosafety Regulation by World Trade Rules," Tulane Environmental Law Journal, Vol. 13, No. 2, Summer 2000.

[7] In the case of Shrimp – Turtle, both parties were also signatories of the Convention on International Trade in Endangered Species (CITES). For an extensive discussion of the evolution of the WTO in this area, see Peter Morici, *Reconciling Trade and the Environment in the World Trade Organization*, Economic Strategy Institute, Washington: DC, 2002.

only be exercised in ways that do not discriminate between domestic and imported products, and thus are not protectionist. And there are certainly limits on the WTO's role as a mediating mechanism in these disputes, especially when the parties have not previously agreed through an MEA to certain environmental objectives that might take precedence. Perhaps most important has been the lack of an effective enforcement mechanism when a party is found to be acting contrary to WTO rules. Most parties accept WTO rulings and come into compliance. But in some cases, such as beef hormones, the domestic political sensitivity surrounding the issue has made the party violating WTO rules decide that the cost of compliance is too high and instead has accepted U.S. retaliatory measures.

Given the growing recognition of such political realities, a consensus has developed in both the U.S. and EU trade policy communities that, in certain instances, a WTO case may simply heighten tensions over controversial matters, while negotiation and mediation may offer more chance of resolution. Accordingly, there has recently been an increased emphasis on bilateral efforts to reduce regulatory disputes. A U.S.-EU Joint Statement on Regulatory Cooperation issued in December 1997 sought to encourage cooperation that would "maintain a high level of protection for health, safety, and consumers and the environment and [to] ensure the integrity of the regulatory processes as both sides seek to improve effective market access." A more specific step in that direction was the "early warning" system announced at the Bonn U.S.-EU summit in June 1999, which was designed to identify regulations, preferably when still in draft form, that might contribute to non-tariff barriers to trade. Efforts could then be made to revise the pending regulation so that it would present fewer difficulties. In April 2002, the United States and the EU reached agreement on Guidelines for Regulatory Cooperation and Transparency. These sought to take the idea of early warning a step further by encouraging U.S. and EU regulatory agencies to consult on a voluntary basis, sharing work plans that identify areas of anticipated regulatory action for the coming year and offering opportunities for reaction before regulations are finalized. Intended both to enhance cooperation between regulators, and to promote transparency for the public, the Guidelines also recommend early publications of draft regulations and opportunities for public comment. It is, however, too early to assess the impact of these guidelines.

Before turning to specific cases of transatlantic regulatory differences over environmental issues and food safety, and the recommendations of the working group, two myths that have grown up around these issues in recent years need to be examined.

Myth #1: Europe is inherently more prone to precaution in adopting new technologies, while the United States is less likely to respond to innovation with restrictions. This is a common charge, with transatlantic differences over food safety, in particular, often being ascribed to differing cultural attitudes toward food and technological innovation. In fact, both the U.S. and European authorities have reacted in a precautionary manner when faced with public perceptions of potential harm. The U.S. bans on alar as a growth-regulating chemical for apples and on cyclamates as sugar substitutes in soft drinks seem now to have been based on alarmist perceptions rather than solid science. Currently, the American Red Cross bans the donation of blood from anyone with recent residence in the United Kingdom for fear that it has been tainted by individuals exposed to Bovine Spongiform Encephalopathy (BSE) or the related Creutzfeldt-Jakob disease (CJD), even though there are no scientific indications that the disease can be transmitted through blood products.

Nor are Europeans as cautious about health and safety as this myth would imply. European regulators have only recently adopted a precautionary strategy, and it has been applied somewhat inconsistently across different industries. For example, the approval process for new drugs has generally been less rigorous in Europe than in the United States. Despite the known risks, exposure to second-hand cigarette smoke remains common in Europe.[8]

Far more important than any innate European tendency toward precaution has been a string of public health crises that has seriously eroded the European public's confidence in the credibility of government food safety and health regulators. The emergence of BSE ("mad cow disease") and variant CJD despite government assurances that humans could not contract the disease; the tainting of French blood supplies with HIV; the discovery of dioxin in Belgian chickens and other food products; and more recently the eruption of hoof-and-mouth disease — these have all been central in shaping European public attitudes. Although none of these issues is in any way related to the issue of GMO foods, European governmental authorities, including the institutions of the European Union, are under severe political pressure to demonstrate their commitment to protecting the public from any danger — real or imagined — that might be related to innovations in the food and health fields.

In the United States, confidence in regulatory authorities, such as the Food and Drug Administration, is generally high. Thus, the revelation that GMO "Starlink" corn, which had been approved for animal, but not human, consumption, had been found in taco shells and other products did not lead to undue public concern. The products were removed from stores, the source of the misused grain was found, and the furor (which was mild by European standards) quickly died down.

In sum, both the United States and Europe have adopted precautionary approaches at different times and on different subjects. The recent European trend in this direction seems rooted more in recent adverse experience than any inherent disproportionate tendency toward precaution.

Myth #2: Current regulatory disputes pit the pro-environment EU against the anti-environment United States. In fact, the United States and the EU have both been leaders in environmental protection domestically and internationally for a number of years. The U.S. Clean Air Act enforces air quality standards and imposes financial penalties on states and cities not in compliance, while the Endangered Species Act has forced developers to cease activities rather than irreversibly harm a protected species. The EPA's Toxic Release Inventory is often cited as one of the most effective information disclosure practices in terms of reducing harmful emissions. In Europe, environmental protection was long the responsibility of the individual national governments, and thus varied considerably from country to country, depending on the parties in power. Along with the rise in the influence of the Green parties, especially in northern Europe, the European Commission and the

[8] For a discussion of trends in the use of precaution in both the United States and Europe, see Jonathan B. Wiener and Michael D. Rogers, "Comparing Precaution in the United States and Europe," Duke Center for Environmental Solutions, Working Paper, August 2001; and David Vogel, "Ships Passing in the Night: The Changing Politics of Risk Regulation in Europe and the United States," European Union Institute Working Papers (Robert Schuman Centre No. 2001/16), Florence, 2001.

European Parliament began, for a range of reasons, to carve out more activist roles on environmental issues. As a result, recent national legislation and EU-wide legislation on such issues as recycling has been both comprehensive and far-reaching, although implementation remains the responsibility of the member states and is thus likely to vary considerably. The EU has also assumed a leading role in international environmental diplomacy, most notably in seeking to shepherd the Kyoto Protocol through to entry into force by the ratification of the required number of signatories. The United States, although one of the early supporters of Kyoto, has declined to ratify the accord, and under the current administration has announced an alternative approach to greenhouse gas emissions that has not met with support from Europe.

The climate change policies of the current U.S. administration and the European Union are far apart. Given the fluctuations in democratic politics, such differences on issues such as environmental protection and GMOs are inevitable from time to time, and ways will have to be found of managing them. But these transatlantic differences should not automatically be viewed as the result of fundamental and permanently divergent trends. Nor should current differences be allowed to eclipse the strides both the United States and Europe have made in protecting the environment during the past few decades.

In seeking to develop recommendations that might foster greater transatlantic understanding and cooperation, despite regulatory and political differences, the working group divided its task into two substantive areas. First, the group considered agricultural biotechnology, particularly food safety and GMOs. The latter is both an environmental and food safety issue; in fact, most scientific assessments of possible dangers from GMOs focus more on the potential environmental consequences and see little likely harm to consumers of GMO foods. But the issue has been linked closely with food safety, especially in the perception of European consumers. That link has made the GMO dispute particularly resistant to resolution, making it unlikely that the current transatlantic standoff over GMOs will be overcome until there is a change in European perceptions and policy concerning food safety. Second, the group reviewed a set of cases involving efforts at environmental protection, both internationally and domestically, and tried to identify factors that had either enhanced transatlantic cooperation or increased tensions. Because the topic of climate change encompasses such a large set of issues and has become so politically sensitive in the transatlantic arena, the group decided not to address the larger political issues, but only the likely impact of Kyoto implementation on European regulation and the possible effect on transatlantic economic flows. Other issues the group considered included hushkits, persistent organic pollutants, ozone-depleting substances, and electronic waste recycling.

By examining these specific issues, the working group set out to develop conclusions and recommendations about the growing impact of regulatory regimes on transatlantic relations, and the potential for even more severe and frequent conflict in the future. A key question then, is the degree to which these regimes can — and should be — reconciled. With this in mind, the working group identified a few overarching queries to guide its work: how do the United States and the European Union seek to balance risk and economics as new technologies emerge? And how can regulatory regimes be shaped to achieve that goal while also reducing the risk of transatlantic conflict? Are there specific steps that the United States and the European Union can take to foster cooperation and collaboration in this area?

GMOs and Food Safety: A Lesson in Consumer Attitudes and Regulatory Policy

Developments in biotechnology in the areas of food and agriculture have presented the transatlantic relationship with one of its most difficult challenges. Differing public attitudes, combined with contrasting regulatory approaches, have affected not only trade relations, but also the climate of the overall partnership. Without changes in the political and regulatory context, future innovations in biotechnology are likely to test the relationship even more severely. Because the financial and scientific gains in the biotechnology field are likely to be significant over the coming decades, the stakes involved in any disagreement — such as the current one over GMOs — are likely to be huge. And because innovations in this area affect not only profit levels, but also have the potential to impact human health and the environment, political — and sometimes moral — sensitivities loom large.

The first step in avoiding a pattern of conflict in this area is to understand the attitudes and regulatory practices that have governed the role of biotechnology in food and agriculture on both sides of the Atlantic. The case of GMOs demonstrates the differences very clearly. In the United States, GMOs have for the most part been accepted as part of the normal process of technological innovation in both farming and the food industry. Technology has long been seen as a way of boosting production and lowering cost, with products such as Bt-corn and "Roundup-ready" soybeans allowing a reduction in the use of pesticides and herbicides. This is not simply a cost efficient measure, but one of environmental importance since pesticide run-off has polluted local water supplies and, in some cases, endangered the health of farm families themselves. GMOs also respond to an agricultural system that emphasizes low-cost, large-scale production and a food industry that seeks year-round availability of perishable crops. The FLAVR-SAVR tomato was one effort to satisfy consumer demands for fresher tasting produce. For the most part, the U.S. consumer has accepted the introduction of GMOs, although there is little public discussion of the subject.

In Europe, by contrast, GMOs are an issue of great public sensitivity. The controversy over hormone-fed beef products, although not technically related to GMOs, had already sensitized the public to the issue of biotechnology in agriculture. Efforts to encourage the acceptance of GMO foods in Europe backfired, leaving more Europeans skeptical about such food than before.[9] The rash of food safety crises that plagued Europe throughout the late 1990s also heightened public fears about any alterations to foodstuffs and reduced public confidence in the ability of government agencies to police such activities. In addition, GMOs have generally not found favor within the European agricultural sector, which has not been subject to the same cost pressures as U.S. farming and where smaller fields make isolation of a particular crop more difficult. Nor have such technologies resonated in a culture that has put great store in traditional family farming.

As a result of these attitudes there have been very different regulatory approaches toward GMOs on the two sides. In the United States, GMOs are considered food additives under the Food Safety and Cosmetics Act, and thus must undergo a lengthy approval process, unless they are defined as

[9] Vogel, p. 11-12.

"substantially equivalent" to existing products, in which case they fall under the GRAS ("generally recognized as safe") process. In that case, the companies manufacturing the GMO product usually conduct extensive scientific reviews and then submit the results to the Food and Drug Administration (FDA), which reviews the companies' data but does not conduct its own separate scientific assessment. Under GRAS, the product can be deemed safe based on publicly available evidence. To date, the GMO products available in the U.S. market have been approved through the GRAS process. Since the genetic modifications have involved materials with which there is already a considerable record of experience and safety, there has been little incentive to treat these products in the same way as unknown food additives. GMO crops are reviewed under a similar process by the Animal and Plant Health Inspection Service (APHIS) of the Department of Agriculture, usually through notification of APHIS before the crop is planted by the developer.

In Europe, the regulation of GMOs has taken a very different tack. In 1998, largely in response to public concerns, five member states blocked the approval process through which new GMO products were allowed into the EU, effectively banning the importation of some U.S. grains and other foodstuffs (the EU had previously approved 18 GMOs, which can enter the European market). With the United States threatening to take action against the EU moratorium in the WTO, the European Commission in mid-2000 launched an effort to resume approval of GMOs, and in particular to review the 14 requests then pending. In principle, the approval process was scheduled to restart on October 17, 2002, but several member states announced that they will continue to block any actual approvals, at least until additional legislation is in place concerning labeling and tracing of GM components. The Commission has proposed such legislation, but in its current form, the labeling and traceability requirements are considered unacceptable by the United States, since their enforcement is expected to lead to the effective exclusion of GM products from the European market. That legislation has now gone through a first reading by the European Parliament, and the Council of Ministers may reach a common position in late 2002.

In a parallel development, the EU has responded to the intense public concern over food safety by establishing a new European Food Safety Authority. The EFSA will be responsible for providing an independent scientific reference point for risk assessments involving both food and animal feeds (especially feeds given to animals destined for human consumption) and to provide independent scientific advice for various government decision makers. The EFSA will also eventually perform scientific risk assessments of so-called "novel food products," including those with GMOs. However, in contrast to the U.S. Food and Drug Authority, the decision as to whether those products will be allowed into the European market will remain with the risk managers and political decision-makers.

In examining these differences in attitudes and regulations, and in seeking to develop recommendations for reducing transatlantic tensions in this area, the working group identified four key issues: risk assessment vs. risk management; consumer confidence and its impact on the market; labeling and traceability; and the international implications of U.S. and EU regulatory outcomes.

Risk assessment vs. risk management. The fact that biotechnology in food and agriculture is a rapidly evolving field means that risk assessment will continue to be important in this debate. The first generation of GMO crops and foods has proved to be as safe as any other comparable innovation, and

certainly safer to human health than some traditional farming practices. Moreover, the benefits promise to be significant. Aside from the environmental impact of reduced pesticide use, GMO crops offer the potential of higher yields at less cost — a development that could significantly reduce hunger around the world. Concerns have, however, been raised about the possibility that biotech crops may interbreed with domestic strains, reducing biodiversity or contributing to the development of unwelcome hybrids, making the practice of crop segregation worthwhile, accompanied by close monitoring.[10]

Adequate scientific risk assessment will continue to be essential in ensuring that developments in agricultural and food biotechnology move forward safely and with the confidence of the public. To date, the use of the GRAS procedure has worked well in the United States. However, if the next generation of GMOs involves more innovative combinations of genetic engineering (rather than the current focus on material with which there is already a long track record of safety), there may be a need for a more rigorous assessment process, but one that is not as onerous as the extensive food additive testing that is currently the only alternative in the U.S. regulatory system.[11] The risk assessment procedures to be established under the European Food Safety Authority may eventually provide not only an additional set of data but also some alternative review procedures.

In the transatlantic debate over biotechnology in food and agriculture, risk assessment is only part of the difficulty. In fact, U.S. and European scientific opinion does not differ significantly on these new technologies, and U.S. policymakers generally regard the inauguration of a European Food Safety Authority with a capacity for independent assessment as a positive step. The differences have instead arisen over risk management, and especially the response of governments to public perception of potential dangers. Just as accurate risk assessments can only be conducted based on a particular product or technology basis, so decisions about how to manage any risk can only be reasonably made on a similarly specific basis. Policy decisions of this sort should be clearly tied to an appropriate risk assessment procedure and take into account the range of costs and benefits presented by a specific technology and its alternatives. There is certainly a role for precaution, as not all risks can be anticipated.

But precaution should be exercised in relation to specific products, when the scientific information is not complete. The most recent European iteration of precaution, in the new Food Safety Law, is relatively limited, calling for restrictions only on a provisional basis pending further scientific assessment, and taking into account other technical and economic considerations.[12] By emphasizing their somewhat

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[10] For a review of the current U.S. procedures on risk assessment of GMO crops, which concluded that risks exist and may be significant but are little different from those presented by the introduction of non-indigenous plant species, see *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*, Report by the Committee on Environmental Impacts Associated with Commercialization of Transgenic Plants, National Research Council (Washington, DC: National Academy of Science Press, 2001).

[11] The U.S. Office of Science and Technology Policy has undertaken the process to add another step to the regulatory review process. The United States is actively reviewing the regulations of biotechnology and this may lead to the addition of an extra step in the review process.

[12] See Article 7 of Regulation No. 178/2002.

different definition of the concept of precaution, the United States and the EU have been distracted from focusing on the specifics of how risk management procedures and decisions might better be reconciled across the Atlantic.

Consumer confidence. Any examination of biotech products in the transatlantic market inevitably raises the importance of consumer confidence. As has been amply demonstrated in Europe (and in earlier incidents such as the alar episode in the United States) scientific assessments are likely to be overridden when public concerns (even ill-founded ones) become significant. Even if no government restrictions are imposed, consumers can quickly abandon a product, making it unlikely that a corporation could recover its investment in that technology. But consumer impact can go beyond causing the collapse of a product market. The current lack of trust in GMOs, and agricultural biotechnology generally, among European consumers has, at least temporarily, stopped the development of any market for these products, and also made it difficult for most of the EU member states to agree to lifting the current restrictions, thus contributing directly to transatlantic tensions in this area.

If there is to be a future for biotechnology in food and agriculture in Europe, a greater degree of public acceptance and confidence will be required. This will not be easy to bring about. Polls indicate strong opposition to GMOs among the European public, although they also demonstrate that the public does not have a great deal of knowledge about this technology.[13] The debate over biotech products has been largely captured by those strongly opposed, with even moderately cautious groups finding it difficult to get a hearing in a polarized environment. As a result, GM foods are largely absent from the European market, and consumers there lack the opportunity to gain any experience with GM products. Nor should it be assumed that consumer opinion in the United States is firmly in support of these products. The polling data that exists is mixed, and, more than anything else, indicates a lack of familiarity with this issue.[14] The general debate in the United States is also more diverse than in Europe, with a range of views among corporations, scientists, farmers, and consumers.

If there is to be a balanced debate about GMOs in both the United States and Europe — one that will allow flexibility in reducing transatlantic tensions in this area — both European and U.S. consumers will need more knowledge and confidence about biotech innovations, so that they can make informed choices about the purchase of such products. This will require that consumers see a direct benefit in GMO products, either in reduced cost, improved taste, or in terms of health-related benefits. To date, while farmers have benefited through lower costs and fewer pesticides, and agricultural corporations have seen financial gains (with promise of more in the future), consumers have not enjoyed genuinely

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[13] In the December 2001 Eurobarometer 55.2, "Europeans, Science, and Technology," 70.9 percent were inclined to agree with the statement, "I don't want this kind of food," while only 14.6 percent were inclined to agree that genetically modified food does not present any particular danger. However, in a poll specifically on biotechnology, Eurobarometer 52.1, only 35 percent of respondents disagreed with the statement, "Ordinary tomatoes do not contain genes, while genetically modified tomatoes do."

[14] In an August 2001 Gallup poll, 52 percent of U.S. respondents supported the use of biotechnology in food production, while 38 percent opposed. However, only 16 percent of Americans indicated that they had heard a "great deal" about the genetic modification of food.

tastier products or a foodstuffs with added health benefits (reduced cholesterol, for example). Even more important than experiencing a demonstrable benefit, in terms of cost or quality, consumers must have more confidence in the potential impact of these products on the environment and on human health. Even among the relatively tolerant U.S. public, the impact of an incident in which GMOs caused serious damage to human health or the environment would be severe. Thus, the key to boosting public confidence in GMOs will rest on these innovations being handled with appropriate caution and in giving consumers adequate information and choice.

Labeling and Traceability. In response to citizens' concerns, several member states have linked the lifting of the current EU moratorium on approvals of GMOs with legislation that would require tracing of all GMO products and mandatory labeling of all foods with a GMO content of greater than one percent (since reduced to one-half percent by the European Parliament). At first glance, such requirements seem sensible ways to provide consumers with the information and accountability that they need. But experience with other similar regimes suggests that the likely consequence of these requirements will be to effectively ban GMOs from the European market. If this legislation is adopted by the European Parliament and Council of Ministers, existing transatlantic tensions over this issue will be further heightened, and the United States may feel its only option is to take the case to the WTO.

U.S. opposition to the current EU proposals does not mean that all forms of labeling and product tracing are unacceptable, especially given the critical need to boost consumer confidence. The EU threshold of one-half percent accidental GMO content is not achievable without enormous expense in a farm industry that produces both GMO and non-GMO goods, and there is some concern that testing for such a low threshold would generate a significant number of false positives. However, a slightly higher threshold may be workable, although still involving a significant increase in cost and infrastructure to maintain separate tracks. U.S. agriculture has already responded to the change in the European market by beginning to develop the capacity for tracing and separate development of non-GMO foods. But there is still much to be done to make this an effective and efficient system.

As for labeling, the experience in other markets suggests that mandatory labeling of GMO foods will lead corporations to remove those products from the marketplace, thus restricting consumer choice. An alternative is a voluntary labeling scheme similar to that which has developed in the U.S. market for organic foods. Although this first emerged on an informal basis, it now involves certification through USDA.[15] In recent years, a strong niche market has emerged, which has allowed those consumers who wish to do so to pay a premium for organic foods, while not restricting the choices of consumers as a whole. Obviously, a voluntary scheme is not suitable for any product that may present a risk to certain populations; for example, by including a gene from a known allergen in a product where it might not be

[15] On October 21, 2002, the U.S. Department of Agriculture launched a program of national organic standards for agricultural products. Goods will be certified and labeled as "100 percent organic" if they contain only organic ingredients, as "organic" if they contain at least 95 percent organic ingredients, and as "made with organic ingredients" if they are at least 70 percent. Ingredients produced through genetic engineering or containing GMOs are not considered organic. See www.ams.usda.gov/nop.

suspected. Any product that poses a specific risk — whether conventional or biotech in origin — should be subject to normal health labeling requirements.

A key element in the success of any product tracing or labeling scheme will be verification and enforcement. If non-GMO foods command a premium price or have greater access to an important market, the temptation for fraud will undoubtedly arise. The labeling claims must be supported by some kind of testing or enforcement regime, so that consumers can be assured of receiving GMO-free food if that is what they believe they are buying. This has implications, however, for the application of any content thresholds to processed foods or to meats from animals that have been fed GMO-feeds.
In sum, labeling and product tracing can be used to enhance consumer confidence. But they must be implemented in a way that is practical, does not reduce consumer choice, and can be verified and enforced. If any labeling or traceability scheme were discovered to be subject to fraud, the blow to consumer confidence, especially in Europe, would be enormous and long-lasting.

International implications. While the current transatlantic disagreement over GMOs is serious, the implications of that disagreement in the international arena are even greater. Most immediately, the stakes for the WTO are considerable. In theory, the dispute resolution procedure should be an appropriate mechanism for addressing U.S.-EU differences. Mindful of the outcome of the beef hormones case, however, and given the likely inability of the EU to comply in the face of domestic political sensitivities if the decision should go in the U.S favor (which is not certain), U.S. trade officials seem reluctant to pursue a complaint. Thus, the WTO risks being sidelined in those cases dealing with politically sensitive issues, especially where compliance is likely to be an issue.

This dispute is also important for the shaping of other markets, especially in the developing world, where the adoption of this type of agricultural biotechnology is still a matter of considerable debate. Biotechnology that provided more reliable and cost-efficient harvests could bring enormous benefits to the people of the developing world. But that must be balanced with the more limited regulatory and administrative abilities of many of the governments that would oversee the use of such crops and foods. There are also difficult issues of intellectual property rights that would have to be resolved.[16] To complicate these issues further, both the United States and the EU have sought to persuade other countries to adopt their approaches towards biotechnology in food and agriculture. The prospect of an EU market that is essentially closed to GMO goods has already led some developing countries to certify their own agricultural sector as GMO-free, even though that is extremely difficult to verify and enforce.

In sum, this issue is rapidly expanding beyond a simple bilateral conflict into a matter of global economic competition, a development that is likely to intensify as both the United States and the EU seek allies during the negotiations in the Doha trading round. The recent controversy over the use of GM foods to alleviate famine in Africa provides a graphic demonstration of the importance of this issue.

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[16] For an extensive treatment of the issues involved in the extension of agricultural biotechnology into the developing world, see David G. Victor and C. Ford Runge, *Sustaining a Revolution: A Policy Strategy for Crop Engineering* (New York: Council on Foreign Relations) 2002.

The Way Forward

Transatlantic differences over biotechnology in food and agriculture will not be resolved solely — or even primarily — through the efforts of governments. Even if EU authorities were to lift the moratorium on GMOs today, there would be no market for these products in Europe as long as consumers see only risk, not benefits. A simple public relations campaign will not reverse these attitudes. European consumers will need to feel that they have reliable guarantees of the safety of these products. New institutions and new processes of scientific risk assessment may have to be developed to provide those assurances.

For this reason, the overall issue of food safety policy in Europe must be addressed. The establishment of the new European Food Safety Authority is a crucial step forward and should be applauded. The European Union should do everything it can to ensure that the EFSA develops into an independent, scientifically-based risk assessment agency with full public confidence. The United States should be as supportive as possible, and should do what it can to ensure that the EFSA is aware of the international ramifications of its work. To that end, personnel exchanges between the FDA and the EFSA, involving both scientists and managers, could enhance the risk assessment capabilities of both institutions and allow them to share perspectives and compare best practices. The international importance of food safety policy could also be reinforced by enhanced U.S. engagement in the Codex Alimentarius, which would bolster that institution's role as the primary body responsible for establishing food safety standards internationally.

As for the specific issue of GMOs, much can be done to bridge the considerable transatlantic gap. The establishment of the EFSA offers new opportunities for U.S-EU collaboration in risk assessment, both in conventional and biotech foods and feed. Especially as the next generation of GMOs is developed, there may be a need for an intermediate course between the U.S. GRAS and food additives procedures that might best be developed jointly. This would not require that the United States or the European Union abdicate their individual responsibilities to establish an appropriate level of risk for each society, but it would provide a more common basis for assessing that risk and might eventually build more confidence in each other's regulations and procedures. Over the long-term, this might make it possible to establish a mutual recognition agreement on GMOs, which would allow at least certain approvals in one market to satisfy the requirements for entrance into the other market.

To go beyond risk assessment, however, and begin to address transatlantic differences in risk management will require addressing the issue of consumer confidence. This will entail providing consumers with the information they need to make knowledgeable choices. For this purpose, some type of labeling and product tracing system is probably inevitable, at least in some countries. A labeling scheme that allows easy identification of "GMO free" products, while preserving the presence of both GMO and non-GMO products in the marketplace, would provide consumers with the most choice. Obviously, any GMO product that contained a potential allergen must carry the required health warning. Such schemes must be practical in the sense that a small but reasonable percentage of accidental GMO presence should be allowed. The scheme also must be enforceable through testing or certification. Without such verification and testing measures, the temptation to label inappropriate products "GMO-free" may be overwhelming for some suppliers. In order for U.S. products to participate in an EU

market requiring traceability, the U.S. government may have to establish a certification program of some sort. The first step in this direction would be a survey of existing certification programs to see which might offer appropriate lessons and mechanisms.

An additional possibility proposed by some members of the Atlantic Council Working Group — but which did not gain the full consensus of the group — was whether consumer confidence in the safety of GMOs might be enhanced by the establishment of an independent assessment and certification body. This might also be useful for some developing countries. Such an institution might function similarly to Underwriters Laboratories, which offers independent assessments of many electrical and electronic products. Initial funding could be provided by a range of donors, but the funds should be placed in an endowment under the control of a board comprised of industry, consumer, and scientific representatives. This institution could establish and manage a risk assessment process specific to GM foods and feeds, and perhaps also establish a voluntary certification/labeling scheme that would certify the safety of GM-products that pass the appropriate risk assessment procedure and identify GM-free products (perhaps with a range of purity levels). Although voluntary, corporations may find participation in this arrangement with its seal of approval to be an essential part of reassuring consumers about the safety of their products. The need for such an institution would depend on the progress (or lack of progress) in developing the bilateral U.S.-EU collaboration in risk assessment and risk management described above. Beyond the transatlantic dimension, however, it might also be useful as GM products become more widespread internationally. It would be important that any such body not interfere with or undermine the Codex Alimentarius.

It is possible, unfortunately, that none of these efforts to build a more collaborative transatlantic approach to this issue will succeed. In this case, and in particular if the proposed EU labeling and traceability legislation takes effect, the United States should give serious consideration to bringing this dispute before the WTO. Although the risk of increased acrimony is high, a continuation of the current stalemate is untenable and sends the wrong message to the larger international community. Any complaint to the WTO should be narrowly based, focusing not on the legitimacy of labeling and traceability per se, but on the workability of a particular tracing scheme. The EU has an obligation to ensure that measures taken to protect its citizens can be applied in a nondiscriminatory manner, based on testing of actual material rather than the presence of GMOs generally in the exporting country.

The current stalemate between the United States and the EU over agricultural biotechnology will not be resolved quickly or easily. The issue has become embedded in domestic politics, especially in Europe, and political sensitivities remain high.[17] However, some of the steps outlined above might eventually move the EU and the United States toward a more collaborative approach. Central to that is an understanding that consumer confidence is key. In the long run, it will be consumers who will determine whether there is a viable market for GMO products in both Europe and the United States.

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[17] It should be noted that there is increasing awareness in Europe of the implications for prosperity and economic competitiveness if biotechnology continues to be regarded with suspicion. See, for example, Commission Communication "Life Sciences and Biotechnology: A Strategy for Europe," adopted by the Barcelona European Council (March 15-16, 2002).

Conclusions

- Consumer confidence is the most important determinant of any future market for agricultural biotechnology. Central to this will be restoring the credibility of European food safety institutions generally, which have been badly damaged by the recent spate of food safety scares.

- A credible scientific risk assessment process is essential as we proceed with the development of agricultural biotechnology products, including GMOs. The current U.S. system has worked well in dealing with familiar materials that already have long safety records.

- Some form of labeling and traceability may be useful in providing consumers with information and choice. But such mechanisms must not effectively close the market to safe products and must be implemented in a workable and verifiable way.

- The continuing U.S.-EU dispute over GMOs threatens to evolve into a global rivalry over the use of agricultural biotechnology that could put enormous pressure on the WTO dispute resolution procedure and the Doha Round. How the United States and the European Union will resolve this dispute — or fail to resolve it — will have significant implications for future trade in biotechnology and similar goods.

Recommendations

- The United States should encourage European efforts to restore public confidence in food safety institutions, and should thus be as supportive as possible of the new European Food Safety Authority. Exchanges between the FDA and the EFSA should be established in order to facilitate sharing of perspectives and best practices, with the goal of enhancing the risk assessment capabilities of both institutions. The United States should also continue to stress the central role of the Codex Alimentarius as the primary body for establishing food safety standards internationally.

- Whenever possible, the United States and the EU should move toward a more collaborative risk assessment process, especially in relation to GM products. The establishment of the EFSA may offer opportunities in this area, as may the current push for increased scientific cooperation under the New Transatlantic Agenda. It might be especially useful to consider whether a scientific risk assessment procedure that falls between the current GRAS and food additives procedures would be useful. The goal of this scientific collaboration should be to establish a foundation for a transatlantic mutual recognition agreement on agricultural biotechnology products.

- Since some form of labeling and product tracing is probably inevitable in some countries, the United States and the EU should focus their efforts on ensuring that such a scheme is workable and not misleading, while providing consumers with sufficient choice. Labeling that allows the

easy identification of GM-free products and the development of a market in those goods is most likely to provide consumers with the widest choice. Any such scheme must be enforceable through testing or certification. This may make it desirable for the U.S. government to establish a certification regime for GMOs, after conducting a survey of existing certification practices to see which might serve as an appropriate model.

- If the EU passes a labeling and traceability measure with requirements that are essentially unworkable, the United States should give serious consideration to starting the process of pursuing a case through the WTO dispute resolution mechanism. That case should not challenge the EU's obligation to establish a certain level of safety for its citizens, but should be focused on the workability of any such scheme and ensuring that it is nondiscriminatory.

Protecting the Environment: Transatlantic Conflict and Cooperation

In recent years, environmental protection has become a central issue in U.S.-European relations. Differences over the Kyoto protocol have contributed significantly to the view that U.S. and European perspectives and interests are increasingly divergent and that the transatlantic partnership generally is at serious risk. Among much of the European public, the refusal of the U.S. administration to participate in Kyoto has come to symbolize many of the tensions in the broader transatlantic relationship.

Yet the Kyoto protocol is only a part of a much broader transatlantic environmental agenda. Over the years, both the United States and the European Union (including the member states) have adopted many laws and regulations designed to protect their environments. Both have in different ways been in the forefront internationally in developing such rules. The different regulatory approaches behind these rules have led to disputes, especially in the trade arena. Although actual disagreements have to date been limited in both number and scope, some have proven to be as persistent and difficult to resolve as any trade dispute. Given the importance of environmental protection for both the European and U.S. public, the political sensitivity of these disagreements is likely to increase. Ignoring these differences — which have largely arisen despite a shared goal of protecting the environment — will lead to increased transatlantic tensions in the future. By examining this set of issues now, before they become another flashpoint in transatlantic relations, it may be possible to identify ways of reducing tensions and even encouraging enhanced transatlantic cooperation in this area.

Since the 1970s, the U.S. and European governments have sought to limit the risks posed to their citizens and environment by the impact of advanced industrial technologies and consumer lifestyles. In particular, they have sought to lessen the burden of pollution through a range of regulatory remedies. In the United States, these efforts resulted in the Clean Air Act, the Endangered Species Act, Superfund clean up of toxic waste sites, emissions trading, environmental impact statements, and many other measures at both the national and state level. These were enforced in part through the threat of litigation, with polluting companies facing the possibilities of steep penalties. In recent years, there has been a greater emphasis on reaching accommodation between government, industry, and civil society, along with a greater reliance on voluntary approaches.

In Europe, environmental regulations initially lagged behind those in the United States. Following Chernobyl and the rise of Green parties in some countries, legislation evolved at the national level that led to significant differences among the member states, with the northern countries generally more "pro-environment" in their regulatory approach than were the southern governments. As the EU's Single Market moved toward completion and as environmental issues were added to the Treaty of Rome as a matter of Community competence, the European Union emerged as a major source of regulation.

At first glance, the differences in U.S. and EU environmental regulation might appear to be nothing more than disparate domestic policies with little, if any, impact on each other. For two reasons, however, these differences have become an increasing focus of transatlantic discussion, and sometimes, dispute.

First, many of the EU rules were initially written to ensure that there would be no discrimination in intra-European trade involving environmentally relevant goods manufactured in the different member states. These regulations inevitably affect products imported into the EU, including those manufactured by U.S. corporations. The development of European standards designed to lessen the environmental impact of certain products has been especially important. For firms with international markets, the tendency is to simplify production as much a possible, and thus to use one standard — generally the strictest one — imposed by a major market. As a result, in recent years, U.S. firms have found themselves directed toward meeting EU standards, rather than U.S. requirements. At the same time, however, they have found themselves with relatively little influence in the design of those standards or the regulations behind them.

A second major element in the development of EU environmental policy is a commitment to play an active role in international environmental fora and negotiations. As in the case of the Kyoto protocol, this can mean providing EU support for a major new international treaty, even in the face of opposition from the United States. It can also mean seeking to have EU standards adopted by international standards setting bodies and other institutions — in effect exporting EU regulations and transforming them into international rules. Thus, because corporations must meet the requirements of multiple markets, and because of increasing EU activism in the global environmental arena, the differences in U.S. and EU regulatory regimes have the potential to cause enhanced friction in the years ahead.

Over the past few years, several cases of transatlantic disagreement over environmental policy have provided an indication of the challenges the United States and the European Union will face in this area. Foremost among these has been the serious disagreement over the Kyoto Protocol establishing limits on emissions of greenhouse gases. But other, lower profile cases have also provided moments of tension, while sometimes also revealing possibilities for a more constructive dialogue. In particular, transatlantic interaction over aviation hushkits, electronic waste recycling, persistent organic pollutants, and ozone-depleting substances provide some valuable insights into the difficulties of reconciling these regulatory regimes.

Hushkits. In the 1990s, the International Civil Aviation Organization (ICAO) agreed on a standard for aircraft noise, which would require many older aircraft to be fitted with a muffler, or "hushkit," to comply. But because the European public continued to complain about aircraft noise, and local

authorities were taking actions such as imposing curfews, the European Commission (which defined this issue as one of noise pollution) saw a need to create a uniform regulatory regime in Europe. It drafted a regulation in effect establishing a new noise standard for aircraft flying into European airports, but did so by using technical specifications for aircraft engines rather than decibel levels to achieve the standard. These effectively restricted U.S.-made aircraft that used hushkits, while European planes, such as Airbus, were not affected. In fact, some European planes allowed under these rules were noisier than some U.S.-made planes that were restricted. The regulations particularly disadvantaged airlines that flew older U.S. planes. Most U.S. airlines flew newer, compliant planes, but found that the resale value of older planes in their fleets had declined significantly. After the United States threatened to take the dispute to the ICAO, the EU agreed to repeal the new regulation and work with Washington to create a new noise standard at the ICAO. But the four major U.S. airlines insisted that the United States pursue its complaint at the ICAO. In early 2002, a settlement was reached under which the EU repealed the regulation and the United States withdrew its complaint, although the U.S. administration has made clear that it will watch implementation of the replacement directive carefully.

Electronic waste. The European Union is currently considering directives on Waste Electrical and Electronic Equipment (WEEE) and Restrictions on Hazardous Substances in Electrical and Electronic Equipment (ROHS), which are likely to be approved in late 2002. These directives arose out of the realization that there was a considerable stream of solid waste from computers, electronic gear, and appliances, and yet it was unclear who was responsible for collecting and recycling that waste. European governments have generally favored a "producer pays" approach, but the cost could vary considerably depending, for example, on whether producers were required to collect material at individual households or could take advantage of existing community collection schemes. In the mid-1990s, some EU member states adopted national legislation aimed at managing this waste, but there were considerable differences of approach. The Commission became concerned that these differences would adversely impact the single market and so began developing EU-wide legislation. The draft legislation developed in 1998-99 would have banned a number of substances, as well as requiring producers to adopt environmental design standards and undertake household collection of waste goods. Eventually, the legislation was broken into three parts: WEEE deals with recycling, ROHS with harmful materials such as lead and cadmium, and EEE with environmental design emphasizing technical standards. The legislation expected to come into effect in late 2002 bans certain hazardous materials, but not those like lead, for which there is no substitute. It also allows for a range of collection alternatives. The measures concerning environmental design are not part of the legislation expected to pass this year.

Persistent organic pollutants. In December 2000, after difficult negotiations, the United States, the European Union, and numerous other countries signed an international treaty banning persistent organic pollutants, or POPs. POPs are highly toxic chemicals (such as PCBs) that persist over long periods of time and can accumulate in biological tissues (animals and humans). The treaty bans twelve chemicals, and includes provisions for banning additional chemicals in the future.[18] The United States and the EU member states phased out the use of the twelve POPs listed by the treaty in the 1960s and

[18] The treaty allows for the continued limited use of some chemicals for which there is no effective alternative in those countries with a particular need (fighting malaria, for example).

1970s, but found that the effects of use elsewhere were still serious enough that an international mechanism to prevent that use was required. This mechanism had to accommodate the differing U.S. and EU regulatory systems and also be open to participation by the developing countries, which were the primary users of POPs. During the negotiations, the major disagreements were between the United States and Europe, and centered on five issues: 1) differences in regulatory approaches and mechanisms; 2) standards for byproducts, and especially over whether elimination was technically feasible; 3) disposal of hazardous waste; 4) trade-related issues (although trade in POPs was declining); and 5) the use of precaution, especially in expanding the list of restricted chemicals. The last was the most difficult issue, with the EU pressing to adapt the precautionary principle language from the Biosafety Protocol, while the United States maintained that any precautionary language should be developed specifically for the POPs case. Moreover, because the POPs treaty was about banning dangerous chemicals from use throughout the world, the U.S. government maintained that it was inherently precautionary. Agreement was eventually reached on language proposed by the United States, which recognized that the committee reviewing chemicals should take scientific uncertainty into account, but that uncertainty should not be a reason for not adding to the list. With this agreement on precaution, the treaty was concluded, and it still represents a successful resolution of transatlantic differences in this area.

Ozone-depleting substances. The success of the Montreal Protocol in phasing out chlorofluorocarbons (CFCs) led to a vigorous transatlantic debate about replacement technologies. Initially, the most popular replacements were hydrochloroflourocarbons (HCFCs), which are to be phased out by 2030 under Montreal. The other alternative, hydroflourocarbons (HFCs), are also classified as greenhouse gases under Kyoto, but as part of the basket of gases to be addressed collectively. U.S. officials maintain that HFCs are safe and energy efficient, although emissions should be controlled. However, the prospect has been raised that the EU — which generally has less need for these substances since they are used primarily for air conditioning and refrigeration — may phase out HFCs by banning them as a greenhouse gas. The EU has focused on the development of hydrocarbons as a replacement for CFCs, even though these substances are flammable and less energy efficient when used. However, while the European Commission has sought to establish an EU position, some member states, such as Denmark, have proposed their own more restrictive legislation, which would phase out HFCs by 2006. Although development of an EU directive would present problems for U.S. industry, it might pre-empt some member states from adopting tougher legislation.

These four cases amply demonstrate the wide range of transatlantic environmental issues and the many complexities that make differences over these matters difficult to resolve. But these complexities can be overcome. Two of the cases — POPs and hushkits — have been successfully resolved, at least for the moment, giving hope that those concerning waste electronics and ozone depleting chemicals may also reach an acceptable accommodation. But these cases also demonstrate that policy choices that in the past were purely domestic in their effect now have a very real international impact. While that impact is most immediately felt by the transatlantic economic relationship, the implications certainly reach beyond to the wider international arena. On one level, corporations seeking to simplify their business practices while meeting the standards imposed by the U.S. and EU markets will export those practices to other markets. On a more formal, legal level, the standards and practices that develop out of the two dominant markets will inevitably affect those adopted by international bodies. This process can be marked either by transatlantic rivalry over practices and standards or by gradual harmonization and

mutual recognition. In either case, the transatlantic experience will undoubtedly set a pattern for the extension of practices and standards worldwide.

A review of these cases reveals some factors that have added considerable complexity to disputes in the environmental field and highlights some critical differences between the United States and the European Union. These factors are: the existence of multiple actors with multiple agendas; the persistence of issues; the issue of risk assessment vs. risk management; and the importance of implementation.

Multiple actors with multiple agendas. As with agricultural biotechnology issues, environmental matters have brought new agencies, both in Europe and the United States, into the transatlantic arena. The U.S. Environmental Protection Agency and DG Environment are only the most obvious. These new actors are rarely directly concerned with the state of the transatlantic economic relationship. They have their own policy priorities and constituencies, usually with a firm domestic orientation. Some agencies may take a primarily technical approach to the issue in question, with little awareness of the international policy implications. In the hushkits example, the Department of Transportation initially treated the development of EU standards as an inconsequential technical matter. The delay in addressing the trade implications of the issue made the situation much more difficult to resolve later on, as it is always easier to revise a proposed regulation than to repeal an approved one. The most obvious response to the entry of these agencies into the transatlantic fray is to educate them about the potential international implications of their actions. However, international concerns are likely to remain a small part of their activities, and their orientation is thus likely to remain overwhelmingly towards their domestic priorities and constituencies.

Domestic agencies are not the only actors complicating transatlantic environmental politics. In the United States, many of these issues are regulated or enforced on a state basis, and so bring another level of government into the arena. In Europe, the major new actor in these areas is the European Commission itself. In three of these issues — hushkits, ozone depleting substances, and electronic waste — the Commission responded to a growing array of divergent national policies by attempting to establish an EU-wide regulatory regime. Observers differ as to whether the Commission was motivated primarily by a desire to enlarge its own area of competence and influence; by a determination to protect European industries; by a concern over the environment (along with a desire to respond to public support for environmental protection); or by some combination of all three. However, it should also be noted that while Commission proposals can sometimes lead to stringent regulations across Europe, they have also sometimes served as a force for the reduction and simplification of regulations when compared to the member states. Whether Commission activism is compatible with or contrary to U.S. goals depends on the particular case.

The emergence of the Commission as an activist in this area does not mean that the member states can be ignored. In the hushkits case, the member states pushed the Commission toward agreement with the United States, and the eventual resolution of the waste electronics issues may depend on the way the member states adopt and implement whatever EU-wide regulations are passed. Yet, the member states are far from unified on these issues. Major differences exist, especially between the more northern "green" member states, such as Denmark, Sweden, Germany, and the Netherlands, and the southern members, who take a much less activist position on environmental protection. Depending on who

holds the rotating EU presidency, these differences can have major impacts on the progress of environmental legislation. In addition, the European Parliament and the NGO community can be powerful actors on these issues. The Parliament has considerable legislative power on environmental matters and has repeatedly demonstrated its willingness to move toward a "green" position. In the case of the WEEE directive, the realization that the Parliament would insist on legislation of some sort led industry to work closely with the environmental NGOs to develop a position with wide acceptance. Indeed, the relative power of the Commission, the member states, and the European Parliament is constantly evolving.

Persistence of issues. All of these cases demonstrated the staying power of environmental issues in the transatlantic arena. As science identifies additional threats and technology makes new alternatives available, regulations must be adapted and new issues will arise. The settlement on hushkits was made possible by an agreement to write new airplane noise standards at the ICAO. The POPs treaty currently lists twelve prohibited chemicals, but includes provisions to add more. Efforts to control ozone-depleting substances have both been made possible and more complicated by the development of different replacements, HFCs in the United States and hydrocarbons in Europe. After the WEEE and ROHS directives are passed, the EU is likely to continue its efforts to reduce waste electronics by developing technical standards, which will need to be harmonized in some way with U.S. standards.

The lesson of all these cases is that these issues will continue to be a significant element in transatlantic relations for the indefinite future. The combination of better scientific risk assessment and evolving technology ensures that the United States and the EU are faced with moving targets as they attempt to construct regulatory regimes that both protect the environment and enhance transatlantic economic relations. In addition, the environmental policies of the United States and the EU will inevitably vary from time to time. Thus, efforts to reconcile U.S. and EU approaches to environmental regulations must cope both with the persistence of issues and the changes in policy that are inevitable over the longer term.

Risk assessment vs. risk management. As in the case of agricultural biotechnology, the scientific assessment of environmental risk is an evolving process. There is an ever-increasing body of scientific knowledge about the environmental impact of various materials and practices, especially as more experience is acquired over time. Substances that were once believed safe have been banned by the POPs treaty and other mechanisms, and this will happen again in the future as more becomes known about society's impact on the environment. But, again as in the case of biotechnology, scientific risk assessment is only the first step in transatlantic reconciliation of these issues. Too often there has been a tendency, especially in the United States, to treat these issues as merely technical questions to be resolved by the scientific community. This attitude has sometimes delayed consideration of the more controversial policy questions involved in risk management.

On environmental issues, differences in risk management policies have been at the heart of transatlantic disputes. In particular, two patterns have emerged as problematic.

First, as demonstrated by the hushkits case, the European Union tends to place much more reliance on design standards, which mandate the inclusion of particular components or other design elements. The

United States has increasingly turned away from design standards to emphasize performance standards, which work by establishing objectives and allowing flexibility in how they might be met. Design standards were included in the initial waste electronic directive, and although such standards for computers and other electronic equipment are not being legislated at the moment, industry does expect this approach to reappear in the future. Likewise, design standards for refrigerators and other equipment that may generate either ozone-depleting chemicals or greenhouse gases loom as a future possibility. The challenge the EU will face in meeting its Kyoto targets will certainly increase pressure for all types of regulations that might contribute to the reduction of greenhouse gases. But too much reliance on design, rather than on performance standards, can add a great deal of inflexibility into the system, especially given the rapid pace of change in environmental technologies.

Second, risk management must take into account both the costs and benefits of a particular course of action. Banning a specific substance or practice that harms the environment makes eminent sense if there are safe and cost-effective alternatives. For example, despite legitimate concerns about the impact of lead on the environment when it is discarded, the current WEEE recognizes the lack of a safe and effective substitute. Similarly, the POPs treaty allows limited exemptions for countries that need to continue using the banned chemicals if there is a specific need and no cost-effective alternative. In the case of ozone-depleting substances, however, the EU trend toward replacing HCFCs and HFCs with hydrocarbons may add new dangers, since these chemicals are more highly flammable. Thus, a thorough consideration of alternatives, including their cost and reliability, not just the environmental impact, is a necessary part of every risk management strategy. Indeed, the need for this balance between safety and cost-effectiveness is recognized in both the Montreal Protocol and the EU Food Safety Law.

Implementation and enforcement. Writing and adopting laws and regulations is only part of any strategy of environmental protection. Implementing those rules and ensuring that they are enforced is equally, if not more, important. A major question mark on any EU environmental legislation must be its implementation and enforcement, since these are mainly left to the member states, which vary considerably in their implementation of EU regulations and directives across a whole range of issues. Given their widely varying attitudes toward environmental protection, we can expect implementation and enforcement of these rules to vary even more than usual. Ironically, the recent trend toward using framework directives, which establish objectives but allow flexibility by the member states in achieving goals, could exacerbate these differences. Although U.S. corporations have generally welcomed the use of framework directives, the diversity this may create in implementation could be to the disadvantage of U.S. business. Another element of uncertainty is the impact of the European Court of Justice, which is charged with making an ultimate determination as to whether a member state has appropriately interpreted and implemented EU law. The degree to which this will encourage compliance by member states is still unclear.

In the United States, the question of implementation and enforcement is central to regulatory policy. Agencies such as EPA both promulgate and enforce regulation, while DG Environment focuses more on the first task. Indeed, many U.S.-EU differences in negotiation both in agricultural biotechnology and in the environmental field center on whether a particular provision can be practically implemented. In the POPs negotiations, for example, the question of whether the byproducts of these chemicals could actually be eliminated became a sticking point. For companies operating in the United States, being

caught in violation of regulations can be a costly experience, involving legal fees, significant fines, and, in some cases, legal damages. Thus, U.S. companies tend to be relatively self-policing, even when faced with the reduced emphasis on enforcement that exists in parts of Europe.

The Way Forward

Environmental regulation has only recently emerged as an area of discussion and disagreement between the United States and the European Union. Given the increasing integration of transatlantic markets, these regulatory issues are likely to become even more important in the future. Moreover, once a dispute erupts, public support for environmental protection, especially in northern Europe, makes the issue politically sensitive and difficult to resolve. Yet these matters have so far received little attention outside a narrow circle of business, NGO, and policy actors.

Environmental regulations and standards have great potential to disrupt the transatlantic trading relationship. But beyond these commercial aspects, the tensions exhibited in the disputes described here demonstrate the difficulties of harmonizing environmental policies, even when the overall goal is shared. Over time, both the EU and the United States have made environmental protection a priority. But they have sought to achieve that objective through regulations and standards developed in isolation from each other and in response to the needs of various domestic constituencies. Reversing this trend at a time when U.S. and EU environmental policies are so different will be extraordinarily difficult. But failure to do so will have negative consequences both in the trade and environmental arenas. Instead, some important steps toward collaboration can be taken if both U.S. and EU agencies and industry can be engaged in this effort.

The first step away from a path plagued by transatlantic conflicts is for the issue of environmental protection to receive the attention and leadership it deserves. This will require that the U.S. government become more engaged on this issue. The environmental policies of the current U.S. administration differ greatly from those of the European Union. But the United States has a significant track record of accomplishment in this area, and there is much that the U.S. and EU can learn from each other. To create a conducive climate for such cooperation, Washington and Brussels should move beyond their disagreement over Kyoto and reaffirm their shared commitment to protecting the environment, even if they approach this task with very different perspectives. The U.S. Congress and the European Parliament should be an integral part of this re-engagement, since both are central to the making of environmental regulations.

Once the importance of this issue has been reestablished, the United States and the EU should look for opportunities to share perspectives, and where possible, develop genuine collaboration. As with food safety, the best initial steps may be in comparing risk assessment procedures, as envisioned in the new U.S.-EU Regulatory Guidelines. This could eventually lead to joint risk assessment projects and other collaborations, especially examinations of best practices in regulatory policy and enforcement strategies. Personnel exchanges between EPA, DG Environment, and other institutions, such as the European Environment Agency, may be useful in encouraging the sharing of perspectives and best practices, and in creating the personal networks that can help defuse misunderstandings and conflicts.

On the multilateral level, the United States must re-engage in the development of international standards. This will require increased attention by both the U.S. government and industry, especially in the private standard-setting bodies. The European Union is already active in this area, but to date the transatlantic dialogue on standards has not been very productive. EU activism cannot be countered effectively by a simple rejection of the notion of international standards. Instead, the U.S. administration and the European Commission should work to develop standards that can be widely accepted and that both protect the environment and are compatible with open markets. Establishing new congressional reporting requirements on the status of international standard setting and U.S. involvement could provide the stimulus needed for U.S. agencies to demonstrate more leadership in this area.

Conclusions

- Although both the United States and the EU share the basic goal of environmental protection, they have pursued this objective through the development of distinct, and sometimes conflicting, regulations and standards. These regulatory differences have the potential to become another acrimonious area of transatlantic relations in the future.

- Efforts to reconcile U.S. and EU regulatory regimes have been hampered by several factors, including: the existence of multiple actors with multiple agendas; the persistence of issues; the issue of risk assessment vs. risk management; and the importance of implementation.

- Transatlantic differences over environmental matters should not be treated either as a mere technical question or a simple trade dispute. They reflect different political choices made in the United States and Europe, and so involve real political issues. As with agricultural biotechnology, the key difficulty lies not in risk assessment, but in different approaches to risk management.

- Avoiding a greater level of transatlantic tension over this issue will require more intense U.S. engagement in creating sound policy on environmental protection, and more willingness by both the United States and the EU to seek out opportunities to share perspectives and develop more collaborative approaches.

Recommendations

- The United States and the EU should reaffirm their common commitment to environmental protection. On the U.S. side, this will require greater engagement and leadership, especially from the White House and Congress. An interagency group on international aspects of environmental protection would help give this issue a higher profile across the government. The commitment of the United States and the European Union could also be demonstrated by a

joint statement on environmental protection and its compatibility with international trade, to be issued at the next U.S.-EU summit in the spring of 2003.

- Although risk assessment has not been the major point of difference over environmental issues, encouraging more collaborative assessments, perhaps through the NTA scientific cooperation agreements, can help build a stronger foundation for U.S.-EU understanding and cooperation in this area. Exchanges between appropriate U.S. and EU agencies could be extremely useful in fostering the sharing of perspectives and development of cooperative activities and should be mandated and funded by Congress. Among the long-term aims of this collaboration might be the joint development of standards for environmental technologies that are compatible with international trading obligations and the design of appropriate mutual recognition agreements.

- Collaboration in risk management will be essential in avoiding future tensions, and could begin with a comparison of best practices, both in environmental protection generally and in regulatory policy. Such a comparison could be undertaken by industry and NGOs, as well as by the relevant U.S. and EU agencies, and could be valuable in identifying specific mechanisms that contribute to environmental protection while not creating barriers to commerce.

- U.S. government and industry must re-engage on the issue of standards, particularly within the international standards-setting bodies. This should not be treated as an area of mere technical discussion, but as an issue in which U.S. leadership (from both the government and private sector) will be key in ensuring that the results are compatible with both environmental protection and the obligations of international commerce. Establishing new congressional reporting requirements on the status of international standards and the actions of U.S. agencies could provide the necessary stimulus. But this is not simply a government responsibility — U.S. corporations should also be prepared to take on the necessary leadership roles in private-sector bodies.

Reconciling Regulatory Regimes

The United States and the European Union face the challenge of reconciling their regulatory regimes to attain two distinct — but not necessarily conflicting — goals: to protect the environment and the consumers, and to fulfill the obligations of the international trading system. Given the interconnectedness of their economies, it is hardly surprising that they have been among the first to experience this clash of international trading rules and domestic regulation. Their early attempts at reconciling these objectives have not been impressive, as evidenced by the continuing disputes over beef hormones and GMOs. But there are other cases that indicate that the United States and the EU can work together to resolve these issues, or at least reach a workable accommodation; the POPs treaty and hushkits are cases in point. Other cases — and many more to come in the future, such as chemicals regulation and restrictions on greenhouse gases — are unresolved.

We are now at a fork in the road. If U.S. and EU regulatory policies continue to be made without adequate regard for the international impact, future regulatory issues could easily erupt into yet another

series of difficult and persistent transatlantic disputes. The implications of this would go far beyond the bilateral U.S.-EU relationship. But if the United States and the EU begin to exercise leadership on this issue, they could foster the development of new strategies for reconciling distinctive regulatory systems. A first step has been made with the agreement on Guidelines for Regulatory Cooperation and Transparency. Further steps, such as negotiating a "time-out" provision that would require each government to suspend the legislative process for a period of consultations, could also be helpful. Over the long term, constructing a more collaborative approach based on the recommendations outlined in this report could be much more effective in protecting citizens and the environment, rather than a future dominated by difficult and persistent confrontations.

The following general principles, drawn from the cases discussed in this report, could help guide that process.

Public confidence in regulatory and enforcement authorities will be critical to building transatlantic agreement. Whether it is about the safety of food or crops, or the treatment of hazardous substances such as lead, the public will be sensitive to any mistakes. Thus, in regulating these substances, it is in the interests of everyone to focus on building credible procedures and institutions. A key test will be the establishment of a credible European Food Safety Authority with appropriate consultative links with the FDA.

The regulatory process should be as transparent as possible, both for the public and for other governments. This does not mean only that documents are plentiful and available after the fact, but that citizens, NGOs, the private sector, and other affected governments have access to the decision-making process. The new U.S.-EU regulatory guidelines identify some important steps to make this a reality, but it is far too soon to assess their implementation. Continuing involvement in these issues by the Transatlantic Business Dialogue, along with revitalized engagement by the Transatlantic Consumer and Environmental Dialogues, could be helpful.

Government agencies and legislatures should pay greater attention to the international implications of the regulatory process. Many domestically oriented regulatory agencies must have a better grasp of the international implications of their work. This will be a long-term educational project, and will probably require exchanges, workshops, and other steps that will at first seem far removed from the immediate needs of these agencies. Because Congress and the European Parliament are central to regulatory politics, members and staff should also be involved in such confidence-building exercises, through the Transatlantic Legislative Dialogue or other mechanisms.

Risk assessment should be an increasingly collaborative undertaking, both on food and environmental issues. The new regulatory guidelines, along with the scientific collaboration encouraged within the NTA, support the exchange of scientific information. This process should go farther, with assessment agencies designing and managing joint assessments that meet the needs of both European and U.S. regulatory regimes.

There is a place for precaution, but it should be exercised in the context of specific cases and should be provisional, pending continuing scientific assessment. There is always a role for

precaution when new technologies are introduced. But because new information and technologies appear at different rates, precaution is best applied in specific instances, while accompanied by further scientific assessment.

Risk management is central to any regulatory system and should be developed in a way that allows reasonable flexibility in achieving performance objectives and that takes into account the costs and benefits of different approaches. Developing a better mutual understanding of U.S. and European perspectives on standards and such tools as cost-benefit analysis will be an integral part of any effort to reconcile regulatory regimes.

Regulations should include adequate provisions for uniform implementation and enforcement. Ensuring that roles and standards can realistically be implemented and enforced is essential. Enforcement should be non-discriminatory and backed up by verification when appropriate and possible.

International institutions remain a key element in the reconciliation of these regulatory regimes. The Codex Alimentarius and the WTO will be central in managing the international implications of U.S.-EU disputes on food safety and environmental regulatory issues. They provide a forum for discussion of these issues, along with a set of established international rules. Even when unable to enforce compliance in very politically sensitive cases, the WTO is still the most appropriate forum for dispute resolution, and its decisions make clear for all members the international legality of various national measures.

Overcoming the current regulatory differences between the United States and the EU will not be easy. The atmosphere surrounding the transatlantic debate over GMOs — both on the public level and among policymakers — will make it difficult to explore opportunities for cooperation. Sensitivities are not yet as great on most issues involving environmental regulation. There is room for compromise and accommodation, but only so long as the public (especially in the northern EU member states, which dominate EU decision-making in this area) is convinced that the goal of environmental protection has priority. As the food safety crises have demonstrated, a serious environmental disaster could have enormous impact on the political context of any transatlantic attempt to reconcile these regulations. Any attempt to reduce transatlantic tensions in this area will be much more productive if both parties are seen by the public as genuinely committed to the overall goal of environmental protection. Even with public acceptance, it will still be a long and difficult road. No single step by itself will make this endeavor a success; instead it will be a lengthy process involving changes in attitudes and procedures across many agencies and institutions.

Neither the United States nor the European Union can afford any longer to write regulations on food safety and environmental protection in domestic isolation, only later to be forced to defend those rules in the international arena. As the transatlantic economies integrate, so must the regulatory processes that affect so much of the economic exchange across the Atlantic. Even though U.S. and EU authorities will remain the ultimate decision-makers for the indefinite future, the final regulations will benefit by extensive transatlantic consultation, both on risk assessment and the appropriate policy response. Greater collaboration will not resolve all transatlantic disputes, for there will be genuine

disagreements. But it may reduce the number of disputes arising out of inattention and a lack of awareness of the international implications of these apparently domestic decisions. By taking advantage of opportunities for greater consultation, and eventually for collaboration, the United States and the EU will reduce the chance that regulatory policy will lead to a series of inevitable and difficult confrontations. Instead they will be able to focus on working together in creating regulatory regimes that effectively protect consumers and the environment.

ANNEX

Comments by Working Group Members

Robbin Johnson

I endorse this report because its overall emphasis on dialogue and collaboration are more likely than confrontation to bridge obvious transatlantic gaps in regulating for food safety and environmental protection. With regard to products of agricultural biotechnology — what the report calls GMOs — the report also gets many of the basic principles right. I would have preferred, however, that the report had handled labeling/traceability differently.

It would be more informative for consumers and more effective for producers to orient voluntary labeling around a product's principal or predominant attributes. Such labels would say what a product is — e.g., this product is grown organically, or comes from conventionally bred stock, etc. Labels that define what is excluded — e.g., "GMO free" — are harder and more costly to enforce. Similarly, labeling requirements triggered by the failure to exclude an ingredient rather than by what constitutes the principal ingredients poorly serve consumer choice. Such "denial" labeling also is more likely to stigmatize products of agricultural biotechnology than to promote a broad range of choices, and it is fraught with execution and enforcement problems.

If labeling follows principal attributes rather than being triggered by detection of minor presence of an attribute, then traceability can take on a different role. It becomes a means of assuring that the principal attributes of a product reach users as promised, which can be done at very reasonable cost. Any tracing back requirements designed to detect a minor presence of an attribute should be limited to real safety risks, given the costs and problems involved in that approach.

Stephen M. Stevick

The report mentions the failure of the working group to demonstrate an explicit consensus on calling for the United States and the EU to go beyond a reconfirmation of their commitment to protect the environment by adopting a common environmental ethic. I believe that this is an error of omission and not commission on the part of the group. It seems to me that a consensus of the group on recommendations to protect the environment by employing clearly defined standards, assessing risk, and identifying best practices would by implication embrace the concept of a common environmental ethic. Otherwise, what would standards, risks, and best practices be based upon? It seems to me, an agreement on a common ethic is a prerequisite to the setting of standards, risks and identifying best practices.

I am puzzled by the recommendation regarding the precautionary principle: "There is a place for precaution, but it should be exercised in the context of specific cases and should be provisional, pending continuing scientific assessment." (p. 29) The excellent treatment of the issue in the beginning of the

report underscores the importance of the precautionary principle in issues of international trade. Yet the recommendation regarding the precautionary principle cited above does not seem to reflect its significance in the international arena, unless one reads the wording "always a role for" as a "principle," and recognizes that, in the final analysis, principles come to life when they "apply to specific issues." It is my impression that the working group acknowledged the significance of the precautionary principle as a concept to be reckoned with, although a number of participants not representing the environmental sector expressed concern, even skepticism, that the precautionary principle provided a reliable basis for setting trade policy and resolving issues of trade and the environment.

I personally believe that much of the concern about the precautionary principle expressed by members of the working group is due to the group's failure to discuss first the concept of an overriding purpose of precaution. Again, the environmental ethic referred to above would help define the goal of the precautionary principle and, in turn, its use as a means of defining, if not resolving, issues of trade and the environment. I think there needs to be further work on the concept of an overriding environmental ethic for transatlantic trade, and, in turn, the role of the precautionary principle in transatlantic trade.

Lawrence F. Williams

This report provides a good overview of the problems and conflicts associated with expanded trade authority as it relates to the environment and food safety. There is one important area, however, where I believe it falls short: the recommendation regarding the precautionary principle. The report cites the various multilateral agreements signed by the United States which acknowledge the importance of allowing each trade partner to take measures designed to "protect the environment if there is a risk of serious or irreversible damage; that is, restrictions can be placed on a product if it is believed to cause serious environmental harm, even if the scientific evidence is incomplete." (p. 5) These agreements include: the 1992 Rio Declaration on the Environment and Development; the Biosafety Protocol; and Article XX of the GATT. As the report notes, the GATT allows the WTO to make "exceptions to normal trading rules for measures 'necessary to protect human, animal or plant life or health' or 'relating to the conservation of exhaustible resources.'" (p. 6)

The report correctly notes that the U.S. government has taken exception to the precautionary principle. Despite the fact that it has signed three agreements acknowledging its importance, the United States has argued for more flexibility in deciding when and how the precautionary principle should be applied. I believe that the United States should be called upon to accept the precautionary principle as agreed to. The basis for judging the validity of a particular trade restriction using the precautionary principle should be based upon how fairly the embargoing country has applied the import restriction or process standard within its own jurisdiction.

For example, if the U.S. government were to require all paper manufacturers to adopt a chlorine-free manufacturing process based on the belief that the use of chlorine in the manufacturing process poses a threat to aquatic life, then this restriction should not be subject to challenge by exporting countries who do not agree with the appropriateness of the restriction. This process standard should not be available

for challenge if the standard is uniformly and universally applied to all domestic and foreign manufactures alike.

Therefore, I would like to add the following to the first recommendation of the section entitled, "Protecting the Environment: Transatlantic Conflict and Cooperation" (p. 26): As a signatory of the 1992 Rio Declaration on the Environment and Development and the Biosafety Protocol in 2000, the United States should reaffirm its commitment to the precautionary principle which holds that the lack of scientific certainty regarding the potential adverse affects on biodiversity and human health should not be used to prevent the importing party from restricting an import based on its desire "to avoid or minimize such potential adverse effects" if the country has fairly and evenly applied such restriction on its own citizens.