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GMO Trade Regulation and Developing Countries

Richard B. Stewart¹

Commercial adoption of genetically modified (GM) foods and crops (also called “genetically modified organisms” or “GMOs”) created through recent innovations in agricultural biotechnology has triggered widespread controversy over the environmental and economic benefits and risks of GMOs as well as a wider range of social, cultural, and ethical values. Differences among nations in their assessments of GMO cost and benefits and in their interests and values have led different countries to adopt quite different environmental health and safety (EHS) regulatory programs for GMO foods and crops. These differences in turn have produced sharp trade conflicts. GMO agricultural exports from countries that favor GMO technologies, such as the U.S., have been blocked by GMO regulations in jurisdictions, such as the EU, that oppose or are skeptical regarding GMOs. Moreover, the advent of domestic labeling and traceability requirements for food imports, such as those recently adopted by the EU, may seriously inhibit the use of GM crops in exporting countries even where those crops are consumed internally or exported to third countries. The advent of dramatically higher food prices has enhanced interest use of GMO crop varieties and led to some softening of regulatory restrictions and consumer attitudes in Europe and some developing countries, but sharp differences and conflicts among states over GMOs remain. Such conflicts have posed a severe challenge to the various international authorities -- including the WTO, international environmental and health standard-setting bodies such as the Codex Alimentarius Commission, and the Biosafety Protocol – that deal with GMO trade and regulation

In analyzing this challenge, this paper focuses particular attention on its implications for developing countries. Unlike many international environmental issues, the divide on GMOs is not North/South. There are sharp differences in GMO policies and regulations among developed countries – most notably between the US and Canada on the one hand, and Europe, Japan and South Korea on the other. There are also sharp differences among developing countries; a number of important countries have, with varying degrees of cautions, embraced GMO crops, but many developing countries are on the fence and a few are strongly opposed. In Africa, South Africa and Egypt are the only countries with authorized commercial plantings of GM crops; South Africa, in particular, is regarded as a leader on GM crop issues in Africa.² In 2006 South African farmers planted GM crop varieties on 1.4 million hectares, making the country the eighth in the

¹ This paper is based on a project on a Project on International GMO Regulatory Conflicts, funded by the Rockefeller Foundation, which I directed. The support of the Rockefeller Foundation is gratefully acknowledged. I also thank my colleagues in the project, Ernestine Meijer (who provided much of the research reflected in this paper) and Jane Stewart, my NYU colleague Rob Howse for helpful comments, and Jeremy Marwell and Nikhil Dutta for excellent research assistance.

² *Egypt Approves BT Corn Cultivation*, INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS CROP BIOTECH UPDATE, Apr. 25, 2008. For a detailed if slightly dated report on GMO policies and regulation in South Africa, see ROSEMARY A. WOLSON, SOUTH AFRICA: GMO REGULATION AND POLICY (Rockefeller Foundation Project on International GMO Regulatory Conflicts 2006).

world in GM acreage. GM varieties accounted for 92 % of South Africa's cotton, 44% of corn, and 59% of soybeans.³ There is, however, domestic opposition to GMOs from environmental and church groups. The government is taking a rather cautious regulatory approach to GMOs; it recently denied approval for GM sorghum and cassava for food and for GM corn to produce biofuel because of concerns over containment of gene flow to non-GM varieties.⁴ Eight other African countries, including Burkina Faso, Kenya, Morocco, Senegal, Tanzania, Uganda, Zambia, and Zimbabwe, have conducted field trials of GMO crops. 20 countries have some form of GMO R&D program.⁵ There is, for example, a marked degree of emerging interest in GMOs in Zimbabwe.⁶ And even countries that remain unwilling to plant GMOs have become more amenable to the prospect of importing such crops; Kenya's agriculture minister, for instance, announced in August 2008 that Kenya would begin importing genetically modified foods in response to food shortages.⁷ There is, however, significant opposition in many countries to GMOs on economic and environmental health and safety (EHS) grounds as well as out of concern that GM crops would threaten traditional agriculture. Zambia, for example, has maintained implacable opposition to commercial use of GM crops despite calls for a group of scientific, agricultural and nongovernmental organizations to use GMOs to reduce poverty and hunger.⁸ At the same time, unauthorized plantings of GM crops may be occurring in Southern Africa as GM seeds can easily cross borders.⁹

Developing countries, however, have much more at stake in resolving these conflicts than do developed countries.¹⁰ The potential economic and environmental benefits and risks are often greater for developing than for developed countries. GMO crop varieties can potentially meet the food security needs of developing countries and enhance crop exports. They can also address the challenges of droughts and other impacts of climate change,¹¹ and provide environmental benefits by reducing use of agricultural chemicals and reducing the need to clear forests to expand crop acreage. . At the same time GMO crops may pose ecological risks that developing countries are often ill-equipped to manage. GMO crops may also encounter consumer resistance and regulatory restrictions in many developed countries. To date, however, most developing countries have been trapped in the crossfire of conflict between the EU and US, which has also

³ GLOBAL AGRIC. INFO. NETWORK, U.S. DEP'T OF AGRIC., REPUBLIC OF SOUTH AFRICA BIOTECHNOLOGY ANNUAL REPORT 2007 (2007).

⁴ See Mariam Mayet, *No Gateway to Africa's Sorghum*, AFR. CTR. FOR BIOSAFETY, July 10, 2006; Tamar Kahn, *Keep Modified Cassava Behind Glass – Regulators*, BUS. DAY (Johannesburg), Mar. 22, 2007; Melanie Gosling, *South African Government Rejects Modified Maize*, INDEP. ONLINE, Mar. 29, 2007.

⁵ See MARIAM MAYET, AFR. CTR. FOR BIOSAFETY, *THE NEW GREEN REVOLUTION IN AFRICA: TROJAN HORSE FOR GMOS?* (2007).

⁶ See Sifelani Tsiko, *Biotech Can Boost Developing Economies*, HERALD (Harare), Oct. 8, 2007; *Cotton Industry Urged to Invest in Biotechnology*, AFR. NEWS, Feb. 14, 2007.

⁷ *Kenya To Import Genetically Modified Foods, Says Minister*, AGENCE DE PRESSE AFRICAINE, Aug. 18, 2008.

⁸ See Michael Malakata, *Zambia Adamant: No GM*, SCIDEVNET, Aug. 3, 2007.

⁹ See Sifelani Tsiko, *GMO Products Spread in SADC – Study*, HERALD (Harare), May 22, 2007.

¹⁰ See generally Ernestine J. Meijer & Richard B. Stewart, *The GM Cold War: How Developing Countries Can Go From Being Dominoes to Being Players*, 13 REV. EUR. COM. & INT'L L. 247 (2004).

¹¹ See Hans Pienaar, *Drought-resistant maize trials to start soon in South Africa*, GENETICS NEWS, Oct. 22, 2007.

prevented international trade regulatory bodies, including the WTO, Codex Alimentarius, and Biosafety Protocol regime, from providing meaningful guidance on GM trade regulatory issues. South Africa and other like minded developing countries interested in responsible use of GMO crops need to develop their own international forum in order to promote their interests. The growing power of developing countries in international trade policy, reflected in the Doha round collapse and the resultant weakening of the WTO, makes such an initiative more realistic and likely.

I. GM Crops and Foods

The new GM agricultural biotechnologies, developed in the past 20 years rely on gene-splicing to transfer traits from one plant or animal species to another and other techniques to genetically modify crop plants with the goals of making the crop plants resistant to pests, herbicides, diseases, draught, and other stresses, including stresses from climate change, and thereby enhancing crop productivity and/or reducing farming costs (“input traits”); or of enhancing the flavor, vitamin content, or nutritional or other medical value of the foods produced by such crops (“output traits”). GM versions of crop plants could reduce farming costs, enhance productivity, reduce clearing for agriculture and pesticide use, facilitate low-till or no-till agriculture and thereby reduce greenhouse gas emissions, and provide tastier and healthier food products to consumers. On other hand, GMO technologies have triggered widespread concern about adverse environmental and health effects, including biodiversity loss and other forms of ecological disruption through gene flow, development of pesticide resistance, increased herbicide use and food allergies and toxins. GM crops are also regarded by many as a social and economic threat to traditional farming methods, organic farming, and “natural” foods. Opposition to GMOs has also been fueled by hostility to and fear of dependence on the multinational companies, many U.S.-based, that have commercialized and secured intellectual property protection for GMO processes and seeds and other crop products.¹² GMO technologies are in a relatively early state of development and there is still considerable uncertainty about the full range of their performance, their benefits, and their risks.

To date most R&D investment in GM crops comes from the private sector, primarily from a relatively few large multinational agrochemical firms with extensive biotechnology capacities, who have focused on engineering and promoting the adoption of four widely grown commodity crops: soy (60 % of total GM acreage), maize (23%), cotton (28%), and canola (6%). Very modest amounts of a few other GM crops are grown, including papaya, green peppers and tomatoes. Transgenic techniques have been used in order to make these crops resistant to pests, or tolerant of broad spectrum herbicides (simplifying weed control), or both. These crops were initially developed for use in industrialized countries, but have since been adopted, sometimes with adaptations, in an umber of developing countries. In 2007 approved versions of these crops were

¹² See generally DAVID C. VICTOR & C. FORD RUNGE, SUSTAINING A REVOLUTION: GENETICALLY MODIFIED ORGANISMS (Council on Foreign Relations Press 2002).

grown on commercial scale by 12 million farmers on 114.3 million hectares of land, up from 10.3 million farmers and 102 million hectares in 2006. The countries making the widest use of GM crops were the US (50.5% of the total world GM acreage), Argentina (16.7%), Brazil (13.1%), Canada (6.1%), India (5.4%), China (3.3%), Paraguay (2.3%), and South Africa (1.6 %). In 2007, 43% of the GM global crop area was in developing countries. Between 2006 - 2007, the increase in aggregate GM crop acreage in developing countries (8.5 million hectares) was greater than that in industrialized countries (3.8 million hectares).¹³

Although GM food crops have been adopted on a commercial scale in only a relatively few countries, as a result of international trade GMO ingredients are found in foods products and animal feeds in most countries in the world.

The evidence to date shows that GM varieties of these crops have, overall, achieved significant increases in productivity and/or reductions in farmers' costs, and have also reduced use of toxic chemicals.¹⁴ These benefits have accrued to farmers in developing as well as developed countries. The available evidence also does not show that GM technologies are suitable only for large farmers; GM varieties have been widely adopted by small farmers, primarily in developing countries, and to many small, poor farmers as well as large farms.¹⁵ These benefits are, however, not discernible to the

¹³ CLIVE JAMES, INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, EXECUTIVE SUMMARY: GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2007 (2007), available at <http://www.isaaa.org/resources/publications/briefs/37/executivesummary/default.html> (last visited Aug. 21, 2008). For additional information, see Louise O. Fresco, Assistant Director-General, Food & Agric. Org., Genetically Modified Organisms in Food and Agriculture: Where are we? Where are we going?, Keynote Address at the Conference on "Crop and Forest Biotechnology for the Future," Royal Swedish Academy of Agriculture and Forestry (Sept. 16-18, 2001), available at <http://www.fao.org/ag/magazine/GMOs.pdf> (last visited July 27, 2008).

¹⁴ See Graham Brookes & Peter Barfoot, *GM crops: the global socio-economic and environmental impact – the first nine years 1996-2004*, at p. 8, PG Economics Ltd. UK (October 2005), found at <http://www.pgeconomics.co.uk/pdf/globalimpactstudyfinal.pdf> (last visited on 18 October 2005). This report was conducted by PG Economics Ltd (UK) and funded by Monsanto. Depending on the crop and the country, the increase in farm income benefits consists of a reduction in production costs (less pesticides, less labor hours for applying pesticides or for removing weeds etc.) and/or increased yields. See also Graham Brookes, *The impact of using GM insect resistant maize in Europe since 1998*, 10:2-3 INT'L J. BIOTECHNOLOGY 148 (2008); Manda G. Cattaneo et al., *Farm-scale evaluation of the impacts of transgenic cotton on biodiversity, pesticide use, and yield*, 103:20 PROC. NAT'L ACAD. SCI. 7571 (2006), available at <http://www.pnas.org/content/103/20/7571.abstract> (last visited August 21, 2008); Jikun Huang et al., *Plant Biotechnology in China*, 295 SCIENCE 674-676 (2002), available at <http://www.sciencemag.org/content/vol295/issue5555/index.shtml> (last visited July 27, 2008); Michelle K. McDonald, *International Trade Law and the U.S.-EU GMO Debate: Can Africa Weather This Storm?*, 32 GA. J. INT'L & COMP. L. 501, 504, 520 (2004); FOOD & AGRIC. ORG., REPORT OF THE FAO EXPERT CONSULTATION ON ENVIRONMENTAL EFFECTS OF GENETICALLY MODIFIED CROPS (2003), available at <ftp://ftp.fao.org/docrep/fao/field/006/ad690e/ad690e00.pdf> (last visited July 27, 2008).

¹⁵ See FOOD & AGRIC. ORG., THE STATE OF FOOD AND AGRICULTURE 2003-2004: AGRICULTURAL BIOTECHNOLOGY: MEETING THE NEEDS OF THE POOR? (2004), available at <http://www.fao.org/docrep/006/Y5160E/Y5160E00.HTM> (last visited July 27, 2008); see also African Center for Technology Studies, <http://www.acts.or.ke/prog/agriculture/faq.html> (last visited Aug. 21, 2008); Marnus Grouse et al., *Three Seasons of Subsistence Insect-Resistant Maize in South Africa: Have Smallholders Benefited?*, 9(1) AgBioForum 15 (2006), available at <http://agbioforum.org/v9n1/v9n1a02-grouse.htm> (last visited Aug. 21, 2008).

ultimate consumers because the cost reductions achieved are too small a percentage of the delivered product.¹⁶ Although no evidence of adverse health effects or widespread ecological harm has emerged, concerns over such risks are reflected in consumer and public hostility or suspicion and restrictive governmental regulation of GM crops and foods in many countries.

A variety of GM crops other than the four major commodity crops already in widespread use are in the process of research and development, primarily through public funding; many of these varieties would be suitable for adoption in developing countries. These include rice, wheat, sorghum, millet, barley, beans, cassava, chick peas, potato, sweet potato, banana, yam, plantain, pigeon peas, lentils and groundnut that are resistant to pests, droughts and other stresses, adapted to poor soils, or provide enhanced nutrition or meet vitamin deficiencies could potentially be of great value, especially to developing countries for both cash and subsistence crops. The commercial market prospects for alternative crops such as these have thus far been too limited or uncertain to attract significant private sector investment in their development. Private sector efforts have been primarily focused on the four commodity crops discussed above plus wheat. Crop traits must often be engineered for local agro-ecological conditions in particular regions and countries. The scope for commercial demand for GMO versions of many developing country crops is limited.

A limited number of developing countries, including China, Brazil, and India, have significant public sector GMO R&D programs. The most important new GM crops in development include GM versions of rice, cotton, maize and cassava. These efforts have been supported by some international donors, especially the US. The private sector agricultural biotechnology multinationals are a growing presence in developing countries, through acquisitions or investments in local seed companies, joint ventures with both private sector and public sector research institutes, and technical assistance to public sector researchers.

R&D efforts to develop “second generation” GM crops focused on “output” traits in food products (as opposed to “input” traits in crop plants) that could provide benefits to consumers in the form of enhanced nutrition, vitamins, and improved taste and shelf life, are underway in both the private and public sectors for both developed and developing country applications, but these products are still in the development stage and their future potential is uncertain.

II. GMO Regulatory Diversity and Conflict

GMO technologies have generated fierce debate across the globe between GMO proponents and opponents. Public and political reactions to GMO technologies have varied quite widely in different countries and regions of the world, and resulted in quite different GMO domestic regulatory and development regimes. GMOs have excited more concern and conflict than any new technology since nuclear power. The complexity of

¹⁶ An exception to this generalization is provided by the use of GMO technologies to greatly enhance the resistance of mangos to rust, which has produced a large drop in the price to consumers of mangos.

the issues involved and the uncertainties regarding the technology's future development and its benefits and risks have served to foster a polarization of views. Among developed countries, a sharp divide in regulatory policies has emerged between the generally pro-GMO U.S. and the GMO-skeptic EU. This divide has produced sharp trade conflicts, culminating in the WTO EC Biotech case discussed below. Developing countries, which are powerfully affected by the US-EU conflict, display a wide range of GMO policies.

The North Atlantic Divide

The EU and most of its member states have taken a quite restrictive and precautionary approach to GMOs as a class, while the U.S. has sought to facilitate the development of GMO technologies while protecting against any identifiable, distinctive hazards posed by particular GMO products.¹⁷ These different approaches reflect a complicated set of differing institutional, historical, economic, political, and cultural factors. The U.S.-EU conflict has powerfully shaped the global debate over GMO trade regulatory policies and had major influences on developing country policies regarding GMOs.

The U.S. and Canada are major industrialized country agricultural exporters that have embraced GM crops, which are also grown on a more limited scale in Australia and small amounts are grown in Spain and Romania. Canada has followed the general approach of the U.S. to GMO regulation. Consumers in the U.S. and Canada are not very aware of GM foods and are generally not opposed to them, and major environmental groups have not made GMOs an issue.

Public attitudes and government EHS regulatory policies with respect to GMOs in the EU and many of its member states and other OECD countries, including Japan, South Korea and Switzerland, differ sharply from those in the U.S. and Canada. Many of their consumers are quite concerned about GMO health and environmental risks of GMOs and an appreciable number also have cultural and ethical objections to the technology. Environmental and consumer NGOs have mobilized against GMOs. As a result of series of regulatory scandals, Europeans have also lost confidence in government food and health safety authorities. Reflecting consumers and public attitudes rather than the interests of major EU-based biotech companies, GMO regulatory policies in these countries and at the EU level have in recent years been highly precautionary and quite restrictive.

Developing Country Interests and Policies

GMO development and regulatory policies among developing countries shows a wider range than in developed countries. Overall, developing countries display three basic differences from developed countries that have important implications for GMO policies. First, agriculture plays a comparatively much larger role in developing country economies in terms of GDP, employment and, for many countries, international trade, than in developed countries. Second, while the rich industrialized countries have large

¹⁷ DAVID VOGEL & DIAHANNA LYNCH, *THE REGULATION OF GMOs IN EUROPE AND THE UNITED STATES: A CASE-STUDY OF CONTEMPORARY EUROPEAN POLITICS* (Council on Foreign Relations 2001).

food surpluses stimulated by government subsidies, many developing countries face serious food security problems with large numbers of malnourished citizens and growing populations. The better-off developing countries will also need to expand agricultural production significantly in the next several decades in order to feed growing and more affluent populations. Third, developing countries are generally less well equipped, in terms of trained personnel, legal and administrative infrastructure, and other resources, to carry out GMO R&D programs and to manage the environmental and health risks that GMOs may pose. Yet they also generally place a lower priority on EHS objectives than more affluent developed countries.

By enhancing productivity and outputs, GM crops could potentially contribute to developing countries' food security, rural economic development, and export earnings. "Second generation" crops could potentially benefit the poor by providing enhanced nutrition and meeting vitamin deficiencies. Countries might also seek to build a domestic agricultural biotech sector that could export GMO seeds and plant materials to other developing countries as well as meeting domestic needs. Yet the practical ability of most developing countries to realize these advantages in the near term is limited by the narrow range of current GM crops developed by the private sector, which are suitable for use in only some developing countries, and the limited or non-existent agricultural biotech R&D resources and capacities. Development or adoption of GM crops is also restricted by the reluctance of many developing countries to become dependent on foreign multinationals for seeds and GMO-specific crop herbicides and pesticides or to recognize strong intellectual property rights in crop processes and products.¹⁸ Many also view GMO crops as a threat to traditional farming methods and knowledge.

The environmental risks posed by GM crops may be greater for developing countries that are especially rich in biodiversity or are centers of origin for crops, or that have limited health and biosafety regulatory capacities. On the other hand, GM crops can provide potentially provide greater environmental benefits for developing countries by reducing heavy pesticide use and reducing the need for agricultural clearing in order to expand food production. Insofar as developing countries may wish to import GM crop materials, they will need information and analytic capacities to assess their risks and benefits, which may often be lacking. Food products containing GMOs are now widely traded internationally, and regulating imports of such foods may be beyond the practical ability of many developing countries, although high-profile imports such as GM food aid have been targeted by some countries.

These and other factors vary widely among developing countries, which will also assess their relative importance differently based on local social, economic and political factors.

The World Food Crisis and GMOs

¹⁸ See Third World Network, <http://www.twinside.org.sg/> (last visited July 27, 2008); Shundahai Network, <http://www.shundahai.org/> (last visited July 27, 2008); Indigenous Peoples Council On Biocolonialism, <http://www.ipcb.org/> (last visited July 27, 2008).

The spiraling of food prices in 2007-08 has succeeded somewhat in shifting the terms of the GMO debate. Attributed by commentators to “high oil prices, changing diets, urbanization, expanding populations, flawed trade policies, extreme weather, growth in biofuel production and speculation,”¹⁹ rising food prices sparked riots in several developing countries²⁰ in 2008 and protests even in the developed world.²¹ The potential for GMO crop varieties to help meet this crisis has fostered greater receptivity to GM technologies.

For example, states and leaders in the EU have begun to soften their opposition to GMO crops. In June 2008, the EU launched a study of whether genetically modified crops might help mitigate rising food prices and also agreed to review the complex system whereby the EU approves GMO. Noting that European refusal to import GMO crops might drive up European food prices, European Commission President Jose Manuel Barroso endorsed this move, as did British Prime Minister Gordon Brown,²² who also called on the EU to relax its rules on importing GMO animal feed.²³ A few days later, the EU announced that Austria was lifting its ban on importing genetically modified corn, characterizing the move as an effort to comply with the WTO decision in EC-Biotech.²⁴ And less than a month later, in mid-July, leaders of the G8 agreed at their annual summit that biotechnology could help increase crop productivity and pledged to “promote science-based risk analysis” of GMOs²⁵ – a notable development, given that the G8 includes France and Germany. The relaxing of European opposition to GMO crops seems to have been driven by two motivations: worries about food prices at home,²⁶ and concerns about food security in the developing world.²⁷

For their part, developing countries have also increasingly embraced GMO technology as the food crisis has worsened. In 2007, the biggest growth in the popularity of biotechnology came in the developing world, where for the first time more countries planted GMO crops than in the developed world.²⁸ In July 2008, China announced that its new budget would include significant growth in funding for biotechnology research, with an emphasis on safety research; China has been a world leader in the development of GMO rice, but had delayed commercializing its strains due to concerns about the safety of transgenic crops.²⁹ July 2008 also brought news of an agreement on agricultural

¹⁹ *World Bank to boost food aid*, SAN JOSE MERCURY NEWS, May 30, 2008.

²⁰ Richard Wachman, *Surging food prices put the world on high alert*, OBSERVER, Mar. 2, 2008; Peter Popham, *Call for trade barriers to be removed to ease crisis*, INDEPENDENT, June 3, 2008.

²¹ Mary Riddell, *Rich and poor will both pay a high price for world food crisis*, DAILY TELEGRAPH, Apr. 24, 2008.

²² Andrew Grice and Vanessa Mock, *Europe warms to GM crops as possible solution to food crisis*, INDEPENDENT, June 21, 2008.

²³ Andrew Grice, *Brown pushes EU to allow more modified animal feeds*, INTERNATIONAL HERALD TRIBUNE, June 20, 2008.

²⁴ *EU says Austria has lifted ban on importing, processing genetically modified corn*, ASSOCIATED PRESS, June 24, 2008.

²⁵ *G8 Supports Biotech's Role in Addressing Global Food Security*, MEDICAL NEWS TODAY, July 9, 2008.

²⁶ Grice and Mock, *supra* note 22.

²⁷ Andrew Grice, *GM crops needed in Britain, says minister*, INDEPENDENT, June 19, 2008.

²⁸ Marcus Wohlsen, *Developing world in GM drive*, ADVERTISER, Feb. 16, 2008.

²⁹ See Agence France Presse, *China to Urgently Boost GM Crop Development*, July 10, 2008; Niu Shuping,

cooperation between the U.S. and the Philippines aimed in part at encouraging the use of biotechnology in the latter country.³⁰ In Africa, Malawi approved research into genetically modified crops,³¹ Egypt approved the cultivation and commercialization of a pest-resistant genetically modified corn variety,³² South Africa took steps towards introducing the world's first genetically modified potato,³³ and Kenya announced plans to import genetically modified food crops,³⁴ all in the summer of 2008. And in Latin America, Honduras made plans to increase the area planted with GM corn in an effort to meet the growing demand for food.³⁵

The movement is by no means all in one direction, however. South Korea recently unveiled plans to adopt rigorous "EU-style" food testing standards in an effort to protect "national health security" from genetically modified crops,³⁶ while Tanzania recently reiterated its opposition to any use of GM crops. Rising food prices, however, did seem to have sparked a broad shift in many parts of the world from opposition to or ambivalence about GMOs toward acceptance.

International Influences on Developing Countries

Developing country choices regarding GMOs are also strongly influenced and often constrained by a range of international circumstances and influences.

International competitiveness concerns may favor adoption of GMO varieties of commodity crops. The adoption of GM soy in Argentina and in Brazil was strongly motivated by producers' desire to remain competitive in international commodity export markets with producers in the US and Canada using GMO varieties. But uncertainties about export markets created by regulatory restrictions and consumer opposition to GMOs in many developed countries create strong pressures in the opposite direction. China and other developing countries have been reluctant to authorize the use of GM food crops for fear that actual or perceived GMO "contamination" of non-GM crop varieties will harm exports to markets in Europe, Japan, and South Korea, whose consumers are hostile to or suspicious of GM foods. This same concern is not as acute with respect to cotton, a non-food crop.³⁷ Regulatory barriers to GM products in many

China approves big GMO budget amid food worries, GUARDIAN, July 10, 2008.

³⁰ USDA, *USDA Signs Agreement with Philippines on Agricultural Cooperation*, July 2, 2008, available at <http://www.merid.org/fs-agbiotech/print.php?id=6894>.

³¹ *Malawi govt. okays research into genetically modified crops*, AFRIQUE ACTUALITE, July 2, 2008.

³² Wagdy Sawahel, *First Egyptian Approval of Genetically Modified Corn Raises Questions*, INTELLECTUAL PROPERTY WATCH, June 16, 2008.

³³ Tamar Kahn, *Farmers May Grow 'Super-Spud'*, BUSINESS DAY, July 11, 2008.

³⁴ *Kenya To Import Genetically Modified Foods, Says Minister*, AGENCE DE PRESSE AFRICAINE, Aug. 18, 2008.

³⁵ International Service for the Acquisition of Agri-Biotech Applications, *Honduras to Increase GM Maize Cultivation*, June 13, 2008, available at <http://www.isaaa.org/kc/cropbiotechupdate/online/default.asp?Date=6/13/2008#2665>.

³⁶ Bae Ji-sook, *Seoul to Adopt EU-Style Food Testing Rule*, KOREA TIMES, July 11, 2008; Neema Werema, *Tanzania: Keep GM Seeds Out – Burian*, THE CITIZEN, Dar es Salaam, August 10, 2008.

³⁷ By contrast, a number of developing countries, including China, India and South Africa, have authorized widespread planting of GM cotton, a non-food export crop. See, regarding China, CLIVE JAMES, ISAAA BRIEF 32-2004, EXECUTIVE SUMMARY: GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2004,

developed countries, which may reinforce consumer suspicion, are also a major consideration.³⁸

The new EU GMO labeling and traceability regulations, which require segregation of and extensive “farm to fork” documentation for crops containing even very small percentages of GMOs are likely to be especially burdensome for developing country producers to comply with because of the lack of GMO testing capability³⁹ and the difficulties of establishing separate, reliable, farming, collection, and transport systems for GMO and non-GMO products. These difficulties may lead developing countries to avoid GM crops altogether, including crops grown for domestic consumption or export to third countries, especially if these EU regulations are followed by other developed countries. The Director of the Beijing Genomics Institute recently asserted that Europe should change its current GMO policies, which are preventing China and other developing countries from adopting beneficial new agricultural technologies.⁴⁰

There are also conflicting considerations at work in developing country decisions whether or not to approve GM food imports. Allowing imports of GM foods or GM seeds or crop products for use for domestic food production may benefit developing country consumers through lower prices or better product quality. On the other hand, allowing such imports threatens local farmers and efforts to develop a domestic agricultural biotechnology industry. Evidence suggests that China, for example, has sought to use GMO EHS regulation to limit GMO imports in order to protect local non-GM agriculture and China’s own GMO industry.

In deciding whether or not to adopt EHS regulations that restrict sale or use of GMO food or plant products, including GMO imports, developing countries must also consider the validity of such restrictions under the WTO agreements and other international trade law as well as bilateral investment treaties.

GM policy choices in developing countries are also strongly influenced by the GMO superpower “cold war” conflict between the EU and the U.S., both of which are actively lobbying developing countries to side with their respective positions on GMOs, exerting pressure through trade pact negotiations and development assistance policies.

available at <http://www.isaaa.org/resources/Publications/briefs/32/executivesummary/default.html> (last visited July 27, 2008); regarding India, MINISTRY OF ENV’T & FORESTS, GOV’T OF INDIA, BACKGROUND PAPER ON BT COTTON CULTIVATION IN INDIA, available at <http://www.envfor.nic.in/divisions/csurv/btcotton/bgnote.doc> (last visited July 27, 2008); regarding South Africa, Y. Ismael, R. Bennett, & S. Morse, *Farm level impact of Bt cotton in South Africa*, 48 BIOTECHNOLOGY & DEV. MONITOR 15 (2001).

³⁸ GMO feeds have been widely sold to Europe because they have not been subject to the stringent regulatory requirements applicable to GMO foods for human consumption, but they are now required to be labeled. Meat from animals fed with GM feed products are encountering sharp resistance from environmental and consumer groups and supermarkets in many areas of Europe.

³⁹ EU law requires that laboratories in third countries verifying compliance with EU GMO food regulatory laws be accredited by the EU.

⁴⁰ See Jia Hepend, Sci/Dev.Net, “Negative Attitudes ‘Hindering China GM Commercialization,’” at <http://www.scidev.net/en/news/negative-attitudes-hindering-china-gm-commercialis.html> (last visited Jul 31, 2008). See also Reuters, “Japan Finds Unauthorized GM Rice in China Products,” <http://www.agbios.com/main.php?action=Show> NewsItem&id=9852 (last visited July 31 2008)

For example, the U.S. has demanded adoption of pro-GMO positions by developing countries as a condition of bilateral trade agreements. It has consistently provided food aid in the form of US GMO food, and tied funding to fight AIDS to acceptance of GMO policies. Both the EU and individual EU countries and the US have used capacity building assistance in agricultural development and biosafety regulation to push their agendas. Various international aid donors, multilateral development and environmental organizations, and industry and NGO groups also try to influence developing country GMO policies.

Developing Country Dilemmas and Choices

In assessing GMO policy choices, developing countries confront an uncertain and evolving complex of issues. Developing countries that invest in and adopt GM crops may gain “early mover” advantages if the technology and its products win progressively wider acceptance. On the other hand, there is the risk that the technology will fail to develop new varieties that are successful in aerobiological and economic terms, and the risk that opposition by consumers and civil society interests will grow stronger and spread to more countries.

A few advanced developing countries – Argentina, Brazil and South Africa – have embraced GM technology and its commercial application. Argentina and Brazil grow and export huge amounts of GM soy. Brazil has a large public sector GMO R&D program. Argentina and South Africa grow GM maize, and South Africa grows GM cotton.

Around another dozen of the more advanced developing countries, including China, India, Kenya, Egypt, Cuba, Thailand, Indonesia, and Columbia, have undertaken significant GMO R&D programs, but hedged their bets by not proceeding with full commercial scale use of GM crops or approving only non-food crops (i.e., GM cotton), and not taking a firm overall position on GMOs.⁴¹

The third group includes by far the largest number of developing countries, including almost all of the least developed countries. These countries either do not have GMO R&D capacities or those that they do have are quite limited. They have not approved the use of GM crops. However, these countries have not ruled out potential future use of GMO crops.

Finally, some poor African countries have vehemently rejected GMO technologies as an instrument of neo-colonialist exploitation and subordination fostered by Western multinational corporations and their governments. Zimbabwe’s President, Robert Mugabe refused to accept food aid from the United States in the form of GMO corn despite the threat of starvation for many.⁴² Zambia initially refused to accept such aid, but eventually did so only after insisting that the corn be milled. Madagascar is another country that has adopted a strong anti-GMO stance.

⁴¹ See GMO Africa, Agricultural Biotechnology International Conference Kicks Off Today (Aug. 6, 2006), available at <http://www.gmoafrica.org/2006/08/agricultural-biotechnology.html> (last visited July 27, 2008).

⁴² Rich Weiss, *Starved for Food, Zimbabwe Rejects U.S. Biotech Corn*, WASH. POST, July 31, 2002, at A12.

Environmental and food safety regulatory programs for GMOs in developing countries also exhibit a wide range. Many developing countries lack adequate regulatory legal and administrative infrastructure. The countries that have adopted GM crops on a commercial scale or that have extensive GMO R&D programs have in most cases developed special biosafety regulatory programs for GM crops, and a few have special measures for GM foods including labeling requirements. These programs are often incomplete, and the quality of implementation and enforcement uneven. Most other developing countries are in the beginning stages of developing distinctive biosafety regulatory programs for GMOs. These efforts have been stimulated by the Biosafety Protocol and a UNEP/GEF program to assist developing countries in implementing the Protocol.⁴³ Many of these countries lack food safety or labeling regulatory programs for GMOs.

Given the significant uncertainties about the future development of GMO technologies and their environmental and economic performance, as well as conflicting international pressure and influences, many developing countries will sensibly seek to preserve policy flexibility and decisional options, in order to be in a position to make better decisions in the future when more information is available.

III. The Current International Trade Regulatory Regime Complex for GMOs

Although the diversity of local GMO regulations has undoubtedly created structural problems and increased transaction costs for producers who have to cope with quite different regulatory regimes in different countries of the sort previously reviewed, controversy has focused on restrictive regulatory measures adopted by the EU and other jurisdictions that have been sharply attacked by GMO producer states as unjustified and protectionist. This regulatory conflict, which became a matter of rather high transatlantic politics, also produced substantial regulatory controversy and uncertainty for other countries, including developing countries. It also posed serious challenge for international institutions concerned with trade policies and environmental regulation in the context of crops and foods. The most important of these institutions are the World Trade Organization (WTO); the several international bodies that set standards for food safety and animal and plant protection, the most important of which is Codex Alimentarius Commission; and the Biosafety Protocol to the Biodiversity Convention, which establishes a framework for international trade in GMO products and has stimulated many developing countries to begin adopting GMO biosafety regulations. These institutions together form a global “regime complex” for GMOs⁴⁴

Overview of the International Authorities for GMO Trade Regulation

⁴³ United Nations Environment Programme: Biosafety, <http://www.unep.org/biosafety> (last visited Aug. 21, 2008).

⁴⁴ See Kal Raustiala & David G. Victor, *The Regime Complex for Plant Genetic Resources*, 58 INT’L ORG. 277, 279-80 (2004). In addition to those already noted, other international institutions that play a major role in the development and regulation of GMOs include the UN Food and Agriculture Organization (FAO), the United Nations Environmental Program (UNEP), and the World Intellectual Property Organization (WIPO).

The WTO. Domestic GMO regulations affecting trade in GM crops and foods are subject to the disciplines of the WTO GATT, Sanitary and Phytosanitary (SPS) and Technical barriers to Trade (TBT) agreements. These agreements were adopted before GM technologies were deployed on a broad scale. As a result of the difficulty of agreement among all WTO members to revise the agreements to address GMO issues and the absence of any subsidiary legislative or administrative lawmaking authority within the WTO, it falls to the WTO dispute settlement process to address has assumed a major role in resolving international trade regulatory conflicts through adjudicating the WTO validity of individual regulatory measures adopt by member states (negative harmonization). The EC Biotech case represents the first occasion on which a dispute settlement panel has addressed GMO issues. That case and the relevant provisions of the SPS agreement as they relate to GMO regulation are discussed more fully below.

Codex and other international standard-setting bodies. The Codex Alimentarius Commission (Codex), the International Office of Epizootics (OIE) and the International Plant Protection Convention are among the international bodies that promulgate environmental health and safety (EHS) standards for internationally traded products, including GM products. Other international organizations with functions that involve crops and foods include the World Health Organization (WHO), the U.N. Food and Agriculture Organization (FAO), and the United Nations Development Program (UNDP). Of these, bodies, the Codex has most directly addressed GMO regulatory issues.

The Codex is composed of national delegations from its 165 member states. Its stated purpose is to protect consumers' health and ensure fair practices in the food trade. It seeks to promote the adoption of uniform EHS standards for internationally traded food products through a complex, highly structured process of discussion and consensus among member state government representatives including experts; recently, business and NGO representatives have been allowed to attend and participate in discussions of standards committees.⁴⁵ The Codex thus establishes a system of subsidiary legislation that is lacking in the WTO. Although acceptance by member states of Codex standards is voluntary, the organization has had considerable success in developing widely adopted consensus standards. The influence of Codex standards gained new significance in 1994 when the SPS Agreement gave explicit reference to the Codex standards in Article 3.2, and created a presumption of compliance for a government's trade-restrictive SPS measures which conform to Codex standards. The TBT has similar provisions. The new legal status of Codex standards under these WTO agreements has made it more difficult to reach agreement on standards in controversial matters, including GMOs.

⁴⁵ The Codex is composed of a set of hierarchical committees. At the top is the Codex Alimentarius Commission (Commission), composed of the national delegates sent by the Codex's member states, The main work of the body is accomplished by specialized committees composed of government, industry and NGO experts. Most standards are drafted according to an eight-step procedure which rotates decision-making responsibility between the Commission and a specialized committee twice before the Commission makes a final determination, and includes procedures for consultation with national governments. See FOOD & AGRIC. ORG., UNIFORM PROCEDURE FOR THE ELABORATION OF CODEX STANDARDS AND RELATED TEXTS, available at <http://www.fao.org/docrep/w5975e/w5975e04.htm> (last visited July 27, 2008).

In 1999 Codex established the ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology to consider the health and nutritional implications of such foods and develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology. The Task Force concluded its work in 2003 and promulgated a number of guidelines:

- Principles for the risk analysis of foods derived from modern biotechnology
- Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants/
- Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms.

Apart from these guidelines, the international conflicts over GMO regulation have prevented the adoption of any substantive regulatory standards for GMO by any international body.⁴⁶

The Biosafety Protocol. Cartagena Protocol on Biosafety (Biosafety Protocol),⁴⁷ the first and so far only protocol to the Convention on Biodiversity, was adopted in 2000 after five years of contentious negotiations and entered into force in 2003. It now has over ___ Parties, but not including the U.S., Canada and Argentina, all major GMO producers. It establishes requirements for international shipments of GMO plants and foods, including a requirement for advanced informed consent by importing countries to shipments of GMO seeds and plants and the provision of a risk assessment with respect to such products by the shipper. It also establishes requirement for international shipments of GM products and requires the adoption of appropriate domestic biosafety regulations by parties.

The Protocol, Article 26.1, also gives explicit authorization for parties to take into account “socio-economic considerations arising from the impact of [GMOs] on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.”⁴⁸ Also, the Protocol’s Objective states that it is to be carried out “[I]n accordance with” the “precautionary approach” as established in Principle 15 of the Rio Declaration on Environment and Development (Principle 15).⁴⁹

⁴⁶ See Codex Alimentarius, Current Official Standards, *available at* http://www.codexalimentarius.net/web/standard_list.do?lang=en (last visited July 27, 2008).

⁴⁷ Cartagena Protocol on Biosafety to the Convention on Biological Diversity, UNEP/CBD/ExCOP/1/3, 39 I.L.M. 1027 (Jan. 29, 2000), *available at* <http://www.cbd.int/doc/legal/cartagena-protocol-en.pdf> (last visited July 27, 2008) [hereinafter Cartagena Protocol].

⁴⁸ *Id.* art. 26.1.

⁴⁹ *Id.* art. 1. Principle 15 states that “[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental damage.” United Nations Conference on Environment and Development, June 3-14, 1992, Rio Declaration on Environment and Development 3-8, U.N. Doc. A/CONF.151/26/Rev.1 (Vol. I), 31 I.L.M. 874 (June 14, 1992) [hereinafter Rio Declaration].

The Protocol's adoption was pushed by environmental NGOs, Green political forces in Europe, and many developing countries, with the general support of the EU and a number of other developed countries. The Protocol's proponents feared that many developing countries lack the capacity or the information to make informed decisions whether or not to use GMO crops or animals, or to regulate them adequately to protect the environment and health. The concern was that developing countries might readily succumb to pressures from multinational GMO companies and the U.S. to adopt GMO agricultural products on a widespread basis without adequate regulatory safeguards. . The agreement was also designed to serve as a counterweight to the WTO system for resolving trade-environments disputes, which was regarded as insufficiently responsive to environmental concerns. Its proponents feared that domestic regulatory restrictions on GMOs might be vulnerable to WTO legal challenge sought in the Protocol to bolster their legality under international law.

A pervasive and highly contentious issue throughout the Protocol's negotiations was the relationship between the Protocol's provisions and a Party's WTO obligations. The Protocol addressed this relationship with three arduously negotiated "savings" or "conflicts" clauses in its Preamble that fail to provide any clear answer. As the Protocol lacks any compulsory dispute settlement machinery, it seems most likely that the relation between the Protocol and the WTO Agreements, including the extent to which the Protocol validates, as a matter of international law, domestic GMO regulations that would otherwise violate WTO agreements, will ultimately be decided by the WTO Appellate body. The Biosafety Protocol has been unable to resolve the EU-US GMO conflict or give clear direction to other countries, including developing countries, on the legality of domestic measures restricting import or use of GM crops and foods.

As a result of these various circumstances the WTO Dispute Settlement system is the primary international authority for addressing GMO trade regulatory conflicts.

The WTO SPS Agreement and Domestic GMO Regulation

The WTO agreement that is most pertinent to EHS regulations that affect trade in food and other agricultural products is the 1994 SPS Agreement, negotiated in the Uruguay Round as a response to the perceived inadequacies of the 1947 GATT system in this context.⁵⁰

⁵⁰ The SPS applies to domestic regulations addressed to the following types of risks: (a) risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms threatening animal or plant life or health; (b) risks arising from additives, contaminants, toxins or disease causing organisms in foods, beverages or feedstuffs threatening human or animal life or health and (c) risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests threatening human life or health. WTO Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex A, ¶ 1 (1994) [hereinafter SPS Agreement]. While the SPS governs many aspects of GMO regulation, the exact extent of its coverage is disputed. To the extent that the SPS Agreement is inapplicable, GMO regulation would be subject to the TBT and/or GATT.

The SPS was negotiated because of perceived deficiencies in the GATT, which relies almost exclusively on general non-discrimination principles to discipline EHS regulation. The negotiators, especially representatives of agricultural exporters including the U.S. and many developing countries feared that the GATT would fail to prevent use EHS regulations of foods and other agricultural products for protectionist purposes, or even the adoption of non-protectionist regulations that unjustifiably restrict trade.

The SPS Agreement retained three requirements like those found in 1994 GATT.⁵¹ These include two non-discrimination requirements, providing for most-favored-nation (MFN) status⁵² and national treatment,⁵³ both of which prevent a nation from discriminating against imported products in favor of similar domestic products or products imported from other countries. The SPS also requires that EHS measures be the least trade restrictive measures reasonably available.⁵⁴

The SPS contains requirements which take important steps beyond GATT' by requiring a sound scientific basis for EHS regulations. It requires that governments either (a) base their EHS regulations on a relevant international standard such as the Codex,⁵⁵ or (b) if no such standard exists or a government chooses to develop its own separate standard, show that the standard is supported by an adequate risk assessment grounded in scientific principles.⁵⁶ The international standards provision functions as a legal “safe harbor” because conformance to such a standard creates a presumption of compliance with the SPS requirements.⁵⁷ This provision was adopted in order to encourage states' adoption of international standards by international bodies such as codex with expertise in EHS regulatory issues. National regulatory measures that are more restrictive than a relevant international standard, or measures adopted in the absence of an international standard, are subject to the risk assessment requirement.⁵⁸

Among the AB decisions interpreting the provisions of the SPS, the most relevant for GMO issues is EC-Measures Concerning Meat and Meat Products (Hormones).⁵⁹ The

⁵¹ These SPS measures are adapted from GATT Article XX(b) and its Chapeau. Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 1 (1994), 33 I.L.M. 1125 (1994), Annex 1A, General Agreement on Tariffs and Trade, 1994.

⁵² SPS art. 2.3.

⁵³ SPS art. 5.5. The SPS Agreement elaborates the national treatment requirement by adding a “national regulatory consistency” requirement, stating that governments “shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.” This has proven to be one of the most controversial disciplines because it allows Panels to assess the level of health protection a government chooses through its regulations and demand they be consistently applied. See Steve Charnovitz, *The Supervision of Health and Biosafety Regulation by World Trade Rules*, 13 TUL. ENVTL. L.J. 271, 283- 84.

⁵⁴ SPS art. 5.6. Adapted from GATT XX Chapeau's use of “necessary” as interpreted by Thailand — Restrictions on Importation of and Internal Taxes on Cigarettes, adopted on 7 November 1990.

⁵⁵ SPS art. 3.1.

⁵⁶ SPS arts. 5.1 (regarding risk assessment), 2.2 (regarding science requirement). The Appellate Body in *Hormones* has recognized that compliance with Article 5.1 implies compliance with Article 2.2..

⁵⁷ SPS art. 3.1.

⁵⁸ SPS art. 3.3.

⁵⁹ Appellate Body Decision, *EC – Measures Concerning Meat and Meat Products (Hormones)*, AB-1997-

EC banned the use of six growth hormones in Europe, and banned the importation of meat produced with such hormones. There was no international standard providing for such a ban. In response to a complaint filed by the U.S. and Canada, the Appellate Body in 1998 ruled against the EC. The EC, however, has retained the ban despite retaliatory trade measures by US and Canada. The Appellate Body found that the ban contravened Article 5.1 because the EC failed to produce a risk assessment that included an evaluation of the incidence of the risk invoked by the EC. The AB rejected the notion that there must be some minimum quantum or threshold of risk shown in order to impose regulatory controls or that it would review the justification for the regulatory measures in relation to the risk. But it required that *some* ascertainable risk be established.⁶⁰

The AB also rejected that EC's argument that the precautionary principle had become established as a rule of customary international law and relieved the EC of any obligation under Art. 5.1 to demonstrate an ascertainable risk based on risk assessment.⁶¹ Without deciding the status of the principle under international law generally, the AB concluded that it did not override the specific treaty obligation set forth in Art. 5.1.⁶²

The AB did, however, state that, in determining whether a regulatory measure is adequately supported by a risk assessment, states may rely on scientific theories or conclusions embraced by only a minority of scientists.⁶³ On the other hand, it found that a risk assessment which only demonstrated a "theoretical" risk in the context of scientific uncertainty would be insufficient.⁶⁴

Although it has adopted a somewhat strict interpretation of the SPS *risk assessment* requirements the AB has indicated that countries enjoy great latitude in *risk management* decisions. Thus, it stated that the SPS does not establish a minimum threshold of risk that needs to be shown in order to justify an EHS measure.⁶⁵ It is sufficient if the risk assessment finds evidence of an "ascertainable" risk. Further, countries may adopt a ban or other measure to reduce the risk to zero, even if that risk is very small.⁶⁶

The EC Biotech Case

In August 2003, the U.S., Canada and Argentina initiated dispute settlement procedures against the European Community (EC) for delaying approvals of genetically

4, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998) [hereinafter AB Hormones].

⁶⁰ *Id.* ¶¶ 2-5. [NKD to supply paragraph citations]

⁶¹ AB Hormones ¶¶ 16, 121

⁶² The AB has also limited the extent to which members can avoid the SPS Art 5.1 risk assessment requirement by invoking Art 5.7 to justify a regulatory measure. Art. 5.7 establishes a qualified exemption from the Art 5.1 risk assessment requirement by allowing governments to "provisionally" adopt EHS measures "[i]n cases where relevant scientific evidence is insufficient... on the basis of available pertinent information" to prepare a risk assessment. SPS art. 5.7.

⁶³ AB Hormones ¶ 194.

⁶⁴ AB Hormones ¶ 186. See also Case C-236/01, Monsanto Agricoltura Italian SpA v. Presidenza del Consiglio dei Ministri, 2003 E.C.R. I-8105, ¶ 128 (2003).

⁶⁵ AB Hormones ¶ 186.

⁶⁶ AB Hormones ¶ 187.

modified (GM) crops within its borders and for the adoption by certain member states of prohibitions against certain GM products previously approved by the EC (EC Biotech case.)⁶⁷ The panel ruled in their favor on several issues, rejecting other claims.

The Panel addressed the question whether the various challenged measures were subject to the SPS Agreement, or to other WTO agreements such as GATT and TBT. It reasoned that the application of the various agreements depends on the purpose or purposes of the measure in question. It decided that if a measure has at least one purpose that falls within the SPA Agreement – for example, preventing the spread of pests – the measure is subject to SPS disciplines, although other purposes may also subject it to disciplines under other agreements. It then considered the various types of risks addressed by the SPS agreement, concluding that [all] the challenged measures included among their purposes regulation of such risks and were therefore subject to the SPS disciplines.⁶⁸

The Panel then decided that there was a general *de facto* moratorium in effect from June 1999 until 29 August 2003. It found, contrary to the arguments of complainants, that the general and product-specific moratoria were not themselves SPS regulatory measures under the SPS Agreement subject, among other requirements, to the risk assessment requirements in Art. 5.1. But it did find that the both the general moratorium and most of the product specific moratoria violated the provisions in SPS Art 8 and Annex C(1)(a) requiring that regulatory authorization procedures be carried through to a final resolution “with no unjustifiable loss of time.”

In examining the safeguard measures imposed by certain member states,⁶⁹ the Panel held that they were required under SPS Art. 5.1 to base these restrictions on a risk assessment, unless there was insufficient scientific evidence to conduct such an assessment, in which case they might provisionally restrict the products in questions pending the development of adequate scientific information. In this case, the Panel found sufficient information was available to conduct a risk assessment, as evidenced by the fact that assessments had been prepared on each of the products in question in connection with their approval by

⁶⁷ On May 14, 2003 the U.S., Canada and Argentina first called for consultations regarding European Community’s alleged *de facto* moratorium on GM crops. On August 8, 2006 the three countries requested the establishment of a Panel to hear the dispute. See Permanent Mission of the United States to the Chairman of the Dispute Settlement Body, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products: Request for the Establishment of a Panel by the United States*, WT/DS291/23 (Aug. 8, 2003); Permanent Mission of Canada to the Chairman of the Dispute Settlement Body, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products: Request for the Establishment of a Panel by Canada*, WT/DS292/17 (Aug. 8, 2003); Permanent Mission of Argentina to the Chairman of the Dispute Settlement Body, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products: Request for the Establishment of a Panel by Argentina*, WT/DS293/17 (Aug. 8, 2003).

⁶⁸ For critical analysis of these jurisdictional rulings, see Jacqueline Peel, *A GMO by Any Other Name . . . Might Be an SPS Risk!: Implications of Expanding the Scope of the WTO Sanitary and Phytosanitary Measures Agreement*, 17(5) EUR. J. INT’L L. 1009 (2006). For an overview of the SPS provisions and their application, see UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT, *DISPUTE SETTLEMENT, WORLD TRADE ORGANIZATION, 3.9 SPS MEASURES* 2003.

⁶⁹ Six different EC Member States adopted nine safeguard measures in total, which they allege prohibit the importation or marketing of various biotech products, including maize and oilseed rape.

the EC, and that these assessments had been found sufficient by the EC's relevant scientific committees to serve as a basis for such approval. Accordingly, the member states could not invoke Art. 5.7, which allows for Signatory Members to provisionally adopt SPS measures without being subject to the Art 5.1 risk assessment requirement "in cases where relevant scientific evidence is insufficient." for such an assessment. Further, the member states could not point to any other risk assessments which justified their safeguard measures. The measures accordingly contravened Art. 5.1 Thus, the national-level bans should be brought into conformity with WTO law, by either their revocation or their justification based on risk assessments.

The Panel also rejected the EC's contention that the challenged measures were justified under the Cartagena Protocol on Biosafety and the precautionary principle, finding the Protocol inapplicable because not all the parties to the case had ratified it and that the precautionary principle lacked independent effect in the context of the SPS Agreement.

The US used impacts on developing countries to support the "moral" argument, claiming that the European Communities measures have hindered developing countries' agricultural and economic interests by blocking exports of biotech products and by discouraging imports and cultivation of biotech seeds. The EC responded to this argument by invoking potential and proven risks of biotech products. They also pointed out trade statistics to prove that the EC policies had not restricted exports of developing countries to the EU.⁷⁰ Argentina argued that the EC had violated SPS Art. 10.1 because it had failed "to take account of the special needs of developing country members" in the preparation and application of its GMO regulatory measures. The Panel rejected this claim. The implications of the Panel decision for developing countries are discussed in greater detail below.

Notably, the Panel stressed its report left unaddressed many issues raised by the parties, considering that it need not decide them in light of its holdings and disposition. These issues included the safety of biotech products, whether the prohibited GM products could be considered "like products" in relation to similar permitted non-GM products for purposes of the GATT's national treatment discipline, and the WTO consistency of the current EC legislation regarding the approval procedures and national safeguards.

GMO Labeling and Traceability Requirements. The GMO labeling and traceability regulations adopted by the EU, which we not in issue in *EC Biotech*, pose significant burdens, especially for developing countries, that wish to grow GM crops and export non GM foods and agricultural products to the EU. These requirements, which may be emulated by other GMO-skeptic countries, may well be the subject of a future WTO challenge.

The basic argument of the EU in justification of requiring GMO products to be labeled is that they meet a strong and legitimate interest in informed consumer choice. The counterargument of producers and the U.S., echoing the position of the FDA, is that

⁷⁰ See HEIKE BAUMÖLLER ET AL., OVERVIEW OF THE WTO BIOTECH DISPUTE AND THE INTERIM RULING (International Center for Trade and Sustainable Development 2006).

there is (as the FDA has concluded) no material difference between GMO and non-GMO foods as respects food safety or other relevant characteristics of the food, and that labeling GMOs products as such falsely implies that they are more dangerous or otherwise less desirable than non-GMO foods. The EU's argument with respect to traceability is that it is necessary to police violations of labeling requirements and requirements that GMO foods obtain regulatory approval, and also to trace the origins of food products that cause health problems. GMO producers maintain that the traceability requirements, coupled with the low labeling threshold for GMO content, will require complete segregation of GM and non-GM products throughout the production, transportation, processing and distribution chains, imposing major economic burdens (cost increase of up to 25% or more) that will depress trade. Compliance with these requirements will be especially burdensome for many developing countries. Critics of the regulations contend that the labeling/traceability thresholds are arbitrarily low and that there are alternative, far less burdensome means of meeting the regulatory goals invoked by the EU.⁷¹

In the 1991 and 1994 Tuna-Dolphin decisions, which were unadopted GATT panel rulings, the panel upheld the validity of voluntary labeling practices adopted by distributors of canned tuna informing consumers that the tuna was caught on the high seas by fishing boats using measures to protect dolphins against bycatch.⁷² There is, however, no WTO precedent on mandatory labeling requirements imposed by a state. There is essentially no precedent on the compatibility of the EU traceability regulations with WTO trade disciplines.

Another cluster of important legal and policy issues presented by the labeling and traceability requirements is their "extraterritorial" impact on process and production methods (PPMs) in exporting states. Although justified by the EU as a product regulation to protect European consumers, the regulations are likely to discourage exporting countries, especially developing countries from using GMO crops generally, including for production of food products destined for domestic production or export to other jurisdictions. This impact may well have been foreseen and actively sought by many Green interests in the EU. It is quite unclear whether a WTO tribunal would consider these "extraterritorial" impacts in assessing the validity of such regulations and the result if it did so.

The question of the WTO validity of product regulations based on or aimed at the method by which a product is produced outside of the importing jurisdiction is strongly debated. Critics of such measures, including the WTO Secretariat, argue that such measures are improper because they intrude on the sovereign discretion of other states to

⁷¹ It is somewhat unclear which provisions of the various WTO Agreements, including SPS, TBT and GATT, apply to these labeling and traceability measures. Under EC Biotech, insofar as the goal of labeling and traceability requirements is to support effective EHS regulation, their validity would be reviewed under the SPS Agreement. Insofar as labeling and traceability requirements have the goals of promoting informed consumer choice and the avoidance of consumer deception, they would, as EC Biotech suggests, likely be reviewed for consistency with the TBT Agreement.

⁷² Panel Report, *United States—Restrictions on Imports of Tuna*, WT/DS21/R (Sept. 3, 1991); Panel Report, *United States—Restrictions on Imports of Tuna*, WT/DS29/R (June 16, 1994).

make their own regulatory decisions regarding the PPMs to be used by their citizens, and because such measures readily lend themselves to protectionist abuse.⁷³ They violate the GATT because they impose different regulatory requirements on products that are “like” or even identical in terms of the characteristics of the products themselves, based on differences in the methods by which they are produced. Outside of the GMO context, Representatives of developing countries have strongly opposed such measures as a form of “eco-imperialism” designed to impose developed country environmental standards on developing countries for which they are inappropriate, and to impose trade barriers.⁷⁴ Defenders of PPM-based product regulations contend that the environmental characteristics of the means by which products are produced are matters of legitimate concern for many consumers, that countries may properly implement through regulatory restrictions their citizens’ desire not to support environmentally unsound PPMs by purchasing their products, and that accordingly such measures should be upheld so long as they have a reasonable basis and are not in fact protectionist.⁷⁵

In a series of *Shrimp-Turtle* decisions,⁷⁶ the AB considered a challenge by several developing countries to the GATT validity of U.S. regulations banning imports of shrimp products caught outside of the U.S. on the high seas or in territorial waters by citizens of other countries that did not require use of protective devices to prevent harm to endangered turtles subject to by catch. The AB eventually upheld a modified version of the U.S. measures after the U.S. had taken steps, outlined by the AB in an initial decision, to address developing country concerns over arbitrary regulatory unilateralism and protectionism and lack of fair procedures in the adoption of the measures.⁷⁷ The AB relied in part on the circumstance that the turtles migrate into international waters and were recognized as entitled to protection under international treaties. There is considerable uncertainty as the implications of the *Shrimp-Turtle* decisions for the EU labeling and traceability regulations. The EU can strongly argue that their objective is to protect EU consumers, and that any broader extraterritorial impact is incidental and irrelevant. On the other hand, critics argue that the consumer protection justifications for the specific measures are weak, that other less trade restrictive means of protection are

⁷³ See WORLD TRADE ORG., *TRADING INTO THE FUTURE: INTRODUCTION TO THE WTO* 47 (1998).

⁷⁴ See Magda Shahin, *Trade and Environment, How Real is the Debate?*, in INTERNATIONAL TRADE AND SUSTAINABLE DEVELOPMENT 205 (Kevin P. Gallagher & Jacob Werksman eds., 2002); Steve Charnovitz, *Solving the Production and Processing Methods (PPMs) Puzzle*, in INTERNATIONAL TRADE AND SUSTAINABLE DEVELOPMENT 227 (Kevin P. Gallagher & Jacob Werksman eds., 2002). In addition to implementing the desire of citizen consumers not to support economically PPMs that they view as environmentally or socially unsound, PPM-based trade restrictions may have the objective of pressuring other countries to regulate those PPMs, join international agreements providing for such regulation.

⁷⁵ See Robert Howse & Petros C. Mavroidis, *Europe’s Evolving Regulatory Strategy for GMOs — The Issue of Consistency with WTO Law: Of Kine and Brine*, 24 *Fordham Int’l L.J.* 317, available at <http://www.worldtradelaw.net/articles/howsemavroidisgmos.pdf>; Robert Howse, *The Appellate Body Rulings in the Shrimp/Turtle Case: A New Legal Baseline for the Trade and Environment Debate*, 27 *Colum. J. Envtl. L.* 489 (2002).

The potential WTO validity of these rationales is even more controversial.

⁷⁶ Panel Report, *United States – Import Prohibition of Certain Shrimp Products*, WT/DS58 (May 15, 1998); Appellate Body Report, *United States – Import Prohibition of Certain Shrimp Products*, WT/DS58/AB/R (Nov. 6, 1998) [hereinafter AB Shrimp Products Report].

⁷⁷ See AB Shrimp Products Report at 138.

available, and that at least in these circumstances the adverse extraterritorial impacts of the measures should be considered and weigh against their WTO validity.

IV. The GMO Challenge to International Trade Regulation

The regulatory and other responses of different countries to GMO technologies pose a series of challenges to the existing international trade regulatory system.. Any one of these challenges would impose significant strains on the current international system. The mutually reinforcing combination makes the strain acute.

First, the GM technologies are both new and powerful. They have the potential for great economic, social and environmental benefits, but also pose substantial environmental economic, social and risks. Because the technologies are new, there is very considerable uncertainty about both the benefits and the risks, especially in the longer run. These circumstances require well functioning systems of technology assessment and management, tasks unfamiliar to the international legal system. They also pose serious strains on the institutional capacities of the WTO dispute settlement system.

Second, GMOs have sparked a sharp and highly polarized global conflict over their development and regulation. The US and a number of other major agricultural exporters including Canada, Argentina and Brazil, along with large multinational firms, are strong proponents. The EU and a number of other OECD countries, driven by anti-GMO NGOs and popular sentiment, have taken a highly restrictive approach to the technologies. In the past, international conflicts over EHS regulation have been episodic and rather sporadic in character. The GMO debate has become a matter of high politics. International institutions have difficulty in dealing with deeply polarized conflicts involving large numbers of major countries on both sides.

Third, the international trade regulatory system, and especially the WTO, is to a substantial extent focused on policing local regulation that is protectionist. But protectionism is not, at least thus far, a major factor in EHS regulation of GMOs, although its importance may grow. As critics of restrictive EU GMO regulation point out, it has the effect of protecting European farmers against foreign competition, and thereby reducing the EU Common Agricultural Policy subsidies that might otherwise be needed to support them. But environmental, consumer, and general public opposition to GMOs on environmental, cultural and t ethical grounds has been the driving factor in EU regulatory policy towards GMOs over the past decade. China appears to have used EHS regulation to protect its non-GM domestic soy farmers against GMO imports. This and other protectionist uses of EHS regulation of GMOs may well become more frequent.

US and other critics of restrictive European regulations of GMOs assert that even if not primarily protectionist it is nonetheless unjustified because the risks at which they are directed are at best speculative and the adverse trade impacts of the restrictions are wholly disproportionate to any EHS benefits. The international trade regulatory system has difficulty in grappling with such claims, especially in light of the technology's novelty.

Fourth, the global GMO conflict has been fueled by strong social, ethical and economic concerns as well as concerns over the environmental and health risks that are the focus of domestic and international EHS regulatory systems. Opposition to GMOs has been driven in important measure by concerns over the adverse impact of GM technologies on the agricultural sector and traditional farming practices; the fear that farmers and society as a whole will become dependent for seed/food supply on a few multinational corporations; a related fear of economic exploitation by these firms; the perceived threat posed by GMOs to food as a cultural value; and the view that genetic manipulation is unethical or sacrilegious. On the other hand the regulatory laws enacted by the countries taking a restrictive approach to GMOs are generally based solely on EHS risks, even though the political impetus for those laws is based on a far wider set of concerns. And, the international trade regulatory system also focuses solely or almost exclusively on the EHS risks that might justify such regulation. Thus, the international legal system addresses only a subset of the factors that are driving restrictive GMO regulation and creating international conflict. This mismatch probably makes it much more difficult for the international system to successfully manage the conflict because it is addressing only a subset of the factors driving the conflict.

A fifth distinctive feature of GMO EHS regulatory controversies is that they can not be reduced to a simple conflict between the EHS protection and related social interests of importing states and the economic interests in export earnings of the exporting state and its producers. Although the question is hotly contested, countries that choose to use GMO crops have a legitimate basis for concluding that are likely to provide significant environmental benefits (reduced chemicals use and agricultural clearing). In addition, developing countries might reasonably conclude that GM crops are likely to provide significant health benefits (by enhancing food security) and socio-economic benefits (rural economic development in developing countries) for those countries that choose to use them. Countries that choose to use GMO crops are as entitled to these judgments as the countries that ban or restrict GMOs are entitled to their judgments that the risks of GMOs are potentially large and outweigh potential benefits. GMO restrictions by importing states based on prevention of EHS risk may have the effect of increasing EHS risks in other countries, creating risk-risk tradeoffs.

Sixth, the global GMO conflict and the international trade regulatory rules for addressing it have major consequences for developing countries. The situation is far more complex than is the case with agricultural subsidies, where there is a clear and consistent developed/developing country divide. Such subsidies are maintained by all the major developed country jurisdictions. They undermine the ability of developing countries to build their agricultural sectors. The appropriate policy response – reduce or eliminate developed country subsidies in favor of alternative ways of maintaining their farmers’ income that do not distort trade -- is clear in principle if very difficult to implement in practice. In the GMO case, by contrast, there are conflicting positions among developed countries, and the interests of developing countries are also quite varied. Some are GMO proponents, some are opponents, most are still trying to assess the various benefits and risks of embracing GMOs and are adopting a “wait and see” approach. Notwithstanding these variables, restrictive GMO regulation forecloses many developed country markets

to developing countries that use or might wish to use GMOs, while labeling and traceability regulations on the EU model would have an even broader negative impact that will disproportionately affect developing countries. These restrictions hamper, perhaps significantly, the ability of developing countries to use GM technologies that might be of great economic, social and environmental benefit to them. On the other hand, developing countries face potentially significant EHS risks in using GMOs and most of them have at best limited capacities to assess and manage these risks. Given these stakes, developing countries have a strong equitable claim to have their interests more fully considered in the regulatory, trade and development policies of developed countries and by the international trade regulatory regime. Even if developed countries and international bodies such as the WTO and Codex were willing to make serious, special efforts to meet the concerns and interests of developing countries, however, those interests are so divergent, and their legal and policy implications so unclear given the current state of the technology and what is known about its benefits and risks, that it would be difficult to identify precisely what measures should be taken.

V. New GMO Trade Regulatory Paradigms

The dominant international EHS trade regulatory paradigm, as reflected in the SPS jurisprudence, holds that EHS regulation is valid only if shown to address a scientifically demonstrable risk to human health or the environment. There must be a risk assessment showing an ascertainable risk posed by the product or process regulated. And, the regulatory measure must be “based” on the risk assessment: there must be reasonable basis for concluding that it will materially reduce the risk in question. International EHS standard setting bodies such as the Codex follow this same regulatory paradigm. By including a rather weak version of the precautionary principle and authorizing regulation to be based on socio-economic considerations along with scientifically ascertainable EHS risks, the Biosafety Protocol allows countries greater regulatory flexibility in the case of GMOs. But, as the Hormones and EC Biotech decisions indicate, the WTO will likely continue to follow a more restrictive approach.

Once the risk assessment requirement is satisfied, countries enjoy considerable flexibility in risk management decisions. Thus, the AB has stated that countries can elect to impose a total ban on product that poses only a small risk, and indicated that it will not engage in a proportionality review, weighing EHS benefits against adverse trade impacts, in reviewing such measures.⁷⁸ The SPS and other WTO disciplines also provide that regulatory measures shall not be unnecessarily trade-restrictive or arbitrarily inconsistent, but WTO panels and the AB generally apply these norms with very considerable deference to national decisionmakers. By invoking the precautionary principle and providing for consideration of socio-economic factors, the Biosafety Protocol allows for even broader flexibility in standard setting. Codex and other international EHS standard setting regimes also allow considerable discretion in setting standards, subject to agreement among participating countries. Thus the dominant paradigm sets a somewhat demanding threshold requirement of a risk assessment demonstrating ascertainable risk for the specific product or process regulated, but much

⁷⁸ Most notably in the Hormones decision. AB Hormones, *supra* note 59.

greater latitude in decisions about appropriate regulatory standards for addressing the risk.

The requirement that EHS regulation be justified by scientific evidence that it addresses an ascertainable risk can be viewed as an essentially procedural mechanism that international authorities can use as a prophylactic against local regulatory failures without becoming entangled in intrusive and politically fraught review of the substantive policy merits of particular national regulations. Together with national treatment, less-trade-restrictive-alternative, and regulatory consistency norms, this “sound science” requirement can serve as a prophylactic against the most egregious forms of protectionism and ensure that national restrictions on international trade provide at least some domestic EHS benefit. And, the procedural requirement of a risk assessment may promote more informed deliberation by countries in their regulatory decisions, providing a further check against protectionism and perhaps favoring adoption of regulations with benefits sufficient to justify their costs.

Countries adopting stringent, precautionary GMO regulations, however, may well face continuing difficulties in meeting the requirement that EHS regulations be justified by a risk assessment showing that the specific product or PPM being regulated presents an ascertainable, material risk. Against this background, GMO opponents and skeptics have sharply challenged the prevailing international EHS trade regulatory paradigm, arguing that the WTO and other international authorities should adopt two new decisional constructs: the precautionary principle, and a “social risks” paradigm that explicitly considers a wide range of social, cultural and ethical values along with scientific evidence of risk and trade impacts in determining the validity of trade-restrictive EHS regulatory measures. Under these approaches, GMO bans or restrictions could be upheld notwithstanding an absence of evidence that a particular product poses a material risk. Their practical effect would be too substantial enlarging the scope of deference accorded to national regulatory measures by the WTO and other international authorities.

These two new constructs, propelled by the GMO debate, represent a fundamental challenge to the conceptual and normative foundations of the current international trade and environmental regulatory regimes. If accepted, the same arguments that have been advanced by GMO opponents can readily extend to many other globalizing new technologies and economic practices. The social value paradigm is the more radical; it has far reaching procedural and institutional as well as substantive implications for international risk governance. Such innovations could hardly be limited to GMO regulation, and would extend to EHS regulation generally. The GMO controversy could thus serve as the entering wedge for a broader challenge to and possible transformation of the current EHS trade regulatory regime generally.

At the same time, the pro-GMO position has elements of a counter-challenge to the dominant international EHS trade regulatory paradigm, although this challenge is at present largely implicit. Critics of EU GMO regulation have maintained that even if there were some scientific evidence of ascertainable risk posed by the GM products being regulated, the adverse trade impacts are wholly disproportionate to any EHS benefits that the regulations might provide. The implication is that WTO panels and the AB or some

other international authority should engage in proportionality review of EHS regulations, weighing their domestic EHS benefits against the costs imposed among other countries and their citizens. The critics of EU GMO regulations also charge that they threaten adverse environmental impacts on exporting countries as well as adverse economic impacts, creating EHS risk-risk tradeoffs. The logical implication is that international reviewing authorities should review these tradeoffs and hold invalid measures that impose significant net adverse EHS impacts.

The Precautionary Principle

Invoking the precautionary principle, governments, politicians, and environmental and consumer groups in the EU and many developing countries claim that the new GMO technologies pose such significant, systemic EHS risk uncertainties and present such an appreciable potential for serious harm that they should be tightly regulated without the need to show, through a risk assessment, that particular GM product present a specific, ascertainable risk of harm.

Under the prevailing international EHS regulatory paradigm, decisionmakers draw on expert judgments to make the best available estimate of the risk presented by a particular product or activity, preferably a quantitative assessment. Based on the resulting risk assessment, they should then make their risk management decision as to whether and how to regulate the product or activity based on the circumstances of the particular case, taking into account the magnitude and probability of harm and applicable regulatory norms. These norms may, for example, be based on promoting overall societal welfare by balancing the social costs and benefits of the activity. As another example, they may be based on preventing any significant risk of harm. They may appropriately include aversion to the risk of large harms and the value of being able to revisit a current decision in the future based on additional information.

The precautionary principle has been presented in many different versions in international treaties, government policy statements, decisions of courts and other tribunals, and academic writings.⁷⁹ Accordingly, it is difficult to speak of a single precautionary principle. But most of these formulations have several key features in common. First, they hold that uncertainty regarding risks as such is a proper basis for

⁷⁹ See Richard B. Stewart, *Environmental Regulation Under Uncertainty*, 10 RES. IN L. & ECON 71 (2002) ECON. 71 (2002). Historically, the precautionary principle was first developed in the 1970s for use in German environmental laws, but it soon entered into international environmental legal discourse through the 1987 Ministerial Declaration of the Second Conference on the Protection of the North Sea for use in international multilateral management over marine pollution entering the North Sea. From there the principle developed a life of its own in the international context, proliferating in a variety of international agreements without a common understanding of its meaning or scope. Nevertheless, the principle was given prominent multilateral expression in Principle 15 of the Rio Declaration, which advises that “in order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.” The Rio Declaration has been considered one of the most important, although non-binding, international instrument for environmental control since the Stockholm Declaration of 1972, and Principle 15 again finds prominence as it is invoked in the Biosafety Protocol.

regulatory decisions. Second, they provide a default rule in the presence of uncertainty. Where the uncertainty regarding the risk posed by an activity is appreciable and the potential for harm substantial, the risky activity should, depending on the formulation in question, either be prohibited, or should be subject to highly stringent regulation until the uncertainty is resolved.⁸⁰ In essence, the principle dictates that decisionmakers should, in such cases, assume the worst, and regulate accordingly. Precautionary principle advocates generally advance two related reasons for this approach: first, it is very important to prevent serious environmental harms. Second, due to serious limitations in data and scientific understanding, our ability to predict whether an activity will cause serious environmental harms is quite imperfect, as experience sadly confirms:

Precautionary action requires reduction and prevention of environmental impacts irrespective of the existence of risks . . . The crucial point is that environmental impacts are reduced or prevented even before the threshold of risks is reached. This means that precautionary action must be taken . . . even if risks are not yet certain but even probable, or, even less, not excluded.⁸¹

Critics of the precautionary principle challenge the decisional approach of the precautionary principle on three fundamental grounds.⁸² The first is methodological. In presuming the worst in the face of uncertainty, the principle, it is argued, conflates risk assessment and risk management and makes arbitrary assumptions about risk in order to generate more conservative risk management decisions.⁸³ The second criticism is that aversion to uncertainty as such is not a sound principle for collective decisions.⁸⁴ The third criticism is that the principle produces bad policy outcomes and reduced social welfare by channeling scarce societal resources to the management of uncertain risks, resulting in less control of activities that are known to cause harms. Finally, the critics

⁸⁰ Weaker formulations of the principle do not provide a default decision rule. They allow, but do not require, regulators to adopt regulatory controls notwithstanding a degree of scientific uncertainty regarding the risk posed. One formulation, increasingly found in sources of international environmental law, holds that the absence of “full scientific certainty” regarding the risk posed by an activity should not by itself preclude regulators from adopting preventive measure in appropriate cases. Another weak version of the principle holds that where preventive regulation is adopted under conditions of uncertainty regarding what constitutes a safe level of exposure to a hazard, regulators may incorporate a margin of safety in setting regulator standards in order to address that uncertainty. These principles are relatively uncontroversial, and are reflected in the practice of preventive regulation in the U.S., Europe, and elsewhere.

⁸¹ L. Gundling, *The Status in International Law of the Principle of Precautionary Action*, 5 Int’l J. of Estuarine & Coastal L. 23, 26 (1990), *quoted in* Ronnie Harding & Elizabeth Fisher, *Introducing the Precautionary Principle* (1999), *in* PERSPECTIVES ON THE PRECAUTIONARY PRINCIPLE 11 (Ronnie Harding & Elizabeth Fisher eds., 1999).

⁸² Critics also contend that the various formulations of the principle are so various, vague and often inconsistent that they do not present any coherent principle for decision.

⁸³ See A. Wildavsky, *Trial and Error Versus Trial Without Error*, *in* RETHINKING RISK AND THE PRECAUTIONARY PRINCIPLE 33-34 (J. Morris ed., Oxford, Butterworth-Heinemann 2000).

⁸⁴ Further, the principle of uncertainty aversion is self-contradictory or useless in the frequent case of regulatory decisions involving risk-risk tradeoffs, where regulatory measures to reduce an uncertain risk themselves create uncertain risks of harm. See Frank.B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 908-915 (1996). See also RISK VS. RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT (John D. Graham & Jonathan Baert Wiener eds., 1995).

contend that the prevailing approach provides ample scope for appropriate precaution in regulation in relation to the specific circumstances of particular cases, without the need to resort to over inclusive default rules such as those of the precautionary principle.⁸⁵

Additional institutional considerations come into play when the precautionary principle in the context of international trade regulation. The practical effect of adopting the principle would be to relax the discipline exerted by the currently prevailing risk assessment requirement, and enhance the practical discretion of countries to justify restrictive regulatory decisions against challenge before the WTO or other international tribunals by invoking the presence of substantial uncertainty regarding risks, potential for significant harm, and precautionary norms. It attenuates or even does away with the current requirements for specific evidence of ascertainable risk. Proponents of the precautionary principle argue that it is entirely appropriate, for countries to enjoy this latitude to decide to adopt a precautionary approach to uncertain EHS risks. Opponents contend that the result will be to significantly undermine decisional transparency and the efficacy of review of domestic trade barriers by international bodies. The result, they contend will be undue scope for countries to adopt standards that are protectionist, arbitrary, or otherwise subversive of the welfare of the Members as a whole.

No doubt influence by these implications, WTO decisions have thus far refused to give effect to the precautionary principle in resolving trade regulatory disputes. In Hormones, the AB found that the precautionary principle had not become a rule of customary international law, that it could not be invoked to modify the risk assessment requirement of SPS Art. 5.1 and that it could not be used to interpret SPS Art 5.7 to expand countries' regulatory flexibility because the article's specific provision already gave appropriate effect to the principle. The AB did, however, indicate that the principle might have interpretive significance in other, unspecified circumstances. In EC Biotech, the Panel, without much explanation, found it unnecessary to consider the principle in deciding the case. This limited experience suggests that WTO tribunals will be reluctant to give the principle significant weight in order to relax the risk assessment requirement in Art 5.1 or other SPS disciplines.

The Codex standard setting process has also not been hospitable to the precautionary principle. The Biosafety Protocol, on the other hand, explicitly recognizes a relatively weak version of the precautionary principle as basis for decisions by countries whether to agree to imports of GMOs intended for environmental release and as a basis for the national biosafety regulations on which those decisions would be based.⁸⁶ In the absence of any mechanism for subsidiary legislation or compulsory binding dispute settlement under the Protocol, different countries would have wide latitude in deciding how much weight to give to the interest in precaution, potentially leading to quite divergent biosafety regulatory decisions. The reception of the precautionary principle in

⁸⁵ Such precaution may reflect risk aversion in the face of small possibilities of very serious environmental harms, past experience in predicting environmental risks, a healthy respect for the potential for nasty surprises, and concerns about nature's vulnerability.

⁸⁶ Cartagena Protocol on Biosafety, Preamble, arts. 1, 10.6.

EC Biotech and Hormones⁸⁷ indicate that WTO panels and the AB are unlikely to give a hospitable reception to the Protocol's version of the precautionary principle.

Social Risk Justifications for EHS Regulation

Governments rarely explicitly invoke social risks to justify EHS or consumer protection regulation of GMOs, instead emphasizing risk uncertainties, the need for precaution, and the norm of informed consumer autonomy. But public concerns over the adverse impacts of GMO technologies on traditional agriculture and pastoral landscapes, impacts on the "natural" quality of foods and their cultural value, ethical concerns about tampering with nature, and fears about the spread of factory farms, the implications of intellectual property rights in bioengineered seeds, dependence on multinationals for food supply, and concerns over globalization, have provided strong political impetus for stringent GMO regulation. The restrictive GMO regulatory measures adopted by many jurisdictions have often been propelled by social values that go beyond EHS risks, even where the latter are the stated justification. To a considerable extent, regulation of GMOs and attendant debates over scientific uncertainties regarding risks and the need for precaution are proxies for these broader social values and concerns. Some environmental and other opponents of GMOs contend that these social concerns and values should be recognized as an additional, justifiable basis for GMO regulation in addition to protection of public health and the environment.⁸⁸ They argue that concerns, for example, to protect traditional agricultural practices, to maintain small farms and the associated rural landscape, to safeguard the cultural value of traditional "natural" foods, and avoid dependence on multinational corporations for local food needs are entirely appropriate bases for sustaining GMO EHS regulation. This position represents a far more radical challenge to the prevailing international trade regulatory paradigm than the precautionary principle because it greatly expands the recognized bases for regulation to include values other than EHS protection. It has however, yet to win acceptance in the international trade regulatory system. While the arguments for recognizing broader social values have been focused on GMO regulation, they logically extend to EHS regulation generally, and would if accepted have far reaching implications for the international trade regulatory system. With the somewhat limited exception of the Biosafety Protocol, they have yet to be accepted within that system. They nonetheless represent an emerging and potentially significant challenge to the status quo.

Extrinsic and intrinsic social risks

At the outset, sound analysis requires a distinction between social values that are intrinsic to EHS and consumer protection, and those that are extrinsic. Intrinsic values are those

⁸⁷ Thus far, WTO dispute settlement bodies have declined to give any significant independent or interpretative effect to the precautionary principle.

⁸⁸ Under a welfare economic framework of EHS regulation, so long as products and services comply with EHS regulations needed to redress serious market failures, the decision whether they will be consumed and used is remitted to the decisions of individual consumers. Those who oppose this conception of regulation as too limited fear that decentralized market processes and individual consumer decisions will not adequately protect and secure other social values beyond EHS protection. EHS regulation is thus used to restrict the access to the market or raise the price of those goods and services thought to impair these social values.

shape the public's perceptions of EHS risks, their qualitative character and weight, and their distributional implications. Thus, the public gives greater significance to risks that are "dread" like cancer, involuntary, or that target a defined subgroup of the population, such as a community near a hazardous waste site. Extrinsic social values concern impacts or dimensions of products and processes other than those relating to the physical health of the environment or of consumers and the public. These include socioeconomic impacts on existing patterns of production and consumption, consequences for sociocultural values associated with those patterns (traditional farming practices/communities; seed sharing; traditional knowledge; small scale farming; rural amenity value, food as cultural construct), and ethical objections to technologies and practices on grounds other than their EHS impacts.

Extrinsic social values and concerns have been a major factor in the adoption of restrictive GMO regulations. GMOs often raise cultural, aesthetic, and socioethical concerns because they are considered "unnatural."⁸⁹ But this concern is more widespread and intense in some countries than others, and is often linked with other concerns. A successful anti-GMO campaign by a socialist-leaning labor organization begun in France in 1998 explicitly introduced social and cultural values risk into the debate by linking the proliferation of GMOs with threats to French food and culture and traditional local agricultural *savoir-faire*.⁹⁰ By linking anti-GMO sentiment with a broader anti-globalization sentiments, this group's campaign attracted wide and sympathetic attention on the part of the French public and the European public as a whole, driving the GMO debate beyond questions of EHS risk.

Nonetheless, extrinsic social concerns have implicitly been perceived as inappropriate in the context of official deliberation and decision on GMO EHS regulation.⁹¹ Often unthinkingly, stakeholders in the GMO debate perceived that any question of regulating GMOs must be framed in terms of EHS risks and should be debated using the vocabulary of science. This process of "riskification" in the GMO debate has been explained as a general socializing process whereby relevant social actors, such as regulators, industry leaders, and the concerned public, implicitly translate the many cultural, ethical, and other extrinsic social concerns raised by GMOs into the framework of EHS risks to facilitate and legitimate control on the new agricultural biotechnologies, leaving the underlying social concerns unspoken.⁹² One consequence of this development is that issues of EHS risk have been used as a proxy for dealing with extra-EHS social concerns with GMOs that were not considered proper for official

⁸⁹ For discussion of the various connotations of "nature" and the "natural" in the context of the GMO debate, see Mark Sagoff, *Biotechnology and the Environment: Ethical and Cultural Considerations*, 19:11 *Env'tl L. Rep.* 10520 (1989).

⁹⁰ C. Heller, *From Scientific Risk to Paysan Savoir-Faire: Peasant Expertise in the French and Global Debate over GM Crops*, 11:1 *SCI. AS CULTURE* 5 (2002). It may be relevant to note, however, that these cultural concerns do not always need to fall on the side of more regulation. For example, many traditional French cheeses are not pasteurized, in spite of the health concerns, explicitly (and literally) for reasons of cultural taste.

⁹¹ *Id.* at 10.

⁹² *Id.* See generally MARY DOUGLAS, *RISK ACCEPTABILITY ACCORDING TO THE SOCIAL SCIENCES* (Russell Sage Foundation 1986).

debate.⁹³ Sometimes these broader social concerns have been re-cast in ‘risk’ frames, such as assertions of “risks to culture.” This “social risk” discourse has gradually become more widespread, to the point where the concept of social risks has been explicitly invoked to justify GMO regulation.⁹⁴

What would be the consequences for the international trade regulatory system of accepting extrinsic social risks as a legitimate basis for EHS regulation? First, it would be exceedingly difficult to maintain the current threshold requirement of showing that a regulation is supported by a scientific risk assessment demonstrating an appreciable EHS risk. Conceivably, the requirement of a risk assessment could be expanded to include social as well as EHS risks. But there is as yet no well established and widely recognized set of methodologies for conducting social risk assessments. Because cultural, ethical, and other social values are essentially qualitative, it may be virtually impossible to design sound and practical quantitative measures for assessing them. Second, expanding the permissible bases for regulation to include extrinsic social values along with EHS risks would greatly expand the type and number of considerations that countries could invoke before international tribunals to justify regulatory measures challenged as trade restrictions. The reviewing task would be far more indeterminate than at present, where tribunals’ inquiry is focused on whether there is scientific evidence of a specific EHS risk and, if there is, whether the challenged regulation is reasonably designed to reduce that risk while avoiding unnecessary restraints on trade. Faced with the far more open ended

⁹³ The question remains, why extrinsic social concerns are not addressed through regulatory measures explicitly based on concerns other than EHS protection? Why has EHS regulation been used as the vehicle for advancing the extra-EHS goals?

One possible explanation is political. It may not be possible to build a winning political coalition for restrictive regulation targeted at non-EHS social objectives alone. Building such a coalition may depend on use of EHS regulation as a vehicle for mobilizing political interests concerned with EHS regulation along with interests based on extra-EHS concern or goals/s.

Another possible explanation stems from the fact that there are well established exceptions from free trade disciplines for EHS regulatory measures. There is far less of a well-defined safe harbor for regulation based on extra-EHS values like those implicated in the GMO conflict. Thus, EHS regulation may be used as vehicle for enhancing the international trade legitimacy and validity of regulatory measures that include extra-EHS objectives.

A third potential explanation lies in the liberal conception that the primary role of state regulation is to protect the public from economic and physical harms, while more diffuse social concerns should be addressed primarily through private ordering and civil society institutions. This conception views with suspicion government regulations based on cultural, aesthetic, and socioethical values, where such regulation restricts the free circulation and availability of goods, and thereby limits individuals’ ability to exercise their own judgments about whether one product is culturally salutary, aesthetically pleasing, or ethical. [Jasanoff] It is not the state’s job, so this reasoning goes, to tell people that they should not want to buy GMOs, as long as they are safe. Indeed, even many people who are motivated to restrict GMOs based on conflicting economic interests and cultural values still feel obligated to do so under the auspice of EHS risk regulation, in deference to the prevailing liberal conception of regulation.

⁹⁴ See SAVE OUR SEEDS, CONSIDERATIONS REGARDING THE CO-EXISTENCE OF GMO, NON-GMO AND ORGANIC FARMING 4 (2003), *available at* www.saveourseeds.org/downloads/coexistence_memo_03_2003.pdf (last visited Aug. 22, 2008); Royal Society of New Zealand, Improving the Operation of the HSNO Act for New Organisms (Nov. 2002), <http://www.rsnz.org/news/current/hsno.php> (last visited Aug. 21, 2008).

task of evaluating a host of rather indeterminate social values and the “fit” between those values and challenged regulatory measures, tribunals could well be led to give such measures very great deference. The result would be far greater latitude for local regulations, expanding the scope for protectionist trade restrictions. Because (as illustrated by the GMO debate), producer economic interests and social concerns are often mutually reinforcing, social risks could become a stalking horse for producer interests.

Thus far, neither the WTO AB nor any other international tribunal has recognized extrinsic social risks as a justification for EHS regulation. This circumstance is hardly surprising, for apparently no country has invoked this argument in a decided case. The cool reception by WTO dispute settlement bodies of the precautionary principle strongly suggests that it would not accept a social risks paradigm. Nor have social risks been recognized as a basis for setting EHS regulatory standards by Codex or other international standards. The Biosafety Protocol, however, provides for consideration of socio-economic factors related to biodiversity in risk assessments and regulatory decisions. The scope of these factors and their implications for regulation have yet to be determined. The social risks paradigm has strong popular and political appeal in many developed and developing countries and among many international NGOs. It may yet play a more significant legal role in the international EHS trade regulatory system

Proportionality Review and Risk-Risk Tradeoffs

GMO proponents, on the other hand, not only reject the precautionary principle and social risks justifications for EHS regulation, but would modify the existing approach international EHS approaches to further restrict and discipline regulatory decisions through use of proportionality analysis, balancing the EHS benefits provided by a regulatory measure against its adverse impacts, and through risk-risk analysis, weighing the potential negative EHS consequences of regulatory measures against the positive ones.

Critics of restrictive GMO regulations like those adopted by the EU on the grounds that they are directed at “phantom risks” and that whatever benefits they may provide are exceedingly small and far outweighed by the adverse impacts on trade and on the welfare of other countries. The risk assessment requirement of the existing international EHS regulatory paradigm deal with the first concern but may not adequately address the second. As previously noted, for a AB has stated that once a material risk is established, it will not inquire whether there is a reasonable relation between the EHS benefits provided by a regulation and its adverse impacts on other countries.⁹⁵ Yet WTO panels and the Ab. have been able to use other essentially procedural techniques in addition to the risk assessment requirement to rule against burdensome and potentially protectionist EHS measures. As a result, they have yet to confront a case that would require use of proportionality review to dispose of a local regulation that imposes costs on others that far outweigh any plausible local regulatory benefits. Explicit use of proportionality review could be viewed as a revolution in WTO jurisprudence by

⁹⁵ See text at note 60, supra.

establishing the AB as a social welfare arbiter rather than enforcer of members' agreements.

GMO proponents also assert that use of GMOs will provide important environmental as well as social and economic benefits by, reducing the need for agricultural clearing, and the use of chemicals, limiting greenhouse gas emissions, and so on. Accordingly, they argue, restrictive GMO regulations like those of the EU discourage use of GM crops in agricultural exporting countries, especially developing countries, and thereby cause net environmental harm. If so, these GMO regulations involve risk-risk tradeoffs.⁹⁶ Accordingly, in order to ensure that GMO or other EHS regulation is on balance beneficial, reviewing bodies should weigh the adverse environmental consequences of the regulation against the benefits. Courts in the United States have already begun to require regulatory agencies to address these tradeoffs.⁹⁷

The presence of risk-risk tradeoffs significantly changes the normative framework for proportionality analysis. The issue is no longer environment/health versus cost or reduced trade, but environment/health versus environment/health. In the international context, the issue is no longer the right of an importing jurisdiction to choose its appropriate level of EHS protection; both the exporting and the importing jurisdiction have interests in EHS self-determination of both jurisdictions are involved. It may well fall to the AB to confront the risk-risk tradeoff issues in a case, probably brought by a developing country, challenging restrictive EU or other developed country GMO regulations.

VI. Developing Countries and International GMO Trade Regulatory Rules

Most developing countries have traditionally been hostile to stringent EHS regulation of agricultural products as a developed country tool for imposing protectionist trade barriers to their exports. Consistent with this approach, developing countries largely supported the trade disciplines on domestic EHS regulation adopted in the WTO SPS Agreement. The circumstance that international trade rules might limit their own ability to adopt stringent EHS regulation of food imports was not a major concern. In the specific context of GMOs most developing countries have, for a variety of reasons tended to favor broad authority to limit or exclude GM foods and crops. They supported the development and adoption of the Biosafety Protocol with this objective. This raises the question whether one set of international EHS trade regulatory rules that tightly discipline domestic regulations can be maintained for non-GM agricultural

⁹⁶ It is increasingly recognized that EHS regulatory decisions often involve risk/risk tradeoffs. See Graham & Wiener, *supra* note 84; Cass R. Sunstein, *Health-Health Tradeoffs*, 63 U. CHI L. REV. 1533 (1996). For example, a regulatory decision to reduce ground level concentrations of ozone in order to reduce respiratory-related health risks will have the effect of increasing skin cancers due to higher human exposures to ultraviolet solar radiation that would otherwise be absorbed by the ozone. The precautionary principle is unable to deal with risk-risk problems, Should precaution be targeted at the target risk, or the non-target risk? The precautionary principle affords no guidance. See Cross, *supra* note 72; Sunstein, *supra*.

⁹⁷ See, e.g., *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

products, and another, more permissive set of rules for GMO regulations. The situation is further complicated by the circumstance that a few important developing countries, including Argentina, Brazil, China, and South Africa grow GM crops on a substantial scale, and others, such as India, Indonesia, and Mexico, may be headed in the same direction. Many of these GMO or emerging GMO developing countries have substantial R&D programs to develop GM crops; they have an interest in the extent to which trade regulatory rules will affect their ability to reap economic and other benefits from the technologies that they are developing. Further, some of these countries, most notably Argentina and Brazil, openly oppose stringent regulatory restrictions on trade in GM crop products, while the approach of others is more mixed.

This Part examines the varying interests of developing countries in the international EHS trade regulatory rules applicable to GMOs. It then discusses the implications the interests of the relevant WTO jurisprudence including the interim Panel decision in *EC Biotech*. It examines the possible options clarifying or changing international trade regulatory rules to give greater consideration to developing country interests in the context of GMO regulation and development.

Developing Country Interests in GMO Trade Regulatory Rules

Which international GMO trade regulatory rules countries favor depends to a great extent on their interests in using GMO technologies and products. Currently, many developing countries appear to want the legal ability to limit or exclude GM foods or crops, although the reasons may vary widely, including protection of domestic farmers or domestic agricultural biotechnology enterprises against foreign competition; this interest will likely grow if GMO technologies develop further and spread. At the same time, developing countries that have adopted or are developing GM crop technologies want to restrict the ability of developed countries to use EHS regulation to ban or restrict GMO crop exports or impose labeling and traceability requirements. And, essentially all developing countries presumably continue to wish to limit the ability of importing countries to use EHS regulation to restrict their agricultural exports generally.

Under the international trade norm of reciprocal concessions and commitments, international trade regulatory rules are a two edged sword. Unless some special dispensation is made for developing countries, trade regulatory rules giving developing countries broad latitude to exclude GM crops and foods, including through use of the precautionary principle and invocation of extrinsic social risks, would give developed countries the same latitude to exclude developing country agricultural exports. Further, once the precautionary principle or social risks were accepted as justifying trade-restrictive food and crop regulations, it would be difficult to limit their application to GMOs unless the Biosafety Protocol were successfully invoked to justify special, more restrictive trade regulatory rules for GMOs. At the same time, the practical effect of the current risk assessment requirement may impose a disproportionate burden on most developing countries because they have much more limited capacities to conduct such assessments. Another asymmetry in the practical impact of trade regulatory rules is exemplified by the EU GMO labeling and traceability regulations. Developing countries have more limited abilities to achieve the degree of segregation of GM and non GM

products required by such regulations. Thus, trade regulatory rules favorable to this type of GMO regulation would disproportionately burden developing countries.

Another issue is uncertainty in the international trade regulatory rules governing GMO. Developing country representatives have complained that the current rules are characterized by great uncertainty. As the EC Biotech case illustrates, the WTO dispute settlement process proceeds incrementally and slowly, especially with respect to such hotly contested issues as GMOs. Additional legal uncertainty is created by the existence of the Biosafety Protocol and its relation to the WTO agreements. The resulting legal uncertainty might be regarded as an advantage for developing countries, as it would seem to afford them flexibility in regulatory approaches to GMOs, including the ability to change course in accordance with shifting conditions and assessments of their interests, without running afoul of recognized legal requirements. On the other hand, developed countries may use the flexibility caused by trade regulatory uncertainty to exclude or restrict GMO crop products. Also developing countries that want, for various reasons to limit GMO imports, uncertainty creates the risk (more theoretical than real for most developing countries) of legal action by GMO exporting countries. Perhaps more important, uncertainty allows the U.S. and other exporting countries to argue that such restrictions are in fact WTO-illegal and may not be adopted, and to exert various forms of pressure on developing countries to admit GMOs. Finally, many developing countries are investing, with international donor assistance, substantial resources in writing biosafety laws and regulations. The lawyers, engaged in this enterprise would much prefer certainty regarding applicable international trade regulatory rules.

Implications for Developing Countries of Current International GMO Trade Regulatory Rules

The *EC Biotech* panel decision is the principal guide for determining the current international trade regulatory rule applicable to GMOs. The decision has important and generally adverse implications for developing countries. It restricts their ability to ban or limit GMOs or to postpone definitive decision whether or not to authorize or use GMOs. The Panel held that the risk assessment requirements of the SPS Agreement⁹⁸, which are especially burdensome for developing countries, are broadly applicable to environmental health and safety (EHS) regulation of GMOs. It also refused to recognize norms derived from The Biosafety Protocol or the precautionary principle (PP) as mitigating the rigor of those requirements. It rejected arguments that Members should enjoy special regulatory flexibility in dealing with GMOs because they are products of new technologies whose risks are not adequately known. Further, the Panel held that industrialized countries have no legal obligation to accord special consideration or treatment to the interests of developing countries in adopting restrictions on GMO agricultural products. The decision also leaves many issues unaddressed and raises new questions to be addressed in the

⁹⁸ Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Annex 1A, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS vol. 27 (hereinafter SPS Agreement), available at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf (last visited July 31, 2008).

future. Overall, the decision restricts, perhaps substantially, the ability of developing countries to exclude GMOs or postpone decision on the use of GMOs, while leaving industrialized countries with a large discretion to restrict or ban agricultural products containing even small amounts of GMOs from developing countries.

Risk Assessment Requirements and Regulatory Policies

Under the Panel’s decision, environmental health and safety regulations of GM seeds, crops and foods must generally meet the more burdensome requirements of the SPS Agreement rather than those of the TBT or GATT Agreements.⁹⁹ Because the SPS Agreement imposes burdensome science-based risk assessment requirements that are absent in other WTO agreements, this broad interpretation of SPS Agreement has significant implications.

Consistent with prior AB jurisprudence in decisions such as EC-Hormones, the Panel held that SPS Agreement Art 5.1 requires regulatory restrictions to be “based on” a risk assessment for the risks posed by the specific GM product in question, unless the available scientific evidence is not sufficient for a risk assessment to be made for that product (pp. 923.) Generic risk assessments for GMOs in general or broad categories of GMOs will also not suffice. The risk assessment must identify relevant “disease,” “pest” etc risk posed by the specific product; estimate the magnitude or likelihood of the risk posed; and estimate the extent to which the risk will be reduced by the regulatory measure in question (“before and after analysis”). (p. 929, invoking the AB decision in Australian Salmon).¹⁰⁰ It also stated that measures should not only “be based” on the risk

⁹⁹ The Panel held that whether a regulatory measure falls within SPS Agreement depends on whether its purpose is to address human health or other EHS risks covered by SPS Agreement Annex A(1)(a), (b), and (c). A measure may have several purposes, some of which covered by SPS Agreement and others by other WTO agreements, including TBT and GATT. Its validity must be analyzed correspondingly. Panel Report, *EC – Approval and Marketing of Biotech Products*, 342, WT/DS291-93/R (Sept. 29, 2006) [hereinafter EC Biotech]. The Panel held regulatory measures aimed at the following types of environmental health and safety (EHS) risks are covered by the SPS Agreement: GM plants growing where they are unwanted, unintentional gene flow to non-GM plants including non-GM commercial crops, development of pesticide resistance in target and non-target species, effects including cumulative effects on non-target organisms and biogeochemical cycles, transfer of antibiotic resistance to animals and humans, food safety, allergenic effects of GMOs not used as foods, and health risks resulting from increased use of herbicides resulting from adoption of GMO crops. EC Biotech at 343. The Panel held that regulatory measures aimed at the following objectives are not covered by the SPS Agreement: protecting consumers from being misled and from foods that are nutritionally disadvantageous. EC Biotech at 380.

¹⁰⁰ See SPS Agreement Annex A(4): “Risk assessment – The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.”

The Panel underscored the product-by-product nature of the risk assessment requirement by undertaking a detailed analysis of the documentation for each separate EC safeguard measure to determine whether it met SPS Agreement Art. 5.1 risk assessment requirements.

assessment, but they should also ‘conform with’ the risk assessment, whether favorable or negative. (p. 935.) Thus, Member States cannot ignore a favorable risk assessment.

These risk assessment requirements represent a significant burden for most developing countries, which lack the technical capacities and resources to perform individual risk assessments meeting the requirements for each of the many different GMO products that they may seek to regulate. Some flexibility is, however, provided by the Panel’s conclusion that the risk assessment need not be performed by the country whose regulation is challenged. Also, a Member defending a regulation has to identify a supporting risk assessment only at the time that any WTO challenge is brought. The Panel stated that a regulatory restriction can be justified based on a divergent or minority view among scientists as to the risks posed by GMOs, but this view must be set forth in a risk assessment that meets the requirements set forth above. (pp. 9–3 - 936).

The Panel held that SPS requirements for a risk assessment may not be avoided or eased by invoking the precautionary principle, risk uncertainties, the evolving character of scientific information, the regulatory policies of a country, or the political or social context. These considerations are relevant only to a country’s choice of the appropriate level of protection (a risk management decision), determined after and based on a risk assessment.¹⁰¹ Invoking Art 31(3) (c) of the Vienna Convention, held that the provisions of the CBD/Biosafety Protocol were not applicable to the controversy because not all parties to the controversy before it were members of the Protocol¹⁰² The Panel declined to address the status of the precautionary principle under international law, finding that it is already incorporated in the provisions of SPS Agreement Art. 5.7, and may not be independently invoked to interpret or apply its requirements or those of Art. 5.1.¹⁰³ SPS Art. 5.1 provides for a risk assessment “appropriate in the circumstances.” Developing countries could invoke Art. 5.1 To argue that developing countries’ limited technical capacities and resources are “appropriate circumstances” that justify applying the risk assessment requirement to them in a less rigorous, more flexible fashion. But the Panel rejected the EC’s argument scientific uncertainties were “appropriate circumstances” that justified avoidance relaxation of the risk assessment requirement.

To what extent can a country provisionally regulate a GMO product without a risk assessment by invoking scientific uncertainty and arguing that further information is needed before risk assessment can be conducted? The Panel held that where the available scientific evidence is insufficient to support a risk assessment, a country need not meet the risk assessment requirements of SPS Agreement Art. 5.1, and is instead entitled to regulate the product under SPS Agreement Art. 5.7. Accordingly, the critical question is the standard for determining whether the “available pertinent information” evidence is

¹⁰¹ EC Biotech, *supra* note 99, at 934.

¹⁰² *Id.* at 285.

¹⁰³ The Panel stated that members can in choosing a level of regulatory protection adopt a precautionary approach in light of uncertainties in a risk assessment, but that the EC had failed to identify relevant uncertainties in the documents reports relied on to support the safeguard measures. *Id.* at 934. The Panel stated that it nonetheless had the discretion to consult these or other sources of international law even if not legally applicable if it found them “informative.” *Id.* at 307. But, with little discussion, it did discuss or apply the provisions of the CBD or Protocol.

sufficient to support a risk assessment. The Panel did not resolve this question, however, because the existence of favorable risk assessments for the GMO products in question mooted any need to do so. The Panel, however, did make clear that the sufficiency of the evidence to support a risk assessment is a purely scientific question.¹⁰⁴ It rejected arguments by the EC that the precautionary principle, regulatory and social policies and the political, social and economic context are relevant in assessing whether the evidence is sufficient to support an Art 5.1 risk assessment.¹⁰⁵ A developing country might argue that “pertinent information” is not “available” to it because it lacks the capacity and resources to collect and analyze it, but this argument is most unlikely to succeed.

Consistent with prior WTO SPS Agreement jurisprudence, that Panel indicated that if a relevant risk assessment shows that a GM product poses some EHS risk countries will enjoy very wide discretion in determining how to regulate that product.¹⁰⁶

Regulatory Impasse or Delay

Developing countries may, for various reasons, wish to postpone any definitive decision for or against use of GMOs. Because of internal political disagreements, delays in developing biosafety regulatory laws, limited regulatory capacities, uncertainties regarding the economic and environmental performance, and risks of GMOs conflicting international pressures, and uncertainty over international trade regulatory laws and industrialized countries consumer attitudes and regulations, developing countries may deliberately choose a “wait and see” policy and postpone a definitive decision on GMOs pending clarification or resolution of these issues.. Many developing countries in fact appear to have been pursuing this strategy. In the interim, a country must either prohibit GMOs (perhaps asserting the ban is temporary) or delay granting authorizations of GMO products if domestic laws permit their use GMO use if authorized.

If the country prohibits GMOs outright, then it must either satisfy the risk assessment requirement of SPS Art 5.1 or show, pursuant to Art 5.7, that there is insufficient scientific information to conduct such an assessment. Delaying final decision on pending applications for regulatory approval, may be attacked either as a de facto prohibition requiring a risk assessment, or a violation of SPS Art 8 and Annex C(1)(a), requiring that regulatory measures “be undertaken and completed without undue delay.”

As reflected in the Panel decision, the determination of undue delay is highly context and fact-specific. The decision, however, did provide some general guidelines. It stated that the issue is not the length of the delay as such, but the justifications for it. The longer the delay the greater, presumably, the burden of justification. The Panel rejected the EC’s

¹⁰⁴ *Id.* at 976.

¹⁰⁵ The Panel emphasized that if the first requirement in Art 5.7 -- the evidence is not sufficient to support a risk assessment -- is satisfied, a country seeking to regulate a GM product without a risk assessment must meet the three additional Art 5.7 requirements. *Id.* at 901. It must base its regulatory measures on “available pertinent information”; seek additional information needed for a “more objective assessment” of the risks, which the Panel equated with a risk assessment meeting Art. 5.1 requirements; and review its regulatory measure within a reasonable time. *Id.* at 970 ff.

¹⁰⁶ EC Biotech, *supra* note 99, at 934.

contention that the perceived need to adopt new GMO regulatory laws justified delay in processing applications under existing laws regarded as inadequate. It also rejected the EC's argument that "evolving science" and the "need for a prudent and precautionary approach" justifies postponing authorization decisions, observing that such a "general holding pattern" could be used by Members to evade SPS disciplines (p.634). On the other hand, the Panel acknowledged that the development of new scientific information might require regulatory delay to enable the responsible authority time to assess the information, but stated that the authority should act "as expeditiously as could be expected of it" in the circumstances (p. 630). Developing countries might invoke this statement to justify regulatory delays due to their more limited technical and administrative capacities.

Overall, the Panel's decision rather clearly indicated that it would not accept a developing country "wait and see" policy based on the reasons summarized above. But its rulings on undue delay need to be read and evaluated in light of the rather strong facts of the cases. The EC had adopted an openly avowed "moratorium" on GMO approvals for nearly five years. On less strong facts, panels might accord considerable deference to developing countries in dealing with the complex issues presented by GMO regulation. Moreover, the burden is on the complaining party to show undue delay.

Developed country authority to exclude developing country agricultural exports involving GMOs

Once a suitable risk assessment for a GMO product exists, a Member enjoys broad discretion in deciding how to regulate it. Industrialized countries, however, are much better able, in terms of capacities and resources, to generate suitable risk assessments than are developing countries. Thus, the SPS jurisprudence tends to create a de facto double standard, imposing greater burdens on developing countries.¹⁰⁷

In addition to facing developed country bans or stringent on their GM agricultural exports, developing countries also face GMO labeling and traceability regulations like those adopted by the EC. The Panel decision does not provide much guidance in assessing the consistency of these measures with WTO law, beyond indicating that they must be assessed under the SPS Agreement insofar as their purpose is to protect against EHS risks, and under other agreements, such as TBT or GATT insofar as they are aimed at informing consumers and preventing them from being misled. Because protection of consumer health is among the stated purpose of the EC regulations, they would presumably have to be SPS justified by a risk assessment showing the extent to which they would reduce the risk of adverse health effects; this might be exceedingly difficult to establish.

Challenges for developing countries

¹⁰⁷ In addition, developing countries face GMO regulatory restrictions imposed by other developing countries, Request for Consultations by Thailand, *Egypt – Import Prohibition on Canned Tuna With Soybean Oil*, WT/DS205/1 (Sept. 27, 2000), although this is a far less significant consideration for most developing countries.

The net effect of the Panel's decision is unfavorable for developing countries, in two different ways. First, it restricts the ability of developing countries who wish to restrict, permanently or temporarily, use or authorization of GMOs.¹⁰⁸ At the same time, the panel's decision does not provide much of the relief sought by Argentina, nor does it provide much solace for other developing countries that wish to grow GM crops and export those crops or non-GM counterparts to developed countries. Although the EC moratorium and member country safeguards measures were found to be contrary to SPS disciplines, developed countries that can generate a risk assessment in support of regulating a GM product continue to enjoy broad power to ban or restrict it. The Panel decision makes the Art 10.1 obligation of members to 'take account of the "specials needs" of developing countries in the preparation and applications of SPS measures virtually dead letter insofar as legal enforcement goes.¹⁰⁹

The EC Biotech decision provided some clarification regarding GMO trade regulatory rules, although the decision is only that of a panel.. The decision clarified the application of the SPS Agreement to GMO EHS regulation and the Articles 5.1 and 5.7 requirements. It represents the first panel interpretation of the SPS Agreement Art. 8 and Annex C(1)(a) provisions. It ruled on the application of the Biosafety Protocol to WTO disputes including Members that are not Parties to the Protocol, and the application of the precautionary principle. On the other hand, it left open the standard for determining whether or not evidence is sufficient to produce a risk assessment under Arts 5.1 and 5.7, and identified but did not resolve many other legal issues raised by the complainants under the SPS, TBT, and GATT Agreements.¹¹⁰

The Panel decision will not make it any easier to reach agreement through Codex or otherwise on international substantive GMO regulatory standards, although the Codex process might be able to foster some agreement on when the evidence is insufficient to produce a risk assessment as well as further clarification of the elements of such assessments. It also casts a legal cloud on the Biosafety Protocol regime. Under the Panel's decision, the Protocol has no legal effect in WTO disputes that involve a Member that is not a Party to the Protocol. The Panel also refuses to give independent legal effect to the precautionary principles, an important element in the Protocol's approach. The significance of the Protocol, which many developing countries have regarded as an important protection of their interests in GMO international trade regulatory matters, is thereby marginalized.

¹⁰⁸ The practical likelihood that the U.S. or another pro-GMO country will actually institute a WTO challenge to restrictive developing countries GMO regulations or delays in approval decisions is quite low for all but the largest and most important developing countries. At the same time, US and other pro-GMO countries and agricultural biotechnology firms are likely to use the Panel decision and its implications to pressure developing countries to adopt favorable GMO regulatory policies and measures. US officials initially characterized the Panel's decision as an important warning to other countries against adopting prohibitions on GM crops. *EU loses a round on Biotech crops*, WALL ST. J., Feb. 9, 2006, at A5.

¹⁰⁹ EC Biotech, *supra* note 99, at 651-52.

¹¹⁰ For a summary of all of the various issues presented and the Panel's treatment of them, see CTR. FOR INT'L & ENVTL LAW, EC BIOTECH: OVERVIEW AND ANALYSIS OF THE PANEL'S INTERIM REPORT (2006), available at http://www.ciel.org/Publications/EC_Biotech_Mar06.pdf (last visited July 31, 2008).

Accommodating Developing Countries Interests in GMO Trade Regulatory Rules

There are three basic approaches for developing international trade regulatory rules might better address the varying interests of developing countries in GMO regulation and avoid or mitigate the two-sided adverse impact of those rules in their respective roles as agricultural exporters and domestic regulators of crops and foods.

The first method is to develop trade regulatory rules that explicitly give developing countries as a category distinctive and more favorable treatment with respect to GMO regulation. This might be accomplished by giving stronger legal or political effect to the special and differential treatment (SDT) provisions found in the SPS and other WTO Agreements, and/or be developed independently in Codex and other international standard setting regimes or under the aegis of the Biosafety Protocol. The second method is use interpretation and application of specific provisions in the SPS and other WTO agreements or other international agreements, other than the SDT measures, so as to accord developing countries more favorable treatment, based on specific circumstances (for example, limited capacity to conduct risk assessments) relevant to a particular provision. The third basic approach is to recognize the precautionary principle and or extrinsic social values as justifications for GMO regulation.

In considering these methods, one must continually bear in mind the distinction between the role and interests of developing countries as agricultural exporters, facing regulatory restrictions in other countries, and their role and interests as domestic regulators, including regulators of agricultural products and foods. One must also bear in mind the extent to which regulation of GMOs can or should be considered a special case, distinct from regulation of other food and crop products.

Distinctive and more favorable treatment of developing countries through one or more of these three methods could be justified by a variety of normative and pragmatic considerations.

In their roles both as importers and exporters of agricultural products, developing countries, especially the poorer developing countries, have strong claims to a generous share of the mutual gains from trade in order to help lift their citizens out of poverty and provide them the basic material foundations of individual dignity and capability. In addition to contributing to economic growth generally, GM technologies can, by expanding agricultural productivity and reducing farmer costs, help to meet the needs of developing countries for food security and rural economic development. These claims have a foundation in justice. Further, under plausible utilitarian assumptions, according developing countries a greater share of the gains from trade cooperation will also enhance global welfare because the gains to citizens of poor developing country are likely to outweigh any loss of benefits to citizens of rich developed countries, creating a net increase in overall welfare in the global trading community. Similar justice and welfare considerations underlie the principle of common but differentiated responsibilities operationalized in multilateral environmental agreements such as the Montreal Protocol,

Convention on Biodiversity, and Kyoto Protocol. This principle could dictate that developing countries not be held to the same regulatory burdens as developed countries in regulating GMO imports or complying with developed country labeling and traceability rules

Developing countries may have especially strong justice and welfare interests in regulating GMOs domestically because they face greater risks from their introduction than do developed countries. They often have richer and more valuable ecosystems than developed countries. They are more often the centers of origin for wild ancestors of crop plants. At the same time developing countries have less in the way of administrative and other capacities to effectively regulate sale and use of GMOs, resulting in greater EHS risks from their introduction. These considerations point to giving developing countries greater flexibility in regulating GMOs. On the other hand, they may choose to use GMOs in part because they provide EHS benefits by reducing the need to convert land to agricultural use and reducing pesticide use. This environmental interest may be entitled to special consideration in assessing developed country regulations, including in particular labeling and traceability regulations that penalize domestic use of GMOs by developing countries.

Profound developing country dissatisfaction with the results of the Uruguay Round, and the impasse over the Doha Round, may pragmatically justify more favorable treatment for developing countries in order to secure their continuing engagement in and support for the WTO regime. Developed country agricultural policies are a particular focus of dissatisfaction, especially subsidies but also GMO regulations. It is important to win the adherence of major emerging developing countries many of whom including Brazil, China, India and South Africa are adopting GMOs. A “breadth over depth” approach towards developing countries has often been followed in negotiating WTO agreements, reflected in provision for special and differential treatment (SDT) for developing countries in various agreement provisions. Rather than insisting on full reciprocity of obligation, developing countries are accorded less demanding obligations. These arrangements are generally transitional, in the expectation that developing countries will eventually graduate to the same level of obligation as other members. These arrangements can be regarded as manifestations of the common but differentiated responsibility principle in the trade context. Even incomplete obligations serve to acculturate WTO Member States to the practice of trade liberalization, perhaps ultimately resulting in more complete trade liberalization than could be achieved through insisting on immediate adherence to the same obligations as developed countries. The circumstance that GMOs only became serious international trade regulatory issues after the Uruguay agreements could justify a retroactive application of this strategy to GMO regulation. For example, developing countries would not be obliged to follow the same requirements as developed countries for risk assessment or regulatory decisionmaking dispatch for a transitional period. Here the justification would be not to induce initial but continued participation and support. .

Explicit Special Treatment of Developing Countries

Explicitly more favorable treatment of developing countries as such within the context of the WTO and international trade agreements is prima facie inconsistent with the bedrock principle of reciprocal obligation, under which countries agree to make concessions (in the form of agreeing not to exercise their taxing and regulatory sovereignty) in exchange for mutual commitments by other countries to make the same concessions. The various SDT provisions in WTO agreements, however, represent an important exception to this principle, adopted, as previously discussed, for regime-building reasons. The existing WTO SDT provisions provide an obvious foundation. The WTO agreements contain some 145 provisions affording special or differential treatment to developing countries, of which 22 apply only to least-developed countries.¹¹¹ These provide a ready foundation for according developing countries more favorable treatment in the context of GMO trade regulation. The existing SDT provisions are of four basic types.¹¹²

- Provisions to expand and protect market access for products exported from developing countries;
- Designation of longer time periods for developing countries to implement their obligations under WTO agreements;
- Allowances for developing countries to shield their domestic markets from foreign competition for the purposes of establishing or maintaining industries important to economic development;
- Technical assistance from developed countries to help developing countries meet their WTO commitments.¹¹³

The first of these concerns market access for developing countries in their role as exporters, the remaining concern their role as importers/regulators.

The SPS Agreement Preamble recognizes the interests of developing countries in terms of both market access and the need for flexibility in obligations:

[D]eveloping country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories...¹¹⁴

¹¹¹ These provisions can be categorized as: increased trade opportunities (12), instructions to safeguard the interests of developing countries (49), flexibility in implementing WTO commitments (30), transitional time periods (18), the provision of technical assistance (14), and provisions related to least developed countries (22). See U.N. Comm. on Trade & Dev., *Implementation of Special and Differential Treatment Provisions in WTO Agreements and Decisions*, WT/COMTD/W/77 (Oct. 25, 2000) [hereinafter *Implementation*].

¹¹² See, e.g., MICHAEL J. TREBILCOCK & ROBERT HOWSE, *THE REGULATION OF INTERNATIONAL TRADE* (Routledge 1995) (describing different approaches to special and differential treatment); Frank J. Garcia, *Beyond Special and Differential Treatment*, 27 B.C. INT'L & COMP. L. REV. 291 (2004).

¹¹³ See World Trade Org., Trade Topics: Development: Main Legal Provisions, available at http://www.wto.org/english/tratop_e/devel_e/d2legl_e.htm (last visited July 31, 2008); Garcia, *supra* note 107, at 296 n.3.

¹¹⁴ SPS Agreement, *supra* note 50, at preamble ¶ 6.

Market access for developing country agricultural exports

SPS Article 10.1 provides that Members shall, both “in the preparation and application” of their SPS measures, “take account of the special needs of developing country Members, and in particular of the least-developed country Members.”¹¹⁵ The EC Biotech Panel Report is the first WTO decision to address this provision; it sharply limits the degree to which it can be enforced by a developing country as a binding legal obligation on developed countries in order to open market access for developing country agricultural exports, including GM exports and exports of non-GM varieties of GM crops grown in the exporting country.

The phrase, “take account of,” might be seen as creating either a procedural obligation to consult with and discuss developing country interests in adopting and implementing GMO regulations, and/or a substantive obligation to accommodate their interests in the content of the regulations. The EC Biotech panel first defined the obligation as purely procedural, effectively rejecting any substantive element.¹¹⁶ The Panel also gutted any Art.10.1 procedural obligation on developed countries. It effectively created a presumption that the EC had considered Argentina’s interests, which could be rebutted only by Argentina producing affirmative evidence that at no point had the EC done so. The difficulty of making such a showing makes the Panel’s presumption of procedural compliance effectively irrebuttable. The Panel’s ruling is sharply at odds with the approach taken by the AB in its Shrimp-Turtle decision, imposing affirmative obligations on the part of the U.S. to consult with developing country shrimp exporters and accommodate their interests in formulating and implementing its regulatory requirement for shrimp harvesting methods. True, the AB’s decision was based in part of the circumstances that the turtles were recognized as endangered under international law and inhabited international waters. Also, the US regulation in question was explicitly a PPM measure. Nonetheless, its decision could be a starting point for developing a legally enforceable procedural element in SPS Art. 10.1. Although develop countries would maintain that Art 10 is a political undertaking that is not legally binding or enforceable, a procedural approach would disrupt that conception less than creation of any substantive duty.

SPS Article 10.2 provides that, “[w]here the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.”¹¹⁷ Could a developing country invoke this provision to force a developed country to phase in the application to its exports of a GMO-restrictive regulation, such as the EU’s

¹¹⁵ *Id.* art. 10.1.

¹¹⁶ The Panel held that evenhanded application of a trade-restrictive regulatory measure to develop and developing countries did not constitute a violation of Article 10.1, even if evenhanded application had negative effects on developing countries. (“Article 10.1 does not provide that the importing Member must invariably accord special and differential treatment in a case where a measure has lead, or may lead, to a decrease, or a slower increase, in developing country exports.”) EC Biotech, *supra* note 99, at ¶ 7.1613. Although the Panel did not explicitly hold that an Article 10.1 violation could never be demonstrated based on the substantive content of a state’s regulation, its reasoning points to such a conclusion.

¹¹⁷ SPS Agreement, *supra* note 50, at art. 10.2.

labeling and traceability requirements? Notwithstanding that the article uses the mandatory language “should,” the answer would depend on whether the regulation “allow[ed] scope” for phased introduction. It seems unlikely that a WTO panel or the AB would second guess a developed country’s judgment on this question of substantive regulatory policy, but this provision could be given a procedural dimension by including phased introduction as one of the matters on which developed countries must “take account of” developing country interests pursuant to Art 10.1.¹¹⁸

Developing country flexibility in regulating GMO imports.

SPS Article 10.3 authorizes the SPS Committee (created as a forum for consultations under the SPS Agreement) to grant developing countries “specified, time-limited exceptions in whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs.”¹¹⁹ This provision appears to provide flexibility for mitigation of SPS obligations (for example, risk assessment requirements) as applied to developing countries’ own domestic regulations as applied to imports. However, it has not yet been invoked in the SPS Committee or in any WTO dispute settlement process.¹²⁰

Assistance and facilitation for developing countries.

SPS Article 9 encourages developed countries to provide technical assistance to developing countries but does not create a binding obligation to do so. Article 9.1 calls on Members “to facilitate the provision of technical assistance to other Members, especially developing country Members” to help such Members achieve the necessary level of sanitary or phytosanitary protection to obtain access to that export market. Article 9.2 specifically addresses developing countries for which “substantial investments” are needed to meet the importing country’s SPS requirement, and provides that the importing country “shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.” This provision has not been raised in any WTO dispute settlement proceeding, although technical assistance practices are discussed regularly at meetings of the SPS Committee and several countries have called for increased assistance in the form of human resource development, national capacity building, and technology transfer.¹²¹

SPS Article 10.4 provides that Members “should encourage and facilitate the active participation of developing country Members in the relevant international

¹¹⁸ Argentina did not invoke SPS Article 10.2 in the *Biotech* dispute, presumably because it perceived the food safety and environmental concerns at issue not to “allow scope” for phased introduction. On its face, Article 10.2 applies most naturally to situations where a regulatory measure achieves its goals incrementally; e.g., when an importing country is attempting to reduce and eventually eliminate pre-existing levels of a contaminant, endemic disease or pest infestation by controlling imports. Where an absolute risk threshold has been set (especially if that threshold is zero) a phased approach may be inappropriate.

¹¹⁹ SPS Agreement, *supra* note 50, at art. 10.3.

¹²⁰ *Implementation*, *supra* note 111, at 34.

¹²¹ *Id.*

organizations.”¹²² This provision recognizes that greater participation by developing countries in international organizations, such as Codex, may increase the likelihood that developing country interests will be reflected in the resulting international standards. Such standards are particularly important in the SPS Agreement given their use as a presumptive safe harbor in Article 3.3 and the harmonization goals contained in Article 3.1. Like other WTO agreement provisions authorizing special trade-related capacity building assistance to developing countries, however, this provision clearly makes such assistance discretionary with developed countries

Assessment

This review indicates that developing countries are generally unlikely to be successful in invoking the SPS SDT in a WTO dispute settlement proceeding, either to challenge a developed country’s GMO-restrictive regulation, or to defend their own regulations against a challenge. The qualified and guarded phrasing of these provisions indicates that developed country members have been unwilling to assume legally binding substantive obligations of special and differential treatment for developing countries with respect to SPS disciplines. The relatively high political stakes involved in international trade regulatory rules for GMOs on both sides of the Atlantic would make a dispute settlement panel or the AB especially reluctant to read any such obligations into the SPS provisions. A further complication is that use of the SDT provisions in the SPS agreement to give developing countries as such more favorable treatment might not easily be limited to GMO regulation, or even to EHS regulation, but would extend to other WTO agreements and regulatory matters generally.. Yet, it is conceivable that a procedural interpretation of the SDT provision in SPS Arts 10.1 and 10.2, akin to that fashioned by the AB in Shrimp-Turtle, could emerge to help ease developed country restrictions on developing country agricultural exports. . The Art 10.3 process for time-limited exceptions for compliance with SPS disciplines could be a mechanism for allowing developing countries flexibility in the role as GMO regulators.

Interpretation of Existing Trade Regulatory Rules to Accommodate Developing Country Interests

An alternative approach to accommodating the interests of developing countries in the context of GMO regulation generally is to interpret and apply existing international regulatory provisions or standards, other than SDT provisions, with consideration of their special circumstances and equity claims, so as to afford them greater flexibility as regulators or enhance their access to developed country markets

As regulators, developing countries generally have fewer scientific, technical and administrative capacities and resources than developed countries. SPS Art 5.1 provides for a risk assessment “appropriate in the circumstances.” The lesser capacities of developing countries could well be regarded as “appropriate circumstances” that would either allow them to satisfy the Art. 5.1 risk assessment requirements with less extensive or rigorous scientific documentation, or allow them to forgo those requirements and regulate GMOs

¹²² SPS Agreement, *supra* note 50, at art. 10.4.

under SPS Art. 5.7. Such an approach would help redress the de facto double standard that has resulted from the current SPS risk assessment jurisprudence. In EC Biotech, the Panel rejected the EU's argument that social risk concerns, uncertainty regarding GMO risks, and the evolving state of science justify the adoption of safeguards measures without a full risk assessment as "appropriate in the circumstances". This rejection, however, is not inconsistent with according latitude for developing countries in risk assessment based on their resource and capacity limitations under a common but differentiated.

In their capacity as exporters, developing countries have two types of arguments to limit developed country use of GMO or other EHS regulation to exclude their agricultural products. The first is that WTO dispute settlement bodies should use a proportionality test, balancing the EHS benefits of developed country GMO regulations against their adverse economic, social and environmental impacts on developing countries. Where there is no specific evidence of harm, or where other less restrictive means of informing and preventing deception of consumers (such as voluntary labeling), the justice and system welfare claims of developing countries for market access and freedom to plant GM crops have considerable force. But the high politics generated by consumer and public resistance to GMOs in Europe and many other OECD countries makes it most improbable that a panel or the AB would embrace such an approach. It goes strongly against the grain of WTO jurisprudence, which eschews explicit case-by-case retail balancing among Member's interests, and the AB's strong statements of deference to member risk management discretion under the SPS agreement. A more limited and potentially less threatening version of a proportionality standard could be applied to measures, such as the EU GMO labeling and traceability requirements, involving EHS risk/risk tradeoffs. In these special circumstances, dispute settlement bodies would not be engaged in balancing EHS risk management judgments against economic trade economics, but instead addressing a situation of reciprocity with EHS risks at stake on both sides. EHS regulatory measure that because net environmental harm is tempting targets. But even in this more limited situation would involve complex factual issues and controversial normative judgments which panels and the AB strongly prefer to avoid, and also could not be limited to the developed/developing country context.

Alternatively, developing countries could, invoking the Shrimp-Turtle decision, call on dispute settlement bodies to discipline measures, such as the EU labeling and traceability rules, that operate with "extraterritorial" impacts to limit or foreclose the PPMs chosen by developing countries. As exemplified by Shrimp Turtle, these requirements include procedural requirements of notice, consultation and opportunity for developing country input in the development of such regulatory measures, and substantive provision of appropriate regulatory flexibility to accommodate their interests. The concerns that evidently underlie the AB's decision in Shrimp Turtle – use by powerful developed country jurisdictions of market leverage to regulate PPMs in developing countries without adequate consideration of their interests - - plainly apply to measures such as the EU labeling and traceability rules. The EU, however, would strongly justify its labeling and traceability regulations as a product rather than PPM regulatory measures.

Nonetheless, risk-risk tradeoff cases could be an entering wedge for development of SPS jurisprudence more protective of developing country interests.

Recognizing the precautionary principle and social risks as justifications for GMO regulation

A third approach to meeting the interests of developing countries in their capacity as GMO regulators is to give broad scope to precaution and/or explicit recognition of social risks as legitimate bases for GMO regulation. This approach could give developing countries greater latitude to exclude or limit GMOs without meeting rigorous risk assessment requirements. It could also make it easier for them to pursue a “wait and see” strategy with respect to GMOs. And, the ability of developing countries to use this latitude to protect domestic agricultural biotechnology industry could be limited by established anti-protectionist WTO principles (national treatment, less trade restrictive alternatives, regulatory consistency, etc.).

While enhancing the flexibility of developing countries in their role as regulators, however, this approach would threaten their role as exporters because it would also allow developed countries much greater latitude to exclude GM products. Including social risks as a legitimate basis for regulation could also strengthen the case for developed country labeling and traceability regulations. Further, the notions of precaution or social risks could hardly be limited to GMOs; they would support more restrictive developed country regulation of developing country agricultural products generally.

This last danger might be limited to the extent that WTO panels and the AB or other decisionmakers rely on the Biosafety Protocol as the basis for recognition of the precautionary principle or consideration of socioeconomic factors. This would, at least as a doctrinal matter, restrict their application to GMOs. The Biosafety Protocol might also provide a platform for according developing countries greater flexibility to exclude GMOs than developed countries, based on factors such as their richer and more vulnerable ecological resources, their relative lack of regulatory capacities, and their interests in protecting traditional agriculture. Nonetheless, developed countries in Europe and elsewhere and international environmental NGOs would press strongly for the same latitude for developed countries.

All of the indications, however, indicate that WTO panels and probably the AB will strongly resist recognition of precautionary principles or social risks as a basis for validating EHS regulation that otherwise contravenes SPS and other WTO disciplines. . The global GMO conflict will likely preclude any legislative adoption of these approaches through the WTO or Codex or other international standard setting organizations. The Biosafety Protocol regime provides more favorable ground for such recognition, but if the WTO or international EHS standard setting bodies fail to accede there may be little practical consequence. Developing in more concrete form the recognition of precautionary principles and social risks under the Protocol would, however, have a certain normative gravitational effect on international trade regulatory jurisprudence while also creating an additional degree of legal uncertainty. Such uncertainty can make developing countries more vulnerable to pressures from powerful

developed countries to favor their side in the global GMO conflict, but can also provide useful flexibility. From a broader perspective, it may simply be premature and unwise, at this relatively early stage in the development of GM technologies, for international authorities to attempt to establish firm regulatory rules for GMOs.

Joint Developing Country Initiatives on GMOs

The acute developing country dissatisfaction with the current international trade system for agriculture is primarily targeted on developed country subsidies, but tariff and regulatory barriers to developing country exports including those from GMO regulations are also a significant issue. With the evident collapse of the Doha round, there will be strong pressures to find ways of accommodating developing country interests within the existing system of global trade rules. How this might be accomplished in the GMO context, given the continued if now somewhat muted EU-US conflict over GMOs, strong developed country resistance to any legally binding SDT obligations and the reluctance of WTO dispute settlement tribunals to recognize such obligations or engage in proportionality review?

The political economy of international trade regulation may make it somewhat easier to give at least the less developed countries greater flexibility to exclude GMOs than to force developed countries to relax GMO regulations applicable to developing country food products to allow imports of GM products. The US and other pro-GMO countries will, however, strongly oppose developments in international trade regulatory rules that would facilitate exclusion of GM products, especially by major GMO developing countries such as China, India, or Brazil who could do so to protect domestic GMO producers. . Further, any special rules or applications that would favor developing countries vis-à-vis developed countries would not address potential use by developing countries of GMO regulations to exclude exports from other developing countries to protect domestic agriculture or emerging domestic agricultural biotechnology industries. Clarification of or changes in GMO trade regulatory rules through the WTO dispute settlement process will be slow and uncertain.

In these circumstances, the most promising way forward for developing countries who have adopted or are favorably disposed to GMOs is to mobilize politically by joining together to further their interests. The key countries include Argentina, Brazil, China, India, and South Africa, but smaller nations such as Costa Rica, Egypt Kenya, Uganda, Vietnam as well as others should also play a role. The existing multilateral fora, including the WTO, Codex, and the Biosafety Protocol, are rather paralyzed by the EU-US conflict and also involve too many countries for the mobilization of developing country political initiative on GMOs. The major GMO-favoring developing countries should take the lead in establishing a new plurilateral club for like-minded countries to advance their interests on issues such as risk assessment and management principles and standards and labeling and traceability requirements. The development of a more unified position by these countries, coupled with the Doha Round malaise, could have an appreciable impact on decisionmaking in the WTO, including both in dispute settlement decisions and the SPS Council, as well as other bodies such as Codex and the Biosafety Protocol regime. The club could push for dispute settlement decisions recognizing a procedural dimension to

SDT to impose Shrimp-Turtle obligations on developed countries adopting restrictions on developing country agricultural exports, and interpreting SPS provisions like the “appropriate in the circumstances” qualifier to the risk assessment requirements in Art 10.1 so as to afford more latitude for developing countries in domestic GMO regulation. The club could push for favorable actions or interpretations from the SPS Council, Codex and other international standard setting bodies, and the Biosafety Protocol. of the This global plurilateral developing country club could be supplemented by arrangements for regional cooperation, such as those emerging in southern, east and west Africa.. These arrangements could make it easier for developing countries that wish to move forward with GMOs, but are currently deterred from doing so by regulatory uncertainties and pressures from anti-GMO developed countries and regulatory uncertainty, to adopt GMOs. Such a “club” would be another manifestation of the growing power of major developing countries in international trade regulation.

There are, to be sure, important differences in the positions of major developing countries towards GMOs, Argentina and now Brazil are unabashed proponents. China, India, and South Africa have for a variety of internal political and international trade reasons, taken a more cautious approach. But these differences should not prevent cooperation for mutual benefit. Smaller countries that are now hesitant to embrace GMOs could be encouraged to do so under the protective aegis of the larger countries. But what of those developed countries that wish to continue to exclude GMOs? The larger developing countries may find it in their larger interest as emerging global political leaders to support their right to do, even if it may in the short term foreclose potential export markets for the larger countries’ emerging public/private biotechnology industries. By offering an alternative to western multinationals, these new developing country GMO suppliers could facilitate embrace by smaller developing countries of GMOs.

In the end, international trade regulation rules will be of lesser consequence for the future agricultural biotechnologies than the future development and performance of the technology. If its economic and environmental advantages prove to be as great as GMO proponents predict, widespread adoption is likely to sooner or later follow. Consumer and public attitudes in Europe, Japan, Korea and other OECD countries are another fundamental factor. Already there are some signs in Europe that the more extreme anti-GM positions may be unsustainable, especially in the face of sharply rising prices for food and feed. International trade regulation rules must inevitably adapt to these changes. Rather than being relatively passive bystanders in the transatlantic GMO Cold War. Major developing countries can mobilize to anticipate and promote changes in those rules that will further their interests,

VII. Conclusion

Global trade regulatory regimes are struggling to address the trade and policy conflicts generated by sharp differences among nations in attitudes and regulatory measures regarding GMOs. The fast-changing development of agricultural biotechnologies, spurred by the world food crisis, exceeds the capacity of the WTO dispute settlement system. Nor have other global regulatory bodies achieved much

success in promoting harmonization of GMO regulatory standards. The collapse of the Doha round will create further turmoil in international regulation of trade in food products. The regulatory and policy divide over GMOs is not split along North-South lines. Yet, developing countries' ability to choose and implement their own GMO policies has been constrained by various strong pressures from the pro-GM and GM skeptic developed countries. This situation is beginning to change with the adoption of GMOs by major developing countries – often the same countries asserting greater influence on trade regulatory issues generally. The creation of independent fora, whether global or regional, by like minded developing countries on different sides of the GMO debate is likely to be the best means for advancing their interests. Given the fast-changing character of GM technologies and of world food economics, it may be unwise as well as unrealistic to strive for uniform international rules on GMOs.