RECIEL 11 (1) 2002. ISSN 0962 8797

The Cartagena Protocol on Biosafety: Taking the Steps from Negotiation to Implementation

Stanley W. Burgiel

INTRODUCTION

In a relatively new era of attention to the relationships and potential conflicts between multilateral environmental and trade agreements, the negotiation of the Cartagena Protocol on Biosafety (the Protocol) became a flashpoint for an evolving trade–environment debate, which has proliferated in both policy and academic circles. Despite early concerns regarding legal consistency and jurisdictional issues between the Protocol and the World Trade Organization (WTO), the last 2 years have allowed significant time for further discussion and subsequent events to temper views regarding the interplay of these two instruments. The events leading up to the final meeting to negotiate the Protocol, including the failed biosafety working group meeting in Cartagena (January 1999) and the failed WTO Ministerial meeting in Seattle (November/December 1999), generated significant concern over the interplay of trade and the environment. This was particularly the case regarding the specific issues of biosafety and biotechnology, as well as the intersection of discussions on environment, human health, food safety and agriculture. While many of these fears and their relationships to country negotiating positions stemmed partly from rhetoric, partly from supposition and partly from domestic interests, the subsequent passage of time has allowed reflection on which items are of greatest true importance. Additionally, the impact of external factors, including other relevant negotiating processes and developments at the national and regional levels, is becoming increasingly crucial in setting the context for the Protocol's implementation.

Upon its entry into force, the Protocol will become a cornerstone of an international regime regulating biotechnology and biosafety. While the Protocol deals solely with the international transfer of living modified organisms (LMOs), it has obvious associations with the Agreement on Sanitary and Phytosanitary Standards (SPS Agreement), the International Plant Protection Convention (IPPC), the Codex Alimentarius Commission under the WTO, and to the United Nations Food and Agriculture Organization (FAO). Additionally, with the WTO engaging in discussions on approaches to agriculture in a new trade round, the contentious issues of subsidies and multi-functionality have arisen, which bring other cultural and social considerations into play. Such developments at the intergovernmental level must be viewed within the context of legislative and implementing activities at the national and regional levels.

While it has been relatively easy to fan the flames of the trade–environment debate and to raise public awareness over issues of genetically modified foods or the role of the WTO, there is an obvious need to overcome increasingly entrenched positions on both sides of the debate. The fallout over differences on environmental, labour and other social issues, and their relationships with international trade, has been felt in increasingly difficult and often polarized discussions under the WTO as well as in environmental fora. Such difficulties point to the increasing complexity of addressing trade and environment issues, particularly those that also touch on the commercial aspects of agriculture. These 'sectors' are not separate entities, despite the compartmentalization of institutional processes and the negotiations that address them. The challenge, which may ever so slowly be bearing fruit, is to conceptualize trade and environmental instruments relating to an issue, such as biosafety, as a single regime where coordination and cooperation are essential for moving forward on all fronts.

This article will briefly review the context, actors, areas of conflict and the results of the negotiations for the Protocol. It will then look at subsequent discussions relevant to biosafety at the intergovernmental level under the Interim Committee for the Cartagena Protocol (ICCP) and related developments in other fora such as the WTO and FAO. The article will briefly review relevant national level events and legislation, such as the food safety scares in the US and Europe and the EU's Directives on biotechnology and labelling. The final part of the article will provide some concluding thoughts relating national events to the broader intergovernmental discussions on biosafety.

THE CARTAGENA PROTOCOL ON BIOSAFETY: A BACKGROUND

The Protocol addresses the safe international transfer, handling and use of LMOs to avoid adverse effects on biodiversity. LMOs are defined in Article 3 of the Protocol as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. Concerns regarding LMOs are associated with the uncertainty about the potential impacts of uncontrolled propagation and gene transfer on both particular species (for instance similar non-genetically modified crops) and ecosystems as a whole (for instance pollinators and other species interacting within an agricultural setting). To promote the safe international transfer, handling and use of LMOs, the Protocol establishes an advance informed agreement (AIA) procedure regarding their importation for intentional introduction into the environment.[1] Decision making regarding whether to allow imports of LMOs is to be based on a system of risk assessment and management. The more controversial aspects of the agreement include an alternative AIA procedure for LMOs intended for direct use as food, feed or processing (LMO-FFPs), use of the precautionary principle in decision making on imports, requirements for identification of shipments, and liability and redress provisions.[2] The Protocol establishes a Biosafety Clearing House to facilitate information exchange, including on specific import decisions and on States' legislation and regulatory procedures.[3] The agreement also contains provisions on capacity building and financial resources, particularly for developing countries and those without domestic biosafety systems.[4]

The negotiations to develop a protocol on biosafety under the Convention on Biological Diversity (CBD) date back to the negotiation of the Convention itself from 1990 to 1992. They relate specifically to the language of Article 19(3) of the CBD, which calls for consideration of the need for and modalities of a protocol on the safe transfer, handling and use of LMOs that may have an adverse effect on biodiversity. Debates on the need for a protocol spanned the two Intergovernmental Committee meetings on the CBD (October 1993 and June/July 1994) to the First and Second Conferences of the Parties (November/December 1994 and November 1995). With agreement at the Second Conference of the Parties to move ahead with a protocol, the actual negotiations included six meetings of the Biosafety Working Group, the failed Extraordinary Conference of the Parties (ExCOP) in Cartagena, three sets of informal consultations in Montreal and Vienna, and the final ExCOP, which adopted the agreement in Montreal (January 2000).[5]

AREAS OF DISAGREEMENT

Four key areas of disagreement arose during the negotiations, under the general categories of scope, trade issues, decision-making criteria and exporter responsibilities.[6]

SCOPE

The issue of the Protocol's scope generally revolved around whether and how to include various categories of LMOs within the Protocol's AIA procedure. LMO-FFPs proved to be the most divisive issue and ultimately was covered under a simplified AIA procedure (Article 11 – Procedure for LMO-FFPs). LMOs for transit, contained use and pharmaceuticals for human beings also generated significant debate and were ultimately addressed in separate Articles (Article 5 – Pharmaceuticals; Article 6 – Transit and Contained Use). These Articles exempt inclusion of LMOs for transit, contained use and in pharmaceuticals for human beings in the Protocol's AIA procedure, while allowing parties to take measures at the national level regarding transit and contained use, and to subject pharmaceuticals to risk assessments prior to importation.

[1] See Articles 7 (Application of the AIA Procedure), 8 (Notification), 9 (Acknowledgement of Receipt of Notification) and 10 (Decision Procedure) of the Protocol.

[2] Language reflecting the precautionary principles is contained in Articles 10(6) and 11(8) of the Protocol. These provisions generally state that lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an LMO on the conservation and sustainable use of biodiversity in the party of import, taking into account risks to human health, shall not prevent that party from taking a decision, as appropriate, with regard to the importation of the LMO in question, in order to avoid or minimize such potential adverse effects.

[3] See Article 20 (Information Sharing and the Biosafety Clearing House) of the Protocol. Other Articles, including 6, 10, 11, 12, 13, 14, 17 and 19, specifically address the types of information to be communicated to the Biosafety Clearing House.

[4] See Articles 22 (Capacity Building) and 28 (Financial Mechanism and Resources) of the Protocol.

[5] For a detailed negotiating history of the Protocol negotiations, see the coverage by the *Earth Negotiations Bulletin* available at <http://www.iisd.ca/biodiv.html>. Coverage includes the discussions of the Biosafety Working Group, informal consultations, the ExCOP and the ICCP.

[6] For general discussions on the major issues under debate during the negotiations, see A. Cosbey and S. Burgiel, *The Cartagena Protocol on Biosafety: An Analysis of Results* (International Institute for Sustainable Development, 2000); P. Hardstaff, *The Biosafety Protocol: An Analysis* (Royal Society for the Protection of Birds, March 2000); and 'A Biosafety Protocol at Last!', 114/115 *Third World Resurgence* (February/March 2000).

TRADE ISSUES

Debates over trade issues included the Protocol's relation to other international agreements, most specifically the WTO, and recognition of relevant trade principles. Significant discussion revolved around whether to include a savings clause that would subordinate the Protocol to existing agreements and obligations. This debate also involved deliberation over the inclusion of language on non-discrimination and trade with non-parties. Ultimately, language reflecting all positions was inserted in the Protocol's Preamble, recognizing that trade and environment agreements should be mutually supportive, that the Protocol should not be interpreted to imply a change in rights and obligations under existing international agreements, and understanding that the Protocol is not intended to be subordinate to other international agreements.

DECISION-MAKING CRITERIA

This issue addresses considerations for making decisions regarding LMO imports using the Protocol's risk assessment, risk management and decision-making procedures. It generated the most controversy over inclusion of the precautionary principle and whether to address socio-economic considerations. The general concern with their inclusion was that they could be used to disguise trade restrictions on imported LMOs. In the final version, the precautionary principle was operationalized within the regular AIA decision procedure (Article 10(6)) as well as within the procedure for LMO-FFPs (Article 11(8)), stating that lack of scientific certainty due to insufficient scientific information shall not prevent a party from taking a decision regarding imports of LMOs to avoid or minimize potential adverse effects. The Protocol also includes a provision on socio-economic considerations (Article 26). This provision allows importing parties to consider factors arising from the impact of LMOs on biodiversity, while taking into account concerns of indigenous and local communities and being consistent with other international obligations.

EXPORTER RESPONSIBILITIES AND LIABILITY

Two important areas that were not completely resolved during the negotiations were documentation and identification of shipments of LMO-FFPs and development of a liability and redress system. While most delegations supported thorough identification of LMO-FFPs, major LMO exporters noted that precise determinations of quantities of LMOs was virtually impossible and financially prohibitive, given existing domestic systems for collection of seeds, grains and cereals. The final compromise was to mark such shipments with the label 'may contain' LMO-FFPs, while leaving further discussion on detailed requirements to be decided within 2 years of the Protocol's entry into force (Article 18 – Handling, Transport, Packaging and Identification). On liability and redress, despite support for such a provision by many developing countries since early in the negotiations, significant discussion was continuously deferred to the point that there was insufficient time to detail fully how a liability system would operate. The final agreement was that the First Meeting of the Parties to the Protocol would adopt a process for the elaboration of international rules and procedures for liability with an aim to complete them within 4 years (Article 27 – Liability and Redress).

NEGOTIATING GROUPS

Within this process five major negotiating groups formed and served as the primary actors from the Cartagena ExCOP onward. They included the Miami Group, the EU, the Like-Minded Group, the Compromise Group, and the Group of Central and Eastern European Countries (CEE).[7]

MIAMI GROUP

The Miami Group, composed of Argentina, Australia, Canada, Chile, Uruguay and the USA, represented the major actual or potential exporters of LMOs. The group generally supported a Protocol limited in scope, based on strictly scientific procedures for risk assessment and management (thereby opposing inclusion of the precautionary principle). The group supported inclusion of a savings clause recognizing existing trade principles and obligations, and opposed inclusion of liability and redress provisions and extensive identification and documentation requirements.

EUROPEAN UNION

The EU's position on the Protocol gradually changed over the course of the negotiations, primarily due to increasing public and political attention to biosafety issues within the region and at national levels. By the end of the negotiations, the EU supported a strong Protocol that included LMO-FFPs, the precautionary principle, identification of LMOs, and that strengthened the Protocol's position over pre-existing trade obligations.

[7] Cosbey and Burgiel, ibid.

LIKE-MINDED GROUP

After initial schisms among regional groups of developing countries during early sessions of the Biosafety Working Group, the Like-Minded Group emerged as a significant player, including almost all the developing countries apart from those in the Miami Group. The Like-Minded Group argued for an inclusive scope addressing LMO-FFPs, transit, contained use and pharmaceuticals. It supported the precautionary principle and provisions on liability, identification of LMOs, and socio-economic considerations. Finally, the group called for mutually supportive relations with existing trade agreements.

COMPROMISE GROUP

The Compromise Group worked through the final sets of negotiations, both explicitly and behind the scenes, to generate packages and proposals reconciling the various positions. The group included Norway, Switzerland, Singapore, New Zealand and Mexico, and generally supported a middle ground, while recognizing the right of its individual members to support alternative positions.

CENTRAL AND EASTERN EUROPE

The regional group of CEE countries generally served a swing role, where it frequently added its support to the final positions taken by the EU and the Compromise Group. The central spokespersons were Hungary and Russia, although the group also consisted of Albania, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Georgia, Latvia, Lithuania, Moldova, Poland, Romania, Slovak Republic, the Ukraine and Yugoslavia.

TRADE CONCERNS EMERGING FROM THE NEGOTIATIONS

The central questions emerging from the conclusion of negotiations on the Protocol generally related to how it would relate to the WTO and whether conflicts in implementation of the two agreements were imminent, especially with regard to application of the precautionary principle. Most anticipated that any conflict arising would be addressed under the WTO's dispute-settlement provisions, because the Protocol has no conflict-resolution mechanism itself and because a conflict would likely be raised by a WTO Member State not a party to the Protocol and, therefore, be referred to the WTO's dispute-settlement body. This raised significant questions on how the Protocol's preambular language would be interpreted along with the weighting provided to the Protocol as a specialized agreement in the area of environment and biosafety.[8] Additionally, questions arose about how risk-assessment procedures under the Protocol would relate to similar procedures under the WTO's SPS Agreement.[9]

Such implementation issues supplemented questions over how rapidly the Protocol would enter into force and issues that might arise in the interim. Ultimately, there was a mood of uncertainty over the exact implications of what had been agreed, how it would relate to the WTO and what the near future would bring for its eventual implementation at the national level. Such trade-related concerns have recently been tempered by more basic issues of actually obtaining the requisite 50 ratifications for the Protocol's entry into force. The capacity of developing countries, which are arguably the primary beneficiaries of the agreement, to implement the Protocol's obligations is probably the most pressing concern within discussions around the Protocol to date.

INTERGOVERNMENTAL COMMITTEE FOR THE CARTAGENA PROTOCOL

Discussions under the CBD on biosafety have continued, albeit at a much more relaxed pace than that of the final stages of the Protocol's negotiation. The Protocol was opened for signature at the CBD's Fifth Conference of the Parties (Nairobi, May 2000), which also hosted a ministerial roundtable. Additionally, two meetings of the ICCP (ICCP-1 in Montpellier, December 2000, and ICCP-2 in Nairobi, October 2001) have been instrumental in defining key obstacles at national levels for ratifying and implementing the Protocol's provisions. The slow pace of ratification and accession to the Protocol, at least for many developing countries, relates to issues of having sufficient capacity to implement and being in compliance with the Protocol's obligations. To date, only 13 States have actually ratified or acceded to the Protocol.[10] While

[8] Such preambular references have now become almost commonplace, with similar formulations in the Rotterdam Convention on Prior Informed Consent and in the International Treaty on Plant Genetic Resources for Food and Agriculture.

[9] See T. Stewart, 'A Nexus of Trade and the Environment: The Relationship between the Cartagena Protocol on Biosafety and the SPS Agreement of the World Trade Organization', *Agricultural Sanitary and Phytosanitary and Standards Report* (July 2000).

[10] As of 10 March 2002, 108 countries had signed the Protocol. Those countries that have ratified or acceded include Bulgaria, the Czech Republic, Fiji, Kenya, Lesotho, Liberia, Nauru, the Netherlands, Norway, St Kitts and Nevis, Spain, Trinidad and Tobago and Uganda.

many delegates had hoped to convene the First Meeting of the Parties back-to-back with the CBD's Sixth Conference of the Parties, in April 2002 at The Hague, it is more likely that there will be a third meeting of the ICCP to continue addressing issues of capacity and implementation.

The ICCP-1 was the first formal meeting of many biosafety delegates since the final informal negotiating sessions and the ExCOP, which adopted the agreement in Montreal. While many delegates were concerned that the meeting would become bogged down in a rehash of the political debates that beleaguered the negotiations, the ICCP has maintained a more relaxed, constructive atmosphere, dubbed the 'Montpellier Spirit', without the levels of strife and drama, which had characterized the Protocol's negotiations. The ICCP-2 was responsible for concluding many of the ICCP-1's discussions. The two meetings addressed the following agenda items: capacity building; information sharing; handling, transport, packaging and identification; decision making; the roster of experts; liability; and compliance. In retrospect, the two most important issues were capacity building and information sharing, as they serve as the basis for the Protocol's operation, upon which the other elements and systems are based.[11]

Discussions on capacity provided the first reflections on how much work is needed, first to identify the capacity needs of developing countries, then to discuss how such needs should be addressed. The need for capacity building was highlighted at all levels including personnel, scientific expertise, institutions, legislation and regulation, and is further complicated by the fact that such needs differ from country to country, requiring efforts to be individually tailored. The Global Environment Facility (GEF) has become a major focus of discussion, especially with regard to its work on developing national biosafety frameworks, which most countries recommended expanding. It was evident from country statements that ratification requires a minimum level of capacity to implement the Protocol's obligations, as some developing countries may be reluctant to bind themselves to the Protocol's obligations lest they run the risk of not being in compliance. An intersessional workshop, held in July 2001 at Havana, on developing an action plan for capacity building proved instrumental for furthering the ICCP-2's discussions on the topic. The workshop also helped to serve as a catalyst to push GEF funding beyond the development of national biosafety frameworks and to look at actual implementation.

Discussions at the ICCP-1 also highlighted the crucial issue of information sharing and the development of an operational structure for the Biosafety Clearing House, which is the essential link for distributing information regarding national procedures and decisions on LMO imports among the parties to the Protocol. Again, the process has benefited from intersessional meetings of a liaison group of experts, but their output in the form of a prototype model at the ICCP-2 revealed just how complicated the task of building a serviceable information architecture can be.[12] While having such a model is a significant step, it also presents a further challenge, which relates back to capacity issues, such as training regulators and inspection agencies at the national level on how to use it, while also ensuring the availability of the necessary hardware and software.

If capacity building and the Biosafety Clearing House are the prerequisites for grounding the Protocol's foundation, then components such as identification and documentation, and decision making are crucial parts of the Protocol's operative mechanism. For example, without established practices for the documentation and identification of genetically modified organism (GMO) shipments, border control agents will have little predictable means of assessing what is being imported, let alone how it should be addressed under national implementing legislation.

The ICCP-2's discussions on the topic, most particularly with regard to shipments of LMO-FFPs, were reminiscent of the final hours of negotiations at the resumed ExCOP, where the issue was the last outstanding matter. A proposal discussed within the process was to engage in a procedure in which parties would first examine a general system for identification procedures for shipments that 'may contain' LMO-FFPs before developing a more specialized system with unique identifiers for particular LMO-FFPs.[13] As with the ExCOP's discussions, debates at the ICCP-2 centered around time delays for working on such a tiered system, and on the terms of reference and the timetable for a proposed experts' group to further consider the matter.

Using the analogy of the foundation and operational mechanisms for the Protocol, the third tier of the

[11] For a similar analysis looking at the Protocol from the perspective of foundation, operational mechanisms and supra-structure, see J. Anderson *et al.*, 'Second Meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety: 1–5 October 2001', 9:203 *Earth Negotiations Bulletin* (8 October 2001).

[12] The basic elements of the pilot phase include: a central portal; a database that minimally contains information from countries without databases or electronic infrastructure, and searchable indexes to facilitate decision making; links to national, regional and international databases; common information formats to facilitate data searches; and means to access a roster of biosafety experts. See UNEP/CBD/ICCP/2/9, *Information-Sharing: Progress Report on the Development and Implementation of the Pilot Phase of the Biosafety Clearing-House – Note by the Secretariat* (CBD Secretariat, 31 July 2001).

[13] Those opposing this 'step-wise' approach preferred addressing the issues simultaneously and not in two separate phases.

system addresses supra-structural elements that facilitate implementation, such as compliance, liability and monitoring, providing the carrots and sticks to ensure proper implementation. The ICCP-2's discussions on these issues benefited from intersessional meetings, one held specifically on these issues prior to the meeting on compliance and another held more generally to address issues of liability under the CBD. The most interesting dynamic of the compliance discussions was a slight change in many countries' positions. Several developing countries, who were once advocates of a strong compliance system with the inclusion of punitive measures to track illicit activities from major LMO exporters, now took more constructive and positive views of compliance, recognizing their own potential difficulties in meeting the Protocol's obligations. This may have put more pressure on the liability discussions, which never moved beyond process questions about the need for more information-gathering exercises and workshops before moving ahead to the definition of a liability mechanism. Here the parts played by States were almost predictable. Many developing countries pushed for rapid progress which major developed country LMO exporters resisted.

Should there be a third session of the ICCP, it will more than likely continue to examine these issues, although some delegates have noted the need for concrete decisions by the Protocol's Meeting of the Parties (MOP) to move beyond process into substance. However, any delays before the Protocol's first MOP, while frustrating for making progress within intergovernmental discussions, will certainly be valuable for countries that are developing their national biosafety frameworks and taking the necessary preparations for implementing legislation, regulatory frameworks, and associated institutional and human resources.

RELATED DEVELOPMENTS AT INTERNATIONAL AND NATIONAL LEVELS

Issues of uncertainty gain clarity with the passage of time and by virtue of hindsight. In the case of the Protocol, the initial post-negotiation phase has witnessed some interesting developments, which may impact the future course of the Protocol. Such events have stemmed from two general sources: meetings and discussions under other relevant international fora; and developments at the national and regional levels.

INTERNATIONAL DEVELOPMENTS

With the most difficult part of the Protocol negotiations concluded, the debates over labelling, the precautionary principle and the regulation of biotechnology have arisen elsewhere. Some of these debates are occurring within the rubric of the WTO, most particularly in the Codex Alimentarius Commission, as well as in the FAO.

Codex Alimentarius Commission The Codex Alimentarius Commission (Codex) serves as a standard-setting body for the Agreement on Sanitary and Phytosanitary Standards on issues of food safety. Discussions within this 'trade' body have become increasingly politicized, revealing that the trade–environment or trade–safety debate is not constrained to environmental agreements.

Codex's increasing difficulties have been due to its gradual shift from developing voluntary minimum standards to its role as adviser to the SPS Agreement where negotiations have been proceeding as if such standards were maximum ceilings.[14] The process of setting standards has also become more complex given rapid growth in new food-related technologies, increasing environmental degradation and lack of information on ecosystem effects and functioning, and rapid growth in world trade, which increases the commercial implications of setting standards. Codex has been working in the areas of labelling GM foods and safety standards for foods derived from biotechnology, as well as considering whether products containing LMOs can be considered 'substantially equivalent' to their non-GM alternatives for testing and safety purposes. Debate within Codex has focused on the precautionary principle (without reaching agreement) and on trade in foods that have questionable health impacts.[15]

Food and Agriculture Organization Under the FAO, the Commission on Genetic Resources for Food and Agriculture (CGRFA) has been working on a draft Code of Conduct on Biotechnology. The CGRFA began

[14] See A. Cosbey, *A Forced Evolution? The Codex Alimentarius Commission, Scientific Uncertainty and the Precautionary Principle* (International Institute for Sustainable Development, 2000), at 8.

[15] Ibid., at 5–6. Cosbey also looks at how the political and trade battles over the *Beef Hormone Case* (WTO AB 12 July 1999, *European Communities – Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/ARB (99-2855)) between the EU and the USA under the WTO's dispute-settlement provisions and the EU's restrictions on GM commodities have effectively stalled Codex deliberations on standards for meat products and GM foods. The EU has been the primary proponent within Codex's Ad Hoc Task Force on Biotechnology Foods and Committee on Food Labelling for the precautionary principle and strict regulations on GMOs, including labelling and traceability. The USA and industry groups have been resistant to each of these efforts, essentially resulting in a deadlock. See 'Revised GMO Directive Gets EU Parliament Nod', 5:6 *BRIDGES Weekly Trade News Digest* (20 February 2001); and 'Codex Discussions on GM Labelling Stalled, EU Set to Tighten Rules', 5:17 *BRIDGES Weekly Trade News Digest* (8 May 2001).

work in 1991, although it postponed further consideration in 1993 to focus attention on the CBD negotiations for a biosafety protocol. The CGRFA's work initially focused on biosafety and other environmental concerns, intellectual property rights and farmers' rights, appropriate biotechnology for developing countries, minimizing potential negative effects, and monitoring. The Eighth Session of the CGRFA, which met in April 1999, requested that work recommence in considering relevant biotechnology considerations based on the CGRFA's work on the International Treaty on Plant Genetic Resources for Food and Agriculture, the Cartagena Protocol on Biosafety and other relevant international developments. The Ninth Session of the CGFRA is scheduled to meet in the first half of 2002 in Rome.

Links Between the CBD, WTO and FAO An important question is whether and how the experience gained under the CBD, the WTO and FAO can be integrated in a productive manner. While turf battles have played a significant role in the historical representation of the relations between these institutions, it is becoming increasingly clear that they all dwell on similar political issues thereby risking political paralysis. The CBD has already been cooperating with another of the SPS Agreement's advisory bodies, the International Plant Protection Convention, in areas of invasive species, and it is probable that more involved collaboration on GM plants may follow. CBD ties with the FAO also may be strengthened with the recent International Treaty on Plant Genetic Resources, which spans across the mandates of both agreements.[16] Synergies and links between organizations are the buzzwords of the day, and certainly institutional relations, cooperation and clarification of mandates and work programmes are important as the lines between trade, environment and safety become increasingly blurred. However, such facilitation recognizably cannot overcome intrinsic differences in the interests and philosophies of States. The difference between the EU and the USA over the use of the precautionary principle or a risk-assessment approach remains a philosophical difference that only negotiations between such States, whatever the fora, can resolve.

[16] The IPPC permits parties to take phytosanitary measures regarding pests and any plant, plant product, storage place, packaging, conveyance, container, soil, or other potential carrier of pests. Any LMO that could be considered a pest falls within the IPPC's scope. Other areas of overlap with the Protocol include standards for risk analysis/assessment and interpretation of terms regarding the degree of injury, economic considerations, and phytosanitary concerns as they relate to pests. A meeting of the IPPC's Exploratory Working Group on Phytosanitary Aspects of LMOs, held in Rome in June 2000, discussed issues related to the Protocol including LMOs, biosafety and invasive species. A meeting held in April 2001 addressed how the IPPC and CBD can collaborate in areas of mutual interest, including the elaboration of standards.

REGIONAL AND NATIONAL DEVELOPMENTS

It is also important to recall that political and regulatory discussions on biosafety issues do not take place in a vacuum. They are subject to developments and pressures arising from national, regional and international events. Three particular issues have raised public awareness and concern regarding food safety issues. They are the Starlink GM maize fiasco in the USA, the spread of mad cow disease in Europe, and the spread of foot-and-mouth disease in the UK. Such events have increased the pressure on officials and regulatory systems to respond to the problems, address weaknesses within the web of safety systems that failed to prevent the outbreaks, and to explain the consequences to the general public. As described below, ongoing work in the legislative development of national biosafety and labelling laws will have longer-term implications for international discussions on biosafety by establishing both precedents and baselines for acceptable standards at the national and international levels

Starlink Recently, food-related scandals have raised both public attention and political criticism. The most significant regarding GM foods was the discovery of Aventis' Starlink maize in corn products at grocery stores around the USA. The maize had only been approved by the US Environmental Protection Agency for animal feed. Subsequent testing and tracing of shipments in the USA has generally found evidence of contamination in one out of every ten tests and the scandal has spread internationally with concerns of tainted shipments to Japan and South Korea.[17] The outcome has two important consequences, for the USA in particular, and agriculture and GM products more generally. The first is to question US arguments during the Protocol's negotiations that segregation is unnecessary. The USA had resisted explicit documentation of shipments containing LMOs as unfeasible given the difficulties entailed in reforming a national system of agricultural product distribution that does not segregate among GM and non-GM products. Negotiators of the Miami Group argued that segregation would require duplicate systems for GM and non-GM products. The Starlink episode highlights the dangers of an unsegregated system where different GM varieties can be mixed and can potentially contaminate a significant quantity of GM-free produce. It also is interesting to note that some industry representatives turned their criticism towards the US Environmental Protection Agency stating that it should have been aware that the existing US distribution system would not be able to keep Starlink maize out of the human food supply. This leads to the second

[17] 'Starlink Appears in Ten Percent of Corn Now Tested', *Bloomberg News* (18 May 2001).

consequence of trade impacts. Tainted GM-maize in the US market has created opportunities for other maize producers, such as fellow Miami Group member, Argentina. With US farmers and industry paying the price of continued testing and reduced sales, the market may do what negotiations under the Protocol could not. While the US-based Archer Daniels Midland Company, a major seed provider and grain processor, was already offering a premium for GM-free agricultural products before the Starlink fiasco emerged, rising demand for GM-free goods may be persuading other major companies to follow suit. With potentially higher profit margins, combined with a growing demand for organic food, this carrot approach may prove an indirectly effective means to promote the objectives of the Protocol.

Mad Cow and Foot-and-Mouth Diseases LMO-related fiascos have not been limited to the USA. Europe has continued to deal with food safety issues, most particularly mad cow disease and foot-and-mouth disease. While not particular to LMOs or the Protocol, the outbreaks have furthered heightened public attention to food safety and government regulations. Mad cow disease has prompted more rigorous quality control mechanisms following meat products from pasture to market, arguably providing an easy leap for similar traceability systems on GM products. Again the consequent economic impacts on meat sales have been significant, along with the costs of testing, eradication and other social impacts, such as on tourism. Perhaps of more importance is a general questioning of public faith in regulatory institutions and a perceived tendency that government scrutiny over all food safety should be increased. Miami Group criticisms about EU negotiating positions under the Protocol negotiations being fuelled by public and political interests could certainly get much louder.

The result of the Starlink, mad cow and foot-and-mouth cases is greater attention to food distribution and safety issues. More attention will be paid to country notifications under the WTO's SPS Agreement about heightened national standards, especially within countries having concerned publics or economic stakes in ensuring the purity (whether GM- or disease-free) of their products. This will also arguably strengthen the position of the Protocol against its detractors, especially as the countries facing these problems are those developed countries perceived to have the most developed regulatory systems for food safety.

LEGISLATIVE DEVELOPMENTS

As debates over labelling and the precautionary principle wage at the intergovernmental level, many States are moving ahead with their own domestic legislation, which at times has come under fire. Perhaps the most notable legislative developments have come from the EU, which recently approved Directive 90/220 on the release of GMOs into the environment. The EU has also proposed a Directive on labelling and traceability, which would include a threshold to exempt products with less than 1% GM content from the Directive's requirements. The proposed legislation has been criticized by the US Government, which alleges that the proposed Directive is not scientifically based and is discriminatory against exporters of GM crops. Other countries with biosafety regulations in place or under consideration include the following States: Australia and New Zealand on labelling requirements for GM foods; China on GM seeds; Japan on voluntary standards for labelling; Mexico on labelling of GM foods; the Philippines on a ban for the entry, sale, processing or field release of GMOs; Saudi Arabia on a ban on GM foodstuffs; South Korea on labelling for corn, soybean, bean sprouts and GM fish; Sri Lanka on a ban on GM imports; Taiwan on labelling requirements; and Thailand on the labelling of GM foods. In many of these cases, the USA has directly or indirectly applied bilateral pressure to have the legislation or proposal revised or withdrawn, most particularly in the cases of Mexico, Sri Lanka and Thailand.

As more national labelling systems are established, governments, hopefully reflecting on the experiences of other countries, will be able to develop intermediate alternatives, effectively promoting their environmental and health and safety interests, while mediating any potentially discriminatory trade practices. The EU Directives will be closely watched in this regard as precedents for legislation regulating biosafety. However, as more national labelling systems are established, there will also be increasing market demand for GM-free products, especially for maize and soybean. This has been a boon to many States producing non-GM crops and also has prompted some companies within the USA to purchase only GM-free crops. The twist is that market forces may ultimately be the best way to accommodate more particular needs and requirements regarding GM products. In this regard, efforts to maintain unfettered trade in GM products may hurt US producers in the longer term as they lag behind in segregating their crops and lose market shares in areas of GM-free demand.

CONCLUSIONS

Many of the difficulties faced during the Protocol's negotiations giving rise to the polarization between trade and environmental proponents are now appearing in other processes relating to trade, agriculture and the environment. These subsequent events have generally reflected the expansion of the debate to other

fora and geographic levels of policy making, such that previous representations of the conflict having a single dimension (for instance Protocol versus WTO) are now overly simplified and arguably passé. While it had been perceived that a breakdown or diversion of energy from one process would be a boon to a 'competing' negotiating process, experience is generally showing that such obstacles can lead to paralysis across the board. With so many different institutions and processes relating to issues of biotechnology, food safety, agricultural trade and the environment, the key necessity is to put jurisdictional disputes aside, identify complementary programmes of work and most importantly identify the key underlying issues of conflict.

The list of conflicts between trade and environmental interests is not small. It touches upon the precautionary principle and approaches to managing risk, perverse subsidies and support for the multi-functional aspects of agriculture, labelling and documentation to allow for consumer choice and traceability, and related aspects of intellectual property over plant varieties and their genetic parts and components. However, addressing the debates has almost become a game of cat and mouse as different aspects pop up here and there within the WTO, the FAO, the CBD, the Commission on Sustainable Development, and in numerous other international and regional intergovernmental discussions. The task of addressing these issues directly will be difficult as States generally want to confine debates affecting their national interests to what they consider their strongest fora, while skirting or blocking discussion elsewhere. A broader view of the holistic nature of the issues and fora relating to biosafety, agricultural trade and the environment is necessary to overcome past tendencies for a compartmentalized and ultimately divisive approach. Ultimately, what is perhaps more significant is how such intergovernmental discussions will reflect and respond to events at the national level. Operative biosafety and labelling systems at the national level that maximize scientific inputs and minimize trade distortions are probably the most effective proponent of the Protocol and of allaying trade–environment concerns. Additionally, market and consumer needs will play a defining role in setting commercial demand for GM crops, while public sector institutions will likely remain the most important sources for meeting the particular GM needs of developing countries. The key is not judging victories for trade or for the environment, but finding the middle ground that will allow for safety and productivity on all sides.

Stanley W. Burgiel is currently a Ph.D. candidate at the American University in Washington, DC, where his research focuses on biosafety and intellectual property rights related to genetic resources. He also contributes to *Earth Negotiations Bulletin* coverage of meetings under the Convention on Biological Diversity. He formerly served as program officer and coordinator of the Biodiversity Action Network.