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INTERNATIONAL TRADE IN GMOs AND GM PRODUCTS: NATIONAL AND MULTILATERAL LEGAL FRAMEWORKS

by

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ABSTRACT

The debate about biotechnology applied to agriculture is one of the most vocal and passionate debates that have been taking place in recent years. This is probably the consequence of the diverging appreciation that people and Governments have of the actual or potential risks and benefits that the products of agricultural biotechnology – genetically modified organisms (GMOs) and products thereof – can bring.

For some, they would help addressing some of the most serious problems that people, especially poor people in developing countries, face, such as starvation and malnutrition. For others, they could create serious and unpredictable health and environmental problems and also have negative economic repercussions, in particular in developing countries.

The proliferation of domestic biosafety schemes and the related authorization, labelling, traceability and documentation obligations are likely to further complicate international trade in genetically modified agricultural products and indirectly affect trade in conventional agricultural products.

For developing countries, agro-biotechnology is a particularly challenging phenomenon. They could be the main beneficiaries of it – if indeed agro-biotechnology keeps its promises – but they could also be the main losers if agro-biotechnology negatively affects biodiversity or if patented biotechnology disrupts traditional practices among farmers and makes access to seeds more difficult.

Countries are free to decide how to deal with agro-biotechnology and biosafety at the national level, but domestic legislation has to be WTO-consistent to the extent that it affects international trade. At the same time, this is a field where multilateral rules have been agreed upon in a separate legal instrument, the Cartagena Protocol on Biosafety. The interaction between this specific instrument and the WTO rules adds challenges to an already complex scenario.

While developed countries have established their national frameworks to deal with agro-biotechnology and biosafety focusing primarily on domestic priorities and strategies, most developing countries are doing so under less flexible circumstances. They increasingly seem to be expected to set up their national regulatory schemes based on the requests and expectations of their main trade partners. For developing countries, reconciling their trade interests with their responsibility for improving the quantity and quality of agricultural and food products made available to the population and with their commitment to environmental preservation is proving to be a difficult task.

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I. INTRODUCTION

Biotechnology is a revolutionary technology.[1] It offers humanity the power to change the characteristics of living organisms by transferring the genetic information from one organism, across species boundaries, into another organism. These solutions continue the tradition of selection and improvement of cultivated crops and livestock developed over the centuries. However, biotechnology identifies desirable traits more quickly and accurately than conventional plant and livestock breeding and allows gene transfers impossible with traditional breeding. The use of biotechnology in sectors such as agriculture and medicine has produced a growing number of genetically modified organisms (GMOs) and products derived from them. A GMO can be defined as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination".[2]

Bio-technological improvements present significant opportunities for agriculture and farmers. At present, the perceived benefits of genetically modified crops are better weed and insect control, higher productivity and more flexible crop management. These "first generation" GM crops are mainly benefiting the producers who can obtain higher yields and/or lower costs. The broader and long-term benefits, however, would be more sustainable agriculture and better food security that would benefit everybody, and especially the developing countries. For instance, breeding for drought tolerance could greatly benefit tropical crops, which are often grown in harsh environments and in poor soils. Increasing the amount of food produced per hectare could be a way to feed the world's growing population, without diverting land from other purposes such as forestry, animal grazing or conservation. Scientists have created a strain of genetically altered rice – the so-called golden rice – to combat vitamin A deficiency, the world's leading cause of blindness and a malaise that affects as many as 250 million children. Economic development experts describe the vitamin A rice as a breakthrough in efforts to improve the health of millions of poor people, most of them in Asia.[3] There are a number of examples of food products that are being developed to act as edible vaccines and have raised hopes of solving many of the problems associated with the delivery of safe, effective vaccines in developing countries.[4] A shift is, therefore, occurring from the current generation of "agronomic" traits to the next generation of "quality" traits, from which consumers, more than producers, would to able to benefit.

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[1] The Convention on Biological Diversity defines biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use". The biotechnology industry provides products for human health care, industrial processing, environmental bioremediation, and food and agriculture.

[2] This definition is provided in Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.04.2001, Article 2(2).

[3] See "Generically altered rice: A tool against blindness", *International Herald Tribune*, 15-16 January 2000.

[4] MacKenzie, D.J. and M.A. McLean, "Agricultural Biotechnology: A Primer for Policymakers", in *Agriculture and the WTO – Creating a Trading System for Development*, The World Bank, 2004, pp.237-253, at 238.

While GM crops may offer great benefits to agriculture and farmers and, potentially, to consumers, in particular to poor people in developing countries, biotechnology does not come without risks and uncertainty. There are many fears linked to perceived threats of biotechnology to human, animal and plant life and health, to the conservation of biodiversity and to the environment at large. Although there is not yet any definite scientific evidence of harm to humans, animals or the environment, it is submitted by many that adverse effects may be revealed in the future by more extensive research. The fear is that GMOs may change the toxicity and allergenicity of food, thus fostering allergic reactions or altering antibiotic resistance. A major environmental concern relates to potential consequences of gene flow from GM to non-GM individuals of the same species and to the possibility of unpredictable crosses with other species. Some claim that crops modified to be tolerant to herbicides could foster the development of "super weeds". Another related concern is that GMOs could threaten the world's biological diversity and lead to excessive dependence on few crop varieties, thereby increasing the vulnerability of crops to diseases. Economic preoccupations have also been voiced. They relate to the fact that a large number of patents have been issued in the sector. If the results of plant research continue to be patented, there is a risk that they may become too expensive for poor farmers, especially in developing countries. Moreover, the private sector invests in areas where there are hopes of a financial return; as a consequence, private science may focus on crops and innovations that are of interest to rich markets and put less emphasis on those of interest to poor countries. It is also argued that biotechnology may change the nature, structure and ownership of food production systems by consolidating control in the hands of a few large firms. This could aggravate food security problems that are allegedly caused not so much by food shortages as by inequity, poverty and concentration of food production. Finally, modern biotechnology techniques may raise ethical and religious concerns.

Countries' positions on agro-biotechnology depend on many factors, such as their policy awareness, the level of risk they are willing to accept, their capacity to carry out risk assessments in the sector and implement adequate legislation, their perception of the benefits they could gain from biotechnology, their dependence on agricultural exports, their reliance on food aid, and the investments they have already made in the sector. However, there is a sharp contrast at present between the widespread international acceptance of biotechnology's benefits in pharmaceuticals and industrial products, and the rapidly growing concerns about its possible dangers in agricultural and food production.

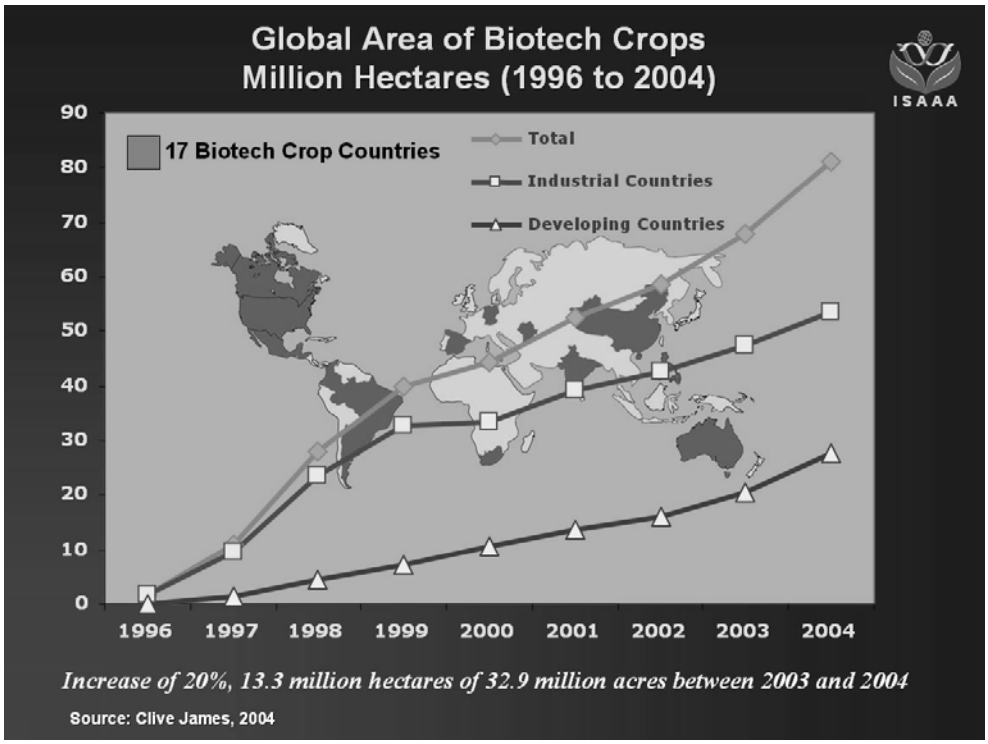
Assessments of the risks and benefits related to agro-biotechnology vary substantially between countries and regions, and so do the regulatory approaches (rules on GM approval, marketing, import, labelling, documentation). When GM products are commercialized internationally, as has been the case since the second half of the 1990s, the diverging domestic requirements may hamper international trade in agro-biotechnology products and further complicate an already difficult regulatory trade system in the agricultural sector.

II. DOMESTIC LEGISLATION ON AGRO-BIOTECHNOLOGY IN SELECTED DEVELOPED AND DEVELOPING COUNTRIES

According to figures from the International Service for the Acquisition of Agri-biotech Applications (ISAAA), the global area of GM crop plantation has grown 47-fold since 1996, and the estimated global GM crop area in 2004 was 81 million hectares, cultivated by approximately 8.25 million farmers in 17 countries. Herbicide-tolerant soybean was the dominant transgenic crop, followed by Bt maize,[5] Bt cotton, and herbicide-tolerant canola. 14 countries grew 50,000 hectares or more of biotech crops; the eight leading biotech crop countries being the United States, representing 59 per cent of global transgenic crop area; Argentina, 20 per cent; Canada and Brazil, 6 per cent each; China, 5 per cent; Paraguay, 2 per cent; and India and South Africa, 1 per cent each. Plantings were also found in Uruguay, Australia, Romania, Mexico, Spain, the Philippines, Honduras, Colombia, and Germany. More than one-third of the global transgenic crop area in 2004 was grown in developing countries (see figure 1).

In 2004, 56 per cent of soybean, 28 per cent of cotton, 19 per cent of canola and 14 per cent of maize planted globally were transgenic. If the global areas (conventional and transgenic) of the four principal GM crops are aggregated, the total area is 284 million hectares of which 29 per cent was biotech in 2004.

Figure 1



[5] Bt plants produce their own pesticide through a gene borrowed from the bacterium *Bacillus thuringiensis*.

In the same year, the global market value of GM crops was $4.70 billion. The market value is based on the sale price of transgenic seed plus any technology fees that apply. [6]

Although continuously expanding, GM crop plantings are still confined to a rather small number of countries. Apart from suspected health or environmental hazards, the reason for the restricted global uptake of GM crops may find its rationale in fear of export loss due to the political and regulatory environment in many countries outside the Americas that oppose GMOs.

GMO regulations are based on an assessment of the actual or potential risks that those products may bring about. Such assessment can be a "conventional" risk assessment or a risk assessment based on the precautionary approach. The former is about relevant scientific evidence, which means that there is sufficient scientific evidence for the perceived risks underlying the measure. Conversely, the "precautionary approach" to risk assessment is concerned with scientific uncertainty, where there is no "adequate theoretical or empirical basis for assigning possibilities to a possible set of outcomes".[7] Three basic conditions may thus trigger application of protective measures: uncertainty, risk, and lack of proof of direct causal link.[8]

With respect to GMOs, the problem of defining the relationship between science and policy in risk regulation is by and large a matter of regulatory culture deeply embedded in underlying socio-economic settings. A previous transatlantic dispute about meat hormones, which shares similarities with the present GMO debate, well illustrates diverging approaches to regulation under uncertainty. It typifies trans-Atlantic differences vis-à-vis the relevance of the precautionary principle in risk assessment (see below in the section on the WTO Agreements that have direct implications for international trade in GMOs).

The United States, Canada and Argentina, major agricultural exporters, have substantially applied the conventional risk assessment approach, especially during the first years of the agro-biotechnology revolution, and have widely authorized most GM products for production and consumption. Regulators in Europe and Japan, on the other hand, have taken up a more cautious approach based on guaranteeing a very low level of risk to human health and the environment. They have therefore imposed strict control measures on approval and marketing of GMOs and GM products. They have also imposed mandatory labelling schemes to allow consumers to make an informed choice in the market place.

Further to the ratification of the Cartagena Protocol on Biosafety, in June 2003 Japan promulgated "The Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms" (LMOs). The law establishes an approval system for the use of LMOs and includes requirements for exports of LMOs.[9] Australia and New Zealand have processes for pre-market approval and implement mandatory labelling of GMOs.

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[6] For detailed information and data, see: James, C., *Preview, Global Status of Commercialized Transgenic Crops: 2004*, ISAAA Briefs, No. 32, 2004, available at: www.isaaa.org . ISAAA is a not-for-profit organization with centres based in the Philippines, Kenya and the United States.

[7] Christoforou, Th., "The Precautionary principle in European Community Law and Science", in J.A. Tickner (ed.), *Precaution, Environmental Science, and Preventive Public Policy* (Washington, DC: Island Press, 2003), pp. 241-257, at 246.

[8] *Ibid.*, at 243.

[9] WTO document G/SPS/N/JPN/107, Committee on Sanitary and Phytosanitary Measures, *Notification from Japan*, 25 September 2003.

As for the developing countries, the major GM crops approved for commercial release are Bt cotton, which is grown commercially in China, India, South Africa, Argentina, Mexico and Colombia. The Philippines approved cultivation of Bt maize in 2002. In October 2003, Brazil authorized the planting of GM soy until the end of 2003 and the sale of GM soy crops until the end of 2004 (authorization later renewed for the 2005 crop year). The law was passed as an emergency measure due to shortage of conventional soybeans and in consideration of the widespread illegal planting of GM soy in southern areas of the country. South Africa has approved GM maize, soybean and cotton for commercial release. Paraguay has approved cultivation of soybean, Uruguay of soybean and maize, Honduras of maize. Argentina, the second world producer of GM crops, grows soybean, maize and cotton.

Since the 1980s, ministries and relevant government agencies in China have been investing significantly in agro-biotechnology research and have established more than 150 laboratories, resulting in the largest plant biotechnology capacity outside of North America.[10] Scientists have developed high-yielding, insect- and drought-resistant plant varieties of several crops that have the potential to allow farmers to produce more food. Moreover, the Chinese Cotton Research Institute has developed several varieties of Bt cotton and a large proportion of the planting seeds in order to reduce China's dependence on cotton imports and on foreign GM cotton technology. The Bt cotton area in China increased for the seventh consecutive year in 2004 and was estimated at 3.7 million hectares, equivalent to 66 per cent of the total cotton planted area,[11] though, due to seed smuggling, the actual GM-planted area may be much bigger. Bt cotton played an important role in the return of production in some provinces where acreage had declined. Indiscriminate use of insecticides had resulted in increased bollworm resistance to the agents, which in turn produced significant yield losses and resulted in cotton becoming unprofitable.[12] China is a significant importer of cotton and a net exporter of textiles and apparel. Changes in China's cotton production have the ability to affect both global cotton production and trade in textiles and apparel.[13]

Criticism of GM crops on environmental, food-safety and ethical grounds, however, have led to some significant changes in the Chinese legal framework on agro-biotechnology. Foreign investment in biotechnology has been prohibited, placing existing biotech joint ventures in jeopardy. The government has allocated research budgets to biosafety and management and nearly all biotechnology research programmes have expanded their scope into biosafety issues.

In 2001, the Government enacted a framework Regulation on the Safety Control of Agricultural GMOs, with the aim of protecting human, animal and plant health and the environment. Subsequently, three implementing regulations were issued on Biosafety Evaluation, Import Safety, and Labelling. The Regulation on Biosafety Evaluation establishes procedures for

[10] Huang J. and Q. Wang, "Agricultural Biotechnology Development and Policy in China", in *The Journal of Agro-biotechnology Management and Economics* (AgBioForum), Vol. 5, Number 4, Article 1, available at: http://www.agbioforum.org/v5n4/v5n4a01-huang.htm.

[11] James, C., *Preview, Global Status of Commercialized Transgenic Crops: 2004, - Executive Summary*, op. cit., *supra,* note 6, at 5.

[12] These conclusions are true when the effects are measured in a short term. When assessed in a long-term, however, the benefits offered by BT cotton may not be undisputed and the possibility of adverse environmental impacts associated with the cultivation of Bt cotton has been raised. See: Wang X., "Challenges and Dilemmas in Developing China's National Biosafety Framework", *Journal of World Trade*, 38(5), 2004, pp. 899-913, at 903.

[13] MacKenzie, D.J. and M.A. McLean, "Agricultural Biotechnology: A Primer for Policymakers", op. cit, *supra*, note 4, at 240-241.

handling applications for GM cultivation and sets up an advisory body – the Biosafety Committee – and a decision-making body – the Biosafety Administration Office, under the Ministry of Agriculture (MOA) – to handle applications. Applicants must provide information on risk assessment. GMOs are classified into four classes depending on their potential danger to human and animal health and to the environment.

The Regulation on Safety of Imports was supposed to enter into force in March 2002, but was temporarily waived under MOA Circular No. 190. Interim legislation on imports of GM crops applied until 20 April 2004, when the Regulation entered into force. The Regulation establishes the requirements that should be met to obtain authorization to import GMOs. Requirements vary according to the intended purposes of the imports, i.e. research, release into the environment, or processing. A 270-day approval procedure applies before the first import of a specific GMO takes place. Applications must be accompanied by a safety assessment carried out in the country of origin of the GM material.

Shortly before the implementation of the Regulation on Import, the Ministry of Agriculture approved the import of five GM crops (i.e. soybean, two varieties of corn and two of cotton) developed by the US biotechnology industry and already approved in the United States. This decision has a crucial commercial value considering that China buys one third of American soybean exports. US authorities have interpreted it as a sign of China's willingness to comply with the obligations it has subscribed to by becoming a Member of the WTO.[14] Others have interpreted it as the result of the political pressure put on the Chinese authorities by the main GM-exporting countries.

The Regulation on Labelling applies to five GMOs: soybean, corn seeds, rapeseeds, cotton seeds and tomato seeds, as well as to products thereof.

Many developing and least developed countries, especially in Africa, still lack, or are in the process of developing, comprehensive regulatory systems to deal with the challenges of agricultural biotechnology. Developing a regulatory framework concerning GMOs may be a costly and lengthy process. Areas for regulation include: (a) research and development (R&D), for example conditions under which laboratory experiments take place and conditions for testing in contained facilities or in the field; (b) approval processes for commercial release, including prior scientific assessment of risks to human and animal health and the environment, the minimum distance from organic agriculture or non-GM fields, labelling, post-commercialization monitoring, and liability; and (c) import regulations.[15] In setting up domestic legislation, developing countries seem to be paying increasing attention to international trade concerns.

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[14] Bradsher,K., "Opening Door to U.S., China Allows Import of Genetically Modified Crops", *New York Times*, 24 February 2004.

[15] The International Service for National Agriculture Research (ISNAR) and FAO, in consultation with UNEP/GEF, have developed a web-based "Decision Support Toolbox for Biosafety Implementation", which describes the key elements to be considered when developing a regulatory framework. The toolbox is designed to assist policy makers, biosafety managers and other stakeholders in understanding and applying a biosafety framework for capacity-building and regulatory decision-making (http://www.isnar.cgiar.org/ibs/biosafety/regulatory.cfm). The UNEP-GEF Projects on National Biosafety Frameworks (NBF) are implementing the GEF Initial Strategy in Biosafety (approved in November 2000) to "assist countries to prepare for the entry into force of the Cartagena Protocol on Biosafety". UNEP has so far been implementing this strategy through three different groups of projects on biosafety. First of all, a global development project is assisting 123 countries in developing their NBFs from the initial country status to an advanced draft NBF ready for government approval. Second, a number of demonstration projects are assisting eight countries in setting up a fully operational NBF. Finally, a last type of project has been approved as an add-on initiative to the Global Development Project and is aimed at building capacity for effective participation in the Biosafety Clearing House (BCH) by those developing countries that are Parties to the Cartagena Protocol. Detailed information on all project activities may be found at www.unep.ch/biosafety.

From an international trade perspective, the major preoccupation of GM producing and exporting countries is to have easy and reliable access to foreign markets for the GMOs they have already developed and for those they may develop in the future. The international policy conflict about GMOs is creating a fragmentation of international markets, decreasing economies of scale; producers of GMOs, however, depend on economies of scale to recoup the considerable research and development costs they incur. Moreover, the rate of technological advance in biotechnology is likely to be very rapid, meaning that the commercial life of any new GMO is likely to be short. This means that easy and quick access to foreign markets is a critical determinant for profitability.[16]

For countries, like the EU, that have adopted a "no-risk" approach, the main preoccupation is to establish strict import measures that would guarantee that the chosen high level of health and environmental protection is indeed achieved.

Developing country preoccupations have several facets. While some developing countries produce GMOs for domestic consumption, very few export them. However, many developing countries are exporters of conventional agricultural products. Those countries find themselves in a particularly difficult situation: in order to preserve their export opportunities, especially towards markets that are sceptical about bioengineered products, they may need to be "GM-free" countries. This means not only that they should not be exporters of GMOs, but also that they should not be producers of GMOs for domestic consumption and not even importers of GMOs. Losing "GM-free" status is perceived by some countries as having negative repercussions for their export opportunities for all agricultural products. This is due to the perception that consumers, especially in Europe, may react negatively towards products that could be linked even remotely to genetic modification. Some trade-diverting effects are apparently already taking place because companies substitute some inputs with others (which do not bear the risk of being genetically modified) or use inputs coming from alternative countries, which are supposed to be "GM-free", to avoid cumbersome documentation and traceability requirements, as well as to meet consumers expectations, especially in Europe.

This perception has been among the reasons why some African countries have refused food aid that includes genetically modified commodities. In 2002, Zambia declined a US offer of maize, some of which contained GM products. Main Zambian concerns related to uncertainty regarding the safety of GM maize for human consumption, as well as the possible contamination of local varieties which could allegedly imply a rejection by EC countries of Zambian food exports. In July 2002, the Zimbabwean Government agreed to allow into the country food aid that contained genetically modified maize, provided it was milled immediately upon arrival to avoid any possible contamination of local varieties. Previously, Zimbabwe had rejected GM food aid due to concerns that it might supposedly threaten beef exports to the EU and local maize varieties.[17] Uganda recently announced that GM crops could be imported into the country, but that they should be used strictly for consumption and not for cultivation. At the same time, a draft law that would regulate both research into GM crops and the release of GM organisms into the environment is under consideration.[18] At the

[16] Isaac, G. E., "The WTO and the Cartagena Protocol: International Policy Coordination or Conflict?", *Current*, Number 4/2003, pp. 116-123, at 117. Available at: www.CAFRI.org.; Phillips P.W.B. and W.A. Kerr, "Alternative Paradigms – The WTO Versus the Biosafety Protocol for Trade in Genetically Modified Organisms", *Journal of World Trade*, 34(4), 2000, pp. 63 ff.

[17] See *Bridges Trade Biores*, 11 July 2002, available at http://www.ictsd.org/biores/02-07-11/inbrief.htm

[18] "Uganda gives cautious approval to GM food", *Science and Development Network*, 2 March 2004, available at: http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=1257&language=1

beginning of May 2004, more than 60 groups representing farmer, consumer and environmental organizations from 15 African countries sent a letter of protest to the World Food Programme (WFP). These groups are protesting against the alleged pressure exerted by the WFP and USAID on Sudan and Angola over their respective decisions to impose restrictions on GM food aid. Sudan has requested that GM food aid be certified "GM-free" (though the Sudanese Government has put in place an interim waiver on GM food restrictions until January 2005), and Angola will accept GM food aid only on condition that all GM grain is first milled. According to the organizers of this initiative, non-GM alternatives exist at national, regional and international levels, and donors should make these available to Sudan and Angola.[19] According to the WFP, on the other hand, the requirement imposed by the Government of Angola would imply substantial extra costs and cause shipment delays of up to two months. This decision is going to further aggravate an already serious funding situation where the WFP has received only 24 per cent of the funds it asked for under its current operation in the country. As a consequence, WFP is to halve the food rations given to the majority of the 1.9 million people it assists in Angola.[20]

In August 2003, the Southern African Development Community (SADC) approved a set of recommendations formulated by the SADC Advisory Committee on Biotechnology and Biosafety as interim measures aimed at guiding the region on those issues. The recommendations are divided into four main sections: Handling Food Aid; Policy and Regulations; Capacity Building; and Public Awareness and Participation. Under "Handling Food Aid", donors providing GM food aid should comply with the Prior Informed Consent principle and with the notification requirements in accordance with Article 8 of the Biosafety Protocol. Food aid consignments containing GM grain should be milled or sterilized prior to distribution to beneficiary populations. The sourcing of food aid should be within the region, and the region should develop and adopt a harmonized transit information and management system for GM food aid designed to facilitate transboundary movement in a safe and expeditious manner. GM food aid in transit should be clearly identified and labelled in accordance with national legislation. In the absence of it, it is recommended that countries make use of the requirements under the African Union model law on biosafety. The recommendations encourage SADC countries to develop national biotechnology policies and strategies to exploit the benefits of biotechnology, to establish national biosafety regulatory systems, and to sign and ratify the Biosafety Protocol and the Convention on Biological Diversity.[21]

Following those recommendations, in May 2004, at the summit on agriculture and food security, SADC approved guidelines on handling GM food aid. The guidelines fully endorse the recommendations of the SADC Advisory Committee on Biotechnology and Biosafety.[22]

These recent developments reflect the preoccupations that several African countries have as potential importers of GMOs and GM crops. Their concerns relate both to the possible adverse effects of agro-biotechnology on human health and the environment, and to the fact that GM imports may jeopardize exports of conventional agricultural products. These preoccupations, however, must be balanced with Governments'

[19] *African countries 'forced' to accept GM food aid*, Mail&Guardianonline, 5 May 2004.

[20] *Food Rations to Be Halved in Angola Amid Funding Crisis and GM Ban*, 2 April 2004, World Food Programme, In Brief, available at: www.wfp.org/newsroom/in_brief/Africa/angola/angola-040402.html

[21] The Recommendations are available in the SADC web site: http://www.sadc.int/fanr.php?lang=english&path=fanr/agrres&page=sadc_biotechnology_gmo

[22] "SADC Sets Guidelines for Gm Food", *Zambezi Times Online*, 14 May 2004.

responsibility to improve the quantity and quality of agricultural and food production made available for domestic uses: agro-biotechnology may prove an effective tool to address food shortage and malnutrition.

The domestic legislation of the European Communities (EC) – which since the 1990s has developed and continuously refined a rather complex legislative framework related to GMOs and GM food – and that of the United States is analysed in detail in the paragraphs below. Table 1 provides information on the regulatory and institutional frameworks put in place in a number of developing and developed countries to address agro-biotechnology and related biosafety concerns.

European Communities

At the beginning of the 1990s, the EC introduced an approval system for the deliberate release into the environment and placing on the market of GMOs for experimental purposes or as commercial products, with the aim of ensuring a high and uniform level of protection of health and the environment throughout the Community and the efficient functioning of the internal market.[23] The 1990 Directive was later replaced by Directive 2001/18/EC, which became fully applicable in 17 October 2002.[24] The new directive deals with the deliberate release into the environment of GMOs for experimental purposes and with the placing on the Community market of products that consist of or contain GMOs, such as maize, tomatoes, or micro-organisms. The Directive does not cover products derived from GMOs – such as food products like paste or ketchup from a GMO tomato – which are covered by the novel food Regulation and the by Regulation on GM food and feed. The Directive has two main objectives: to protect human health and the environment from the deliberate release of GMOs; and to approximate the laws of the Member States on the deliberate release of GMOs and to ensure the safe development of industrial products utilizing GMOs. It introduces a mandatory post-marketing monitoring system for GMOs and traceability at all stages of their placing on the market. It also establishes an advanced system for directly informing and consulting the general public in the authorization procedure and, finally, establishes a labelling system.[25]

The Directive sets up harmonized procedures and criteria that require a case-by-case evaluation of the risks to human health and the environment arising from the deliberate release of GMOs into the environment or their placing on the market. The Directive requires that applications for authorization must be accompanied by a full health and environmental risk assessment, detailed information on the GMO, its release conditions, interaction with the environment, monitoring, waste and contingency

[23] Council Directive 90/220/EEC, 23 April 1990, OJ L 117, 8 March 1990, pp. 15 ff.

[24] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.04.2001. Directive 2001/18 was amended by Regulation 1830/2003. See the EC website on GMOs at: http://europa.eu.int/comm/food/index_en.htm.

[25] For a comprehensive and detailed description and analysis of the EC regulatory framework on GMOs see: Christoforou,Th., "The regulation of genetically modified organisms in the European Union: The interplay of science, law and politics", in *Common Market Law Review*, 41, pp. 637-709, 2004. See also the following European Commission press releases: *Questions and Answers on the regulation of GMOs in the EU*, DN: MEMO/04/16, 28.01.2004, available at:http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=MEMO/04/16|0|RAPID&lg=EN&display=; *State of play on GMO authorizations under EU law*, DN: MEMO/04/17, 28/01/2004 available at: http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=MEMO/04/17|0|RAPID&lg=EN&display= and *GMOs: Commission takes stock of progress*, DN: IP/04/118, 28.01.2004, available at: http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/04/118|0|RAPID&lg=EN&display=. This section of the paper draws on the above-mentioned sources.

plans, labelling and packaging proposals. The risk assessment should identify and evaluate potential negative effects of the GMO, direct or indirect, immediate or delayed, also taking into account the cumulative and long-term effects on human health and the environment. The Directive provides for a rather complex approval procedure involving both national competent authorities and Community bodies.[26]

The level of appropriate health and environmental protection chosen in the Directive is a level of "no risk". Because the authorization is to be based on the precautionary principle (as broadly applied in the EC), it is the applicant who has to demonstrate the "safety" or "lack of harm" of each individual product. The product is deemed to be dangerous until the interested manufacturer carries out the necessary scientific work and demonstrates its safety.

Within the described legal framework, 18 GMOs were authorized under Directive 90/220/EEC for commercial release into the environment for different uses, some for cultivation, some for import and processing, some as feed, some as food. However, around 1996, a number of EC Member States started raising questions on potential adverse effects of GMOs and GM products on health and the environment and also stressed that the EC regulatory framework was inadequate – particularly with regard to risk assessment, labelling, and post-market traceability and monitoring – and was completely lacking in respect of the coexistence of GM crops with conventional and organic farming. Consequently, they raised objections to the placing on the market of new GMOs. As a result of those concerns, and in reaction to the rapid developments on the scientific and regulatory fronts and to the negotiations on the Cartagena Protocol on Biosafety, no new GMOs were approved under Directive 90/220/EEC during the period October 1998 – May 2004. Thirteen applications were pending when Directive 90/220 was repealed. Seven of the 13 pending

[26] Any person intending to market a GMO must first submit an application to the competent national authority of the Member State where the product is to be first placed on the market. The application must include a risk assessment which has to be carried out by the notifier and must contain other information specified in the legislation. The competent authority which has received the notification must undertake an assessment of the potential adverse effects on human health and the environment. It is required to prepare, in principle within a delay of 90 days, an opinion indicating whether the GMO should or should not be placed on the market. During the preparation of this report the authority may address reasoned requests for additional information to the notifier. If the competent authority concludes that consent cannot be granted, it rejects the application and the procedure is ended (without prejudice to the possibility for administrative or judicial review of such a decision in accordance with the national law applicable to the authority). If it concludes that consent should be granted, the procedure moves on to the Community level: the competent authority submits the notification together with the report to the Commission, which forwards it to the competent authorities of all the other Member States. All competent authorities and the Commission may then within a deadline of normally 60 days, ask for further information, make comments or present reasoned objections to the placing on the market of the GMO in question. If there are no objections from other Member States or the Commission, the competent authority that carried out the original evaluation grants the consent for the placing on the market of the product. The product may then be placed on the market throughout the European Union. If objections are raised and maintained, a decision has to be taken at the Community level. The Commission submits a draft decision to a Committee – the so-called "Regulatory Committee" – which is composed of representatives of Member States for opinion. If the Regulatory Committee gives a favourable opinion, the Commission adopts the decision. If not, the proposal for a decision is submitted to the Council for adoption by qualified majority or rejection, also by qualified majority. If the Council does not act within 3 months, the Commission can adopt the decision. In the case of a favourable decision by the Community the competent authority of the Member State which prepared the Assessment Report shall give the consent and inform the notifier, the other Member States and the Commission. While the consent given is valid throughout the Community. the legislation contains a safeguard clause which enables Member States, acting under specified conditions, to prohibit provisionally the marketing within their territory of GMOs for which consent had been given. A final decision on whether or not the safeguard measure can be maintained is to be taken at Community level. Thus, the decision by a Member State to adopt a safeguard measure triggers a procedure that brings the case once again up to Community level.

applications were resubmitted under the new authorization procedure, the remaining six being withdrawn by the applicants. In addition, since the entry into force of Directive 2001/18/EC, 15 new applications have been notified to the EC Commission. The assessment of all these applications is proceeding. On 19 July 2004, the European Commission authorized the placing on the market of Monsanto NK603 GM maize for import and processing for use in animal feed or for industrial purposes. The decision is valid for 10 years, and imports have to be labelled as containing GM maize. The NK603 maize was the first product to be assessed and approved after the entry into force of Directive 2001/18/EC.[27]

In addition to "horizontal" legislation, the EC has adopted a number of "vertical" Directives and Regulations. Legislation related to novel foods and novel food ingredients is part of the "vertical" regulatory approach and deals with products derived from GMOs but no longer containing any GM material.[28] It stipulates that, in order to protect public health, guarantee the proper functioning of the internal market and create conditions of fair competition, it is necessary to ensure that novel foods and novel food ingredients[29] are subject to a Community safety assessment and authorization procedure before they are placed on the EC market. Regulation 258/97 has been substantially modified and reduced in scope by Regulation 1829/2003, which became fully applicable on 18 April 2004 (see below).

The current relevance of Regulation 258/97 rests on the fact that several applications to authorize the placing on the market of novel food and novel food ingredients were made while it was in force: 13 GM food products were approved for marketing while it was in force and eight applications for GM foods are currently pending at different stages in the authorization procedure.

The authorizations made under Directive 90/220 and its successor Directive 2001/18 and those made under Regulation 258/97 have given rise to dispute within the Community. The moratorium on new authorizations, on the other hand, has given rise to a dispute between the EU and three of its trade partners within the WTO dispute settlement system (see section IV of the study).

In July 2003, Community institutions agreed on two new regulations to regulate the placing on the market and labelling of food and feed products derived from GMOs and to establish a system of traceability and labelling of GMOs and GM products.[30] The new Regulations entered into force on 18 April 2004. Regulation 1829/2003, which replaces the GM part of Regulation 258/97, provides for Community procedures for the authorization and supervision of genetically modified food and feed, and includes specific provisions for their labelling. Authorized products are to be entered into a public register of GM food and feed. The authorization should be granted for a period of

[27] European Commission Press Release IP/04/957, *GMOs: Commission authorizes import of GM-maize for use in animal feed*, 19 July 2004.

[28] Regulation (EC) No. 258/97, 27 January 1997, OJ L 043, 14 February 1997, pp. 1 ff.

[29] Under the Regulation, novel foods and food ingredients are those which have not yet been used for human consumption to a significant degree within the Community, in particular those containing or derived from GMOs.

[30] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed; OJ L 268, 18/10/2003, pp. 1-23; and Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC; OJ L 268, 18/10/2003, pp. 24-28. See also European Commission Press Release IP/03/1056, *European legislative framework for GMOs is now in place*, 22 July 2003.

10 years, subject where appropriate to a post-market monitoring plan. Authorizations are renewable for 10-year periods.[31]

The provisions on labelling are a key component of Regulation 1829/2003. Labelling is required for foods that are delivered as such to the final consumer or mass caterers in the Community and which contain or consist of GMOs or are produced from or contain ingredients produced from GMOs. The labelling requirements are applied irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product. In this respect, the labelling requirements of Regulation 1829/2003 go much further than those of Regulation 258/97 on novel foods and food ingredients. The process or production method of the GM food or feed is now a relevant factor that justifies labelling. However, no labelling is required for foods or feed that contain material in a proportion no higher than 0.9 per cent of the food/feed ingredients individually that it contains, provided it is proved that the presence of GM material is adventitious or technically unavoidable.

Regulation 1830/2003, which is instrumental to achieving the objectives included in Directive 2001/18 and Regulation 1829/2003, establishes a system of traceability (i.e. the tracking of the movement of GM products through the production and distribution line) and labelling for two categories of products: products consisting of or containing GMOs; and food and feed produced from GMOs. In both cases the products must have been placed on the market in accordance with the relevant Community legislation. Operators using or handling GM products are required to transmit and retain (for five years) information at each stage of the placing on the market. GMOs are assigned a code (unique identifier), which will be passed in writing to involved operators. Traceability is regarded as a safety net in case of unforeseen effects on human health, animal health or the environment and is meant to facilitate a withdrawal from the market of food and feed if any unexpected adverse effects were to arise.

As expected, following the implementation of the two new regulations, the existing moratorium on authorization of GMOs

[31] The person responsible for placing a GM food on the Community market for the first time - the applicant - must first submit a request to the Member State where the product is to be first placed on the market and copy this request to the Commission. This request must contain certain information and include material which demonstrates the compliance of the product with the following criteria: (1) that the food does not present a danger for the consumer; (2) that it does not mislead the consumer and (3) that it does not differ from foods or food ingredients which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous to the consumer. In addition, where the food contains or consists of a GMO, the application must be accompanied with the information requested under Directive 2001/18/EC. After the Member State has accepted a request it must ensure that an initial assessment is conducted. To that end, following notification from the Member State, the Commission forwards to the other Member States the summary provided by the applicant and the name of the competent food assessment body that will be conducting the initial assessment. The competent food assessment body completes the initial assessment report within three months. It then decides whether or not the food or food ingredient requires additional assessment. Within a period of sixty days from the date of circulation of the initial assessment report, a Member State or the Commission may make comments or present a reasoned objection to the marketing, the presentation or the labelling of the food. Where an additional assessment is not required and no reasoned objection has been presented, the concerned Member State informs the applicant that he may place the food on the market. If objections are raised or an additional assessment is necessary, a decision has to be taken at Community level. If the objections raised relate to public health, as well as when an additional assessment is necessary, the Commission requires scientific opinion from the to the European Food Safety Authority (EFSA). The Commission then submits a draft decision to a Regulatory Committee composed of representatives of all Member States for opinion. If the Regulatory Committee delivers a favourable opinion by qualified majority, the Commission adopts the decision. If not, the proposal for a decision is submitted to the Council for adoption by qualified majority or rejection. If the Council does not act within 3 months, the Commission can adopt the decision.

and GM food was lifted. In addition to the authorization of GM maize under Directive 2001/18/EC, on 9 May 2004 the European Commission authorized the placing on the market of sweet corn from GM maize. The 10-year authorization covers its specific use for imports of canned or fresh sweet corn, while an authorization for cultivation of Bt maize is pending and has not yet been granted.[32] On 26 October 2004, the European Commission authorised as well the placing on the market of foods and food ingredients derived from GM maize NK603 in accordance with the GM Food and Feed Regulation. According to the authorization, it is possible to place on the market NK603 maize and derived products such as starch, oil, maize gluten feed and maize meal for food and feed use. However, the crop will have to be grown and harvested outside the EU. In line with the new EU legislation on labelling, the maize and any product containing it will have to show clearly that it has been genetically modified. The Commission took the decision to authorise NK603 following the failure of the Council either to approve or reject the Commission proposal for authorisation. It remains to be seen what impact the two recent authorizations will have on the current WTO dispute related to the EC moratorium.

The new rules implemented by the EC have not appeased US, Canadian and Argentinean farmers and industry trade bodies, which, on the contrary, have pushed their respective administrations to take further steps against the moratorium in the context of the WTO dispute settlement procedure.

Moreover, more than 20 agriculture and agri-business groups recently called on the US Trade Representative to challenge in the WTO the EC's newly established legislation on GMO traceability and labelling to prevent further disruption of transatlantic trade and to ensure that other countries do not adopt similar legislation. The new labelling and traceability rules, including those requiring the labelling of animal feed products derived from GM plants or seeds, will most likely have a significant impact on agricultural trade between the EC and the Americas.[33] According to the American Soybean Association, US soybean exporters lost around US$ 400 million in the marketing year ending on 31 August 2003, as compared to the previous year. The loss is largely due to the fact that companies manufacturing for the EC market want to avoid the required GM label and are reformulating their products to use oils other than soybean oil or are buying soybeans from Northern Brazil, which is supposed to be a GM-free area. EC legislation is therefore having a major trade-diverting effect, from which Brazilian soybean producers seem to be benefiting. The US agriculture and agri-business group also requested the US International Trade Commission to formally study the economic losses that US farmers, exporters and food companies would suffer as a result of the new EC requirements.[34] Should the Bush Administration endorse this approach, a new GMO-related trade dispute could be launched at the WTO, in addition to the one regarding the moratorium that is presently under consideration.

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[32] European Commission Press Release IP/04/663, *Commission authorizes import of canned GM-sweet corn under new strict labelling conditions – consumers can choose*, 19 May 2004.

[33] For example, in 1999 the EU market represented about 4 percent (US$ 180 million) of total US corn exports. However, the EU represents a much larger export market for corn by-products, such as corn gluten used in livestock animal feed, and accounts for more than 85 percent of total exports. See: MacKenzie, D.J., and M.A. McLean, "Agricultural Biotechnology: A Primer for Policymakers", op. cit., *supra*, note 4, at 251.

[34] Inside US Trade, *Agriculture Groups Seek New WTO Action Against EU on GMO Rules*, 28 November 2003, available at: www.insidetrade.com .

United States of America

The United States' regulatory system relative to biotechnology products is rather different from the one put in place in the EC. Discrepancies mainly reflect the different approach taken by US governmental authorities, citizens and firms towards GMOs and GM food, especially in the initial years of the biotechnology revolution. In the United States, genetically engineered crops have been sold since 1994 and in 2004 were already planted on 47.6 million hectares (soybean, maize, cotton and canola), confirming United States' role as the world leader in agro-biotechnology. Based on the approach that GM products are essentially an extension of conventional products, the US Government has made use of existing laws to ensure the safety of GM products. The current system was delineated under the 1986 Coordinated Framework for Regulation of Biotechnology (United States Federal Register, 26 June 1986, 51 FR 23302). Under the Framework, agencies that were responsible for regulatory oversight of certain product categories or for certain product uses are also responsible for evaluating those same kinds of products developed using genetic engineering. The Food and Drug Administration (FDA)[35] is responsible for food and feed safety; within the Department of Agriculture (USDA), the Animal and Plant Health Inspection Service (APHIS) is responsible for assessing the environmental safety of GM crops;[36] and the Environmental Protection Agency (EPA) is responsible for development and release for GM plants with pest control properties.

The laws currently used to regulate the products of modern biotechnology are the Plant Protection Act (PPA), the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Toxic Substances Control Act (TSCA). New regulations have been developed under these statutes as needed to address genetically engineered products developed.

Under the 1992 FDA "Statement of Policy: Foods Derived from New Plant Varieties",[37] developers have the responsibility to ensure that the foods they offer to consumers are safe and comply with all applicable requirements. For this purpose, food producers using new biotechnology techniques should work cooperatively with the FDA to assess the safety of bioengineered foods under a prudent, but not obligatory, practice of consultations that allows FDA to gather the information necessary to address any safety, nutritional or other regulatory issues before commercialization. In 1996, the FDA provided further guidance to the biotech industry on procedures for these consultations. In 1999, public meetings were held by the agency with the aim of sharing its experience regarding bioengineered foods and soliciting views on whether its policies and procedures should be modified. Public comments indicated considerable public support for a mandatory and more transparent process. After accurate analysis of the evolving and increasingly broad use of rDNA techniques to develop foods for human and animal use, the FDA resolved to subject bioengineered foods to greater regulatory scrutiny to ensure that the agency obtains the maximum amount of relevant information.

In 2001, the FDA issued a proposed rule and a draft guidance document concerning food developed through biotechnology. The proposed "Pre-market notice concerning bioengineered foods"[38] would require, on a mandatory basis, the submission to the agency of data and

[35] FDA, Center for Food Safety and Applied Nutrition: http://www.cfsan.fda.gov/~lrd/biotechm.html.

[36] USDA, APHIS, Biotechnology Permits Branch, at: http://www.aphis.usda.gov/brs/.

[37] Available at: http://www.cfsan.fda.gov/~lrd/biotechm.html#reg.

[38] Available at: http://www.cfsan.fda.gov/~lrd/fr010118.html.

information regarding plant-derived bioengineered foods that would be consumed by humans or animals, to be made at least 120 days prior to the commercial distribution of such foods. The draft guidance on labelling will assist manufacturers who wish to voluntarily label their foods as being made with or without the use of bioengineered ingredients.[39] As of 18 August 2004, the FDA reported having concluded consultations for 58 GM foods.[40]

In 2002, the US General Accounting Office (GAO) issued a report on GM foods stating that GM foods share the same types of health risks as conventional foods and that the current regulatory regime of safety tests is viewed by biotechnology experts as adequate.[41] However, according to the GAO report, the FDA's evaluation process could be enhanced by randomly verifying the test data that companies provide and by increasing the transparency in the evaluation process.[42]

In recent years, however, consumer resistance to GM food has also been growing in the United States, where the public is increasingly demanding that GM food be appropriately labelled.[43] In May 2004, a major US producer of GM products announced that it would not try to market the GM wheat it had developed in recognition that the business opportunities for the product were not very attractive. In Congress, Representative Kucinich has been pushing new legislation on mandatory labelling for GM food since 2000. More recently, he reintroduced six bills in the House of Representatives dealing with the regulation of bioengineered crops. The proposed "Genetically Engineered Food Right to Know Act of 2003" (H.R. 2916) intends to protect consumers by requiring food companies to label all foods that contain or are produced with GM materials and instructing the FDA to conduct periodic tests to ensure compliance.[44]

In a recent development, the Department of Agriculture (USDA) has declared its intention to update and strengthen its biotechnology regulations for GMOs to ensure that the regulatory framework keeps pace with the evolution of science in the biotechnology field. Currently, companies creating new transgenic plants must submit an application to the USDA, and new GM crops must undergo field tests to ensure that they do not pose a threat to agriculture or other plants. The updated rules are likely to be wider in scope, and will encompass threats to the environment and public health. The USDA's Animal and Plant Health Inspection Service will prepare an environmental impact statement to evaluate biotechnology regulations and several possible regulation changes. This will also include a multi-tiered, risk-based permiting system to replace the current permit/notification system, as well as a more flexible process for monitoring.[45]

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[39] See US FDA, Center for Food Safety and Applied Nutrition: "Voluntary labelling indicating whether foods have or have not been developed using bioengineering", January 2000, available at: www.cfsan.fda.gov/~dms/guidance.html.

[40] The list of completed consultations is available at: http://www.cfsan.fda.gov/~lrd/biocon.html#list.

[41] See US General Accounting Office (GAO), "Genetically Modified Foods", GAO-02-566, May 2002, available at: http://www.gao.gov/new.items/d02566.pdf.

[42] *Ibid.*, p. 18.

[43] According to a survey conducted by ABC News in July 2003, with safety concerns widespread, while a third of Americans already try to avoid buying food that has been genetically modified, or treated with antibiotics or hormones, 55 percent, would avoid buying GM food if it were so labelled. See ABC News article available at: http://abcnews.go.com/sections/business/Living/poll030715_modifiedfood.html.

[44] See Kucinich's press release available at: http://www.thecampaign.org/leg2003summary.php. All draft Acts are searchable at: http://www.gpoaccess.gov/bills/index.html.

[45] "US to Strengthen Biotech Regulation for GMOs", in *CropBiotech Update*, 6 February 2004, available at: http://www.isaaa.org/kc/cbtnews/bcentral/cbtupdate.htm#us

Table 1. Summary of domestic GM regulations in selected countries (as of December 2004)[a]

Countries	*Regulatory system and agency(ies) responsible*	*GM products approved*	*Labelling requirements*
European Union (see more details in the text)	Directive 2001/18 on deliberate release into the environment of GMOs entered into force on 17 October 2002: → Harmonized procedures and criteria for case-by-case evaluation of potential risks: mandatory prior notification by applicants, accompanied by full environmental risk assessment, detailed information on the GMO, its release conditions, interaction with the environment, monitoring, waste and contingency plans, labelling and packaging proposals. Complex approval procedure involving competent national authorities, the EC Commission and Council. Regulation 1829/2003 on GM food and feed, replacing the GM part of Regulation 258/97, entered into force on 7 November 2003 and applies as of 18 April 2004: → Authorization procedure for market placement of GM food and feed, including food and feed produced from GMOs, irrespective of whether there is DNA or protein of GM origin in the final product. Approval procedure simplified. The European Food Safety Authority (EFSA) is charged with carrying out scientific risk assessment. Regulation 1830/2003 on traceability and labelling of GMOs, entered into force on 7 November 2003 and applies as of 18 April 2004: → Strengthened rules on (1) mandatory traceability and (2) mandatory labelling.	18 GMOs and 16 GM food products were approved. While no authorizations were granted during the period October 1998-April 2004, three new authorizations were granted in May, July and October 2004, respectively. Currently 21 applications for the placing on the market of GMOs and 9 applications for GM food products are pending.	Mandatory labelling for all GMOs and GM products, including food and feed produced from GMOs but no longer containing GM material, unless presence of GM material is adventitious and below 0.9%. 0.5% threshold for adventitious presence of unapproved GMOs, assessed as risk-free.
Australia and New Zealand	Australia Gene Technology Act 2000 took effect on June 2001: → General prohibition of any dealings with GMOs (e.g. research, manufacture, production, commercial release and import) unless licensed for contained use or intentional release into the environment by the Gene Technology Regulator, based on rigorous scientific risk assessment and extensive consultation with expert advisory committees, Government agencies and the public (http://www.health.gov.au/ogtr/index.htm). Hazardous Substances and New Organisms Act 1996 → New Zealand ended its moratorium on the approval of GMOs on 29 October 2003 with the entry into force of amendments to the Hazardous Substances and New Organisms Act 1996, the main legislation covering GMOs. The revisions introduce the category of "conditional release" to complement the options of full approval or rejection available under the old legislation. Thus, under the new rules, the Environmental Risk Management Authority will be able to attach controls for the release of GM organisms on a case-by-case basis.	In Australia, as of April 2003, numerous field trials are under way. Approved GM crops are: soybean (2 varieties), canola (3), corn (7), potato (3), sugarbeet (1) and cotton (4).	Mandatory for all GM food and ingredients (containing novel DNA and/or novel protein in final product, or having altered characteristics). In contrast with EC legislation, foods derived from but no longer containing GMOs are exempted from labelling.

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Table 1. (cont'd.)

Countries	*Regulatory system and agency(ies) responsible*	*GM products approved*	*Labelling requirements*
	Australia New Zealand Food Standards Code regulates the sale of GM food: → Standard 1.5.2 (1999, amended in 2000) provides for (1) mandatory pre-market safety assessment and (2) mandatory labelling. Food Standards Australia New Zealand (FSANZ) is charged with case-by-case assessment of all GM food applications (http://www.foodstandards.gov.au/whatsinfood/gmfoods/index.cfm).		
United States (see more details in the text)	1986 Coordinated Framework for Regulation of Biotechnology → Based on the equivalence principle, the U.S. government has made use of existing laws to ensure the safety of GM products: the Plant Protection Act (PPA), the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Toxic Substances Control Act (TSCA). Responsible agencies: FDA (food and feed safety); APHIS (environmental safety of GM crops) and EPA (development and release for GM plants with pest control properties). Statement of Policy: Foods Derived from New Plant Varieties, Food and Drug Administration (FDA) 1992: → Developers are encouraged to work cooperatively with FDA under a practice of (non mandatory) consultations to allow FDA to obtain information necessary to assess safety before commercialization Draft Pre-market Notice Concerning Bioengineered Foods, FDA 2001. Draft Guidance for Industry Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, FDA 2001.	105 GM crop plants intended for food or feed have completed all recommended or required reviews for planting, food, or feed use.[b]	Proposals on voluntary and mandatory labelling.
Canada	Canadian Food Inspection Agency (CFIA) regulates the confined field trial evaluation of all novel crops based on a case-by-case environmental safety assessment (http://www.inspection.gc.ca/english/toc/bioteche.shtml) Health Canada is responsible for biotechnology-derived products, as a class of novel foods, regulated under Division 28 of the Food and Drug Regulations (http://www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_division28.html): → Mandatory pre-market notification to the Novel Foods Office, which coordinates a full scientific safety assessment of the product, based on substantial equivalence.	In the 1994-2003 period, more than 60 GM crops were approved.	Standard for voluntary labelling of foods derived from biotechnology.

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Table 1. (cont'd.)

Countries	*Regulatory system and agency(ies) responsible*	*GM products approved*	*Labelling requirements*
	In response to the 2001 Royal Society of Canada Expert Panel Report, "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada", the Government of Canada has prepared a comprehensive action plan with a view to enhancing its regulatory processes and protocols. The Expert Panel Report has in particular introduced elements of precaution in risk assessment and stressed the need to replace the current regulatory reliance on "substantial equivalence" as a decision threshold with testing based on rigorous scientific assessment of potential of transgenic products for causing harm to the environment or to human health. In order to keep up with advances in knowledge and technology, Health Canada has revised its 1994 Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms, to reflect the risk analysis principles and safety assessment guidelines developed by the Codex Alimentarius Ad Hoc Intergovernmental Task Force of Foods derived from Biotechnology. (http://www.hc-sc.gc.ca/ english/protection/royalsociety/index.htm). Canada is examining the possibility of introducing an additional step in its crop and food safety approval system that would assess market acceptance of novel foods before they were grown. Health Canada and the CFIA carry joint responsibility for federal food labeling policies in Canada under the Food and Drugs Act (http://www.inspection.gc.ca/english/sci/biotech/tech/labetie.shtml): → On 15 April 2004, the Government of Canada announced the official adoption by the Standards Council of Canada, of the *Standard for Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering,* as a National Standard of Canada. This means that consumers could start to see more labels on some food ingredients and food items indicating whether or not they are a product of genetic engineering		
Argentina	Resolutions n. 656 (1992), 837 (1993), 39 and 57 (2003) of the Secretariat of Agriculture, Livestock, Fisheries and Food (SAGyP): → SAGyP is responsible for the overall regulation of the use of transgenic organisms in field tests, unconfined releases and commercial applications. The National Advisory Committee on Agricultural Biotechnology (CONABIA), as advisor to SAGPyA, provides science-based environmental risk assessment on the requests for authorization: → "Flexibilization". Once a transgenic plant has been sufficiently field-tested, the applicant may request that the crop be flexibilized, i.e. approved for unconfined planting for certain specified uses (export, pre-commercial multiplication pending variety registration, etc). CONABIA's risk assessment for flexibilization evaluates the transgenic crop's potential hazards for human health and for the environment. (http://siiap.sagyp.mecon.ar/)	In the period 1991-2001, release permits were granted to 495 GMO trials (mainly maize, soybean and cotton).	

.../...

Table 1. (cont'd.)

Countries	*Regulatory system and agency(ies) responsible*	*GM products approved*	*Labelling requirements*
	→ Current guidelines for food-safety approval have been developed by SENASA (National Service of Health and Agrofood Quality), based on the concept of substantial equivalence. Requests for commercialization are reviewed by CONABIA, which provides an approval or denial recommendation to SAGPyA. If the commercialization approval is granted, the applicant is responsible for the safety of the GM food as well as for monitoring its quality and consistency. The authorizations are reassessed periodically. → The Directorate of Agri-Food Marketing (DNMA) determines which GM crop varieties seed companies can sell to Argentine farmers. The applicant must apply to INASE (National Seed Institute) for a New Variety Registration. For pest-protected and herbicide-tolerant crops, commercialization requires specific authorization from SENASA (http://www.senasa.gov.ar/)		
Brazil	Brazilian Biosafety Law No. 8974, 1995, and Draft Law PL 2401/2003: In October 2003 the Federal Government introduced a draft law aimed at amending former legislation on GMOs (i.e. Brazilian Biosafety Law n. 8974, 1995). The draft law (Biosafety Law PL 2401/2003) was approved by the Chamber of Deputies in February 2004 and was submitted to the Federal Senate for approval. The Senate approved it in October 2004, but introduced several amendments. Before becoming law, the amendment bill must be voted on again by the Chamber of Deputies. According to the draft, the Ministries of Health, Agriculture and the Environment have the prerogative to authorize the release of GMOs into the environment and their placing on the market. However, their decisions may be reversed by the National Council for Biosafety (CNBS), which will take the final decision in case of diverging opinions. The newly established CNBS is responsible for developing and implementing national policy on Biosafety in Brazil. It includes 15 Ministers and reports to the President of the Republic. The newly established National Technical Biosafety Committee (CTNBio), within the Ministry of Science and Technology, is fully responsible for scientific research on GMOs, developing standards, carrying out risk assessment and assessing the safety of GMOs. The new legislation incorporates the precautionary principle.[c] Legal and political opposition from NGOs held up the approval process for commercial release of GM soybeans from 1998 to 2003. The State of Paranà passed a law that bans the planting and marketing of GM soy until 2006.	Law 10814/03 passed in October 2003 authorizes the planting of GM soy until the end of 2003 and the sale of GM soy crops until the end of 2004 (authorization later renewed for the 2005 crop year). The law was passed as an emergency measure due to shortage of conventional soybeans and in consideration of the widespread illegal planting of GM soy in southern areas of the country. Four parties have contested the law.	Mandatory labelling for GMO-derived or GMO-containing food and food ingredients for human and animal consumption above the 1% threshold; effective as of 31 March 2004.[d]

.../...

Table 1. (cont'd.)

Countries	*Regulatory system and agency(ies) responsible*	*GM products approved*	*Labelling requirements*
Philippines	Regulations on the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology, Administrative Order No. 8, April 2002 (http://binas.unido.org/binas/regs.php): → All GM products must undergo a safety assessment carried out by regulatory bodies of the Department of Agriculture (Bureau of Plant Industry and Scientific Technical Review Panel). As of 1 July 2003, release into the environment and imports of GMOs need authorization.	Insect-protected GM maize approved in 2002 for commercial release.[e]	
Thailand	Biosafety Guidelines in Genetic Engineering and Biotechnology For Field Work and Planned Release, Ministry of Science, Technology and Environment 1992 (http://binas.unido.org/binas/regulations/thai_field.doc) → The Thailand Biodiversity Center was established in 2000. It is responsible for the implementation of biosafety legislation for sustainable utilization of Thailand's natural resources and is the national focal point for the Cartagena Protocol. In 2001, Thailand banned all GM field experiments and has restricted GM imports by banning the import of 77 plants.	GM maize	Efforts are under way to implement labelling regulations.
China (see more details in the text)	Framework Regulation on Safety Control on GM Animals, Plants and Microorganisms, their Products and By-products, Ministry of Agriculture (MOA) 2001, and relative implementation regulations (see translated text at BINAS UNIDO: http://binas.unido.org/binas/regs.php): → Regulation on Biosafety Assessment: establishes procedures for handling applications for GM production to be carried out by the Agricultural GMO Safety Committee, based on four classes of safety (from "no danger" to "high degree of danger"). Final decision taken by the Biosafety Administration Office under MOA. → Regulation on Safety of Imports: different approval procedures (entry approval, testing, safety evaluation) depending on intended use of GMOs. Final decision taken by MOA. → Regulation on Labelling.	Altered tobacco genes released in 1990. Between 1996 and 2000, 45 GM plant applications were approved for field trials, 65 for environmental release and 31 for commercialization (mainly cotton).[f] The approval process has slowed down since 2000.	Mandatory labelling for five listed GM products: soybean, corn seeds, rapeseeds, cotton seeds and tomato seeds.

.../...

Table 1. (cont'd.)

Countries	*Regulatory system and agency(ies) responsible*	*GM products approved*	*Labelling requirements*
	→ All GM foods and food additives must undergo a safety assessment, carried out by the GMO Food Expert Commission.	In February 2004, MOA approved the imports of one soybean variety, two kinds of corn and two kinds of cotton. The approval does not include environmental release as an intended use of GM imports. 18 more applications for imports of GM crops are being examined.	
India	Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-organisms Genetically Engineered Organisms or Cells, Ministry of Environment and Forests (MEF) 1989, (http://envfor.nic.in/legis/hsm/hsm3.html) → The Review Committee on Genetic Manipulation (RCGM) in the Department of Biotechnology (DBT) is responsible for monitoring safety-related aspects in respect of ongoing research projects and activities involving GMOs and laying down procedures restricting or prohibiting their production, sale, importation and use. → The Genetic Engineering Approval Committee (GEAC) under the Department of Environment, Forests and Wildlife is responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment, including experimental field trials. Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, DBT 1998 (http://binas.unido.org/binas/regulations/indiaguide.doc) → RCGM is responsible for clearance of imports of GM material. → The Government will set up a regulatory body by January 2005 that will replace the multiple agencies that are currently involved in governing the sector at different stages.	Four varieties of Bt cotton approved. Field trials for several GM crops.	

.../...

Table 1. (cont'd.)

Countries	*Regulatory system and agency(ies) responsible*	*GM products approved*	*Labelling requirements*
Egypt	Ministerial Decrees Nos. 85 and 136, Biosafety Guidelines and Regulations, Ministry of Agriculture and Land Reclamation (MALR) 1995 (http://binas.unido.org/binas/regulations/egypt_bs.pdf) → The National Biosafety Committee (NBC) is responsible for the implementation of Egypt's Biosafety Guidelines, conducts risk assessments, and issues permits for field tests and commercial release of GM plants (in collaboration with the Supreme Committee for Food Safety, Ministry of Health, and the Seed Registration Committee, MALR).	Almost 40 GM field trials have been authorized.	
Zimbabwe (see more details in the text)	Under the Statutory Instrument 20/2000 Biosafety Regulations, the Research Council established the Biosafety Board to oversee the conduct of biotechnology in Zimbabwe, including approving the safety of imports of GM products. While initially rejecting GM food aid, Zimbabwe later accepted it, provided all GM maize was milled immediately upon arrival.[g]		
South Africa	Genetically Modified Organisms Act 1997, implemented in 1999 (http://www.africabio.com/policies.shtml) → Executive Council for GMOs, charged with approving imports and release of GMOs. .A Scientific Advisory Committee reviews the human and environmental safety of GMOs and advises the Executive Council. A Registrar administers the GMO Act on behalf of the Minster of Agriculture, and issues permits at the request of the Executive Council. An Inspectorate is responsible for monitoring and inspecting local work with GMOs. Draft Regulations Governing the Labeling of Foodstuffs Obtained Through Certain Techniques of Genetic Modification, Department of Health, Government Notice No. 366, 4 May 2001 (http://www.africabio.com/policies/GMlabellingE.htm).	Four GM crops have been approved for commercial growing: pest-resistant maize for animal feed, herbicide-tolerant and pest-resistant varieties of cotton, GM soybeans.	Mandatory labelling requirements for GM foods that are significantly different and that contain allergens from a list of specific products. Label "not genetically modified" only if produced with an identity preservation system.
NEPAD (New Partnership for Africa's Development)	NEPAD is planning to set up an Advisory Panel on Biotechnology and Biosafety charged with developing an African strategy on biotechnology and bioengineered crops. The Panel will also attempt to harmonize biosafety regulations between African countries in order to facilitate trade (http://www.nepad.org).		
SADC (see more details in the text)	As directed by the 2002 SADC Council of Ministers, a SADC Advisory Committee on Biotechnology and Biosafety was established on 16 April 2003. In August 2003, it approved a set of recommendations "to safeguard Member States against potential risks in the areas of human and animal food safety, contamination of genetic resources taking into account ethical, and trade-related issues including consumer concerns". In May 2004, SADC approved guidelines on handling GM food aid.		

Notes:

[a] This summary table is not intended to be comprehensive. While every effort was made to provide correct information, the correctness of the information cannot be guaranteed. This table updates the one prepared by M. Musollino for the *UNCTAD Training Module on the WTO Agreement on Sanitary and Phytosanitary Measures,* January 2004.For a database on products derived from biotechnology, see the OECD Biotech Database, available at: http://webdomino1.oecd.org/ehs/bioprod.nsf.

[b] See: US Regulatory Agencies Unified Biotechnology Website, available at: // http://usbiotechreg.nbii.gov/database_pub.asp

[c] *Câmara aprova projeto de lei sobre biossegurança*, 5 February 2004, FolhaOnLine, available at http://www1.folha.uol.com.br/folha/dinheiro/ult91u80325.shtml; *Veja os principais puntos do projeto de biossegurança*, 5 February 2004, FolhaOnLine, available at http://www1.folha.uol.com.br/folha/dinheiro/ult91u80332.shtml.; and *Brazilian Senate approves biosafety law*, 13 October 2004, available at http://www.scidev.net/News/index.cfm?fuseaction=readnews&itemid=1659&language=1.

[d] Ministerial Act number 2.658, 22 December 2003 issued by the Ministry of Justice.

[e] See Monsanto Press Release, *Monsanto's Insect-Protected Corn Approved for Planting in the Philippines*, 5 December 2002, http://www.monsanto.com/monsanto/layout/media/02/12-05-02.asp.

[f] See Paarlberg, R., "The Contested Governance of GM Foods: Implications for U.S.-EU Trade and the Developing World", Working Paper, Weatherhead Center for International Affairs, Harvard University, 2002, p. 13.

[g] See *Bridges Trade BioRes*, 11 July 2002, available at: http://www.ictsd.org/biores/02-07-11/inbrief.htm

III. THE MULTILATERAL LEGAL FRAMEWORK

At present, international trade in GMOs and products thereof has to take place according to the rules agreed by WTO Members at the end of the Uruguay Round, in particular those spelt out in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Agreement on Technical Barriers to Trade (TBT Agreement) and the General Agreement on Tariffs and Trade (GATT) 1994. Since biotechnology is by and large proprietary technology, the rules of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) may also have a bearing on international trade in GMOs. Disciplines regarding transboundary movement of GMOs, however, have also emerged from specific multilateral agreements being negotiated outside the purely trade context, in particular the Cartagena Protocol on Biosafety. The rules included in different legal instruments may not be fully consistent with each other and may give rise to conflicts between GMO-exporting countries and potential importers.

Cartagena Protocol on Biosafety

This section is not intended to analyse the Biosafety Protocol in detail, but to single out those trade-related aspects of it that exhibit some potential for tension with WTO law.[46]

The Cartagena Protocol on Biosafety,[47] which was negotiated under the auspices of the Convention on Biological Diversity (CBD, Rio de Janeiro, 1992), was adopted on 29 January 2000, after almost four years of increasingly complex negotiations. It entered into force on 11 September 2003, 90 days after the fiftieth instrument of ratification was received. As of 31 December 2004, 111 countries, including the EC, had ratified or acceded to it (see figure 2 on regional distribution of ratifications). The Protocol entered into force at a critical time in trade policy, with increasing tensions around the restrictive trade regime applied by certain countries on agro-biotechnology. [48]

Negotiating the Protocol in the framework of the CBD made it a predominantly environmental agreement. Environmental ministers took the leading role during the negotiations, as opposed to trade ministers, who negotiated the WTO Agreements and are currently involved in carrying out the Doha Work Programme.[49] This specific negotiating framework may explain why the large majority of developing countries took some negotiating positions that they had constantly rejected within the WTO context, such as those on the precautionary principle; secondly, it provides the ground for the Protocol to be conceived as an

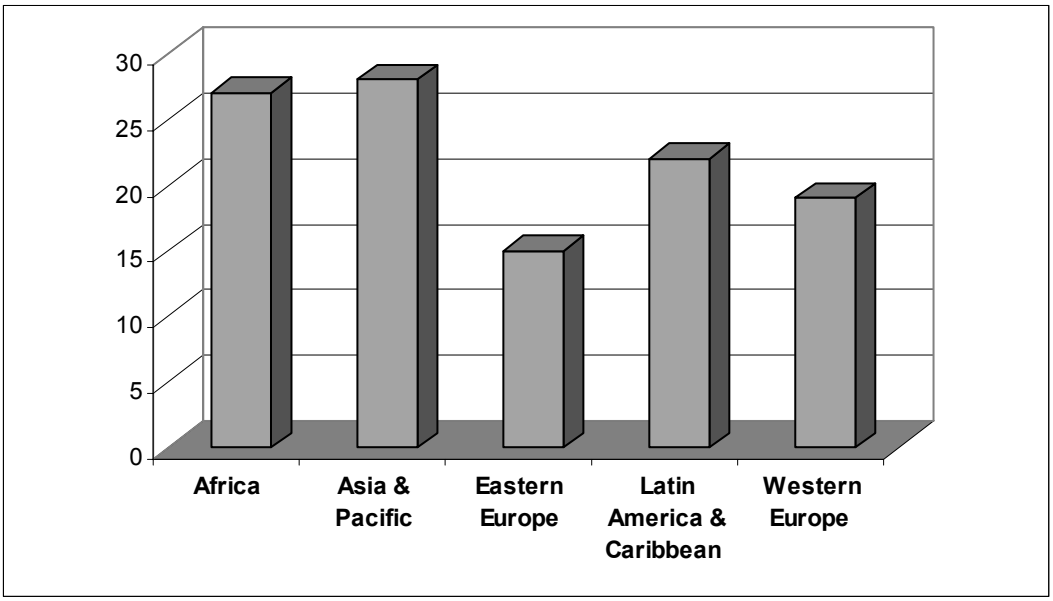
[46] For a detailed and comprehensive description and analysis of the Biosafety Protocol see: Mackenzie, R. et al., *An Explanatory Guide to the Cartagena Protocol on Biosafety*, IUCN Environmental Policy and Law Paper No.46, 2003.

[47] In general, the term "biosafety" describes a set of measures used to assess and manage any risk associated with GMOs.

[48] See: "Biosafety treaty enters into force", *Oxford Analytica* , 29 September 2003.

[49] The Doha Work Programme emerged from the Declarations adopted by WTO Members at the 4th WTO Ministerial Conference held in Doha, Qatar on 9-13 November 2001.

Figure 2. Cartagena Protocol: Regional distribution of ratifications (as of 31 December 2004)



instrument primarily concerned with the conservation and sustainable use of biological diversity, more than with international trade *per se*.

The Protocol provides rules for the safe transfer, handling and use of "living modified organisms" (LMOs). Its aim is to address the threats posed by LMOs to biological diversity, also taking into account risks to human health. Living modified organisms are defined by the Protocol as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology" (Article 3(g)). While the Protocol provides a definition of LMOs, there is not at present a multilaterally agreed definition of GMOs. The EC has defined GMOs in its Directive 2001/18/EC, but this definition cannot be regarded as universally accepted. The Protocol's definition of living organisms – "any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids" (Article 3(h)) – is narrower than the definition of modified organisms provided in the EC Directive – "any biological entity capable of replication or of transferring genetic material" (Article 2 (1)). However, in many countries, the terms "genetically modified organisms", "genetically engineered organisms" and "transgenic organisms" are widely used, including in domestic legislation, to describe groups of organisms that correspond to those covered by the Protocol.

The Protocol distinguishes LMOs in three categories: LMOs for voluntary introduction into the environment – such as seeds for planting, live fish for release, micro-organisms for bioremediation; LMOs destined for contained use, contained used being defined in Article 3(b) of the Protocol to include activities in which LMOs are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment; and LMOs intended for direct use as food or feed, or for processing (LMO-FFPs). The latter represent the large majority of LMOs, i.e. genetically modified crops, such as soybean, maize, canola, tomato, cotton, etc. The Protocol does not cover consumer products derived from LMOs, such as corn flakes, flour, starch, seed-oil, tomato paste or ketchup.

The first Meeting of the Parties of the Protocol (MOP-1) was held in Malaysia on 23-27 February 2004 and ended with the adoption of 10 decisions to govern international trade in LMOs among the Parties. Three of the 10 decisions – on the handling in international trade of LMOs, on compliance with the rules, and on liability and redress – are especially significant for the actual implementation of the Protocol.

On the first issue, MOP-1 decided on the documentation that should accompany the three categories of LMOs, namely those that are used as food, as feed and for processing; those that are for "contained use"; and those for introduction into the environment.[50]

On the second issue – namely how to deal with countries that do not comply with their obligations under the Protocol – some compliance procedures and mechanisms were established and a 15-member Compliance Committee was set up to receive cases of non-compliance submitted to it. The Committee can then take measures, including giving advice or assistance to the non-complying party, developing a compliance action plan with a timeframe, asking the party to submit progress reports, and reporting to the MOP on efforts made by the party. In turn, the MOP can decide on the following measures: providing assistance, technology transfer, training and capacity building measures; issuing a caution; having the cases on non-compliance published; or taking other measures in the case of repeated non-compliance.

The issue of liability and redress was perhaps the most controversial issue discussed, with developing countries, especially from Africa, pressing for MOP-1 to adopt a strong international regime. They argued, in general, that in the event of accidents or incidents where LMOs cause damage to farmers' crops, to human health or to the environment, there should be a legally binding regime to determine who is responsible and how redress or compensation can be made. MOP-1 eventually decided to set up a working group of experts on liability and redress. The group will analyse potential and actual damage scenarios of concern in order to identify situations for which international rules may be needed, and analyse how international rules and procedures on liability and redress can be applied to the damage scenarios. It will also elaborate options for rules and procedures, including definition, nature and scope of damage, valuation of damage to biodiversity and human health, threshold of damage, causation, channelling of liability, roles of parties in import and export, standard of liability, mechanisms of financial security and standing or right to bring claims. An appropriate regime should be developed by 2008.

Besides the measures taken on these three main issues, MOP-1 also took decisions on seven other issues, including capacity building, a

[50] For the first category, the documents should clearly identify that the shipment "may contain LMOs" for direct use as food, feed or for processing and not intended for introduction into the environment. The accompanying documentation should also indicate the contact details of the importer, exporter or other appropriate authority. In addition, Parties decided to expand the existing requirements by urging governments to require information on the name of the organism and the transformation event or unique identifier code. While the additional information is only optional, it nevertheless marks a step beyond the requirements originally included in Article 18.2(a). Over the next year an expert group will further elaborate the documentation and handling requirements for these shipments. Key issues still to be decided include the percentage of modified material that these shipments may contain and still be considered GMO-free and the inclusion of any additional detailed information. A decision on these matters will be considered at the next MOP. For the second category of LMOs, documents accompanying them should clearly identify the LMOs, their common and scientific names, that they are destined for contained use; their commercial names and new and modified traits and characteristics. For the third category, namely LMOs meant to be introduced into the environment, the accompanying documents should clearly identify them as LMOs, specify the common, scientific and commercial names of the LMO, the transformation event code or its unique identifier code, any handling and storage requirements, contact details in the case of emergency and how the LMO is to be used.

medium-term work programme, information sharing and the Biosafety Clearing House, budget and other financial issues. [51]

It seems there are four aspects of the Protocol that might give rise to overlaps with WTO law: (i) the scope for legitimate government action short of conclusive scientific evidence; (ii) risk assessment and risk management; (iii) the socio-economic factors that may be taken into account in the decision-making process; and (iv) documentation obligations. It should also be noted, however, that country obligations should be read together and be considered cumulative. Thus, WTO rules should be interpreted with a view to avoiding conflicts between them and those included in the Biosafety Protocol.

The precautionary approach is one of the main features of the Protocol. Though Article 1 of the Protocol ("Objective") refers to Article 15 of the 1992 Rio Declaration on Environment and Development,[52] the Protocol develops its own interpretation of the precautionary approach by formulating specific language in Articles 10.6 and 11.8, which deal respectively with LMOs for intentional introduction into the environment and LMOs for direct use as food, as feed, or for processing. Articles 10 and 11 include very similar language: "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism …, in order to avoid or minimize such potential adverse effects".[53] Importing countries can, thus, ban imports because of lack of scientific certainty. The ban may last until the importing country decides that it has arrived at scientific certainty about the effects of the products on biodiversity and human health. However, since the importing country is not obliged to seek the information necessary to reach scientific certainty, a trade-restrictive measure may be in force without time limits. On the contrary, the SPS Agreement allows countries to provisionally adopt sanitary or phytosanitary measures when relevant scientific evidence is insufficient, but obliges them to seek the additional information necessary for a more objective assessment of risk and to review the SPS measure within a reasonable period of time.

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[51] See: UNEP, Convention on Biological Diversity, Press Release, *Biosafety Protocol now operational as governments agree documentation rules for GMO trade*; "Biosafety Meeting Moves on Labelling, Compliance and Liability", *Bridges – Trade BioRes*, Volume 4, Number 4, 5 March 2004, available at: http://www.ictsd.org/biores/04-03-05/story1.htm; and Khor, M.,"Environment: Biosafety meet agrees on policy measures on GMO trade", *Suns* 5523, 2 March 2004.

[52] The formulation of the precautionary principle contained in Principle 15 of the Rio Declaration is the following: "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".

[53] One of the central points of contention during the negotiations of the Protocol was whether, in the presence of significant scientific uncertainty, the precautionary approach would represent an appropriate basis on which to take decisions. The Miami Group – which included the main producers and exporters of genetically modified seeds and crops, namely Argentina, Australia, Canada, Chile, the United States and Uruguay - and industry called for all decisions under the Protocol to be based on science, on the assumption that the potential risks posed by LMOs were already well known. According to them, to rely on the precautionary principle would open the Protocol to abuses and trade protectionism and to potential tensions with the SPS Agreement. The EU, the Like-Minded Group – which consisted of the large majority of developing countries - consumer and green groups, on the other hand, argued that while scientific input remained essential in the field of biosafety, risks posed by LMOs were still not fully understood and could be potentially irreversible. Therefore, the possibility of taking a precautionary approach was seen as crucial for the decision-making regime under the Protocol. The final text of the Protocol includes elements from the different negotiating groups; it goes, however, more in the direction of the EU's and the Like-Minded Group's approach.

For LMOs for intentional introduction into the environment, the Protocol allows the exporting country to request the importing country to review a decision it has taken when a change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based, or additional relevant scientific or technical information has become available. The importing country must respond to such a request in writing within 90 days and set out the reasons for its decision (Article 12, paras. 2 and 3). This provision therefore gives the exporter the right to request the importer to review its decision in the light of new information; however, the importer retains the flexibility to confirm its previous decision, though it has to justify so doing. This discipline echoes the need for review contained in the SPS Agreement when precautionary measures are used, although there are some basic differences: in the case of the SPS Agreement, the country implementing the measure is obliged to seek additional information and review the SPS measure within a reasonable period of time. In the case of the Protocol, the country implementing a restrictive measure is obliged only to consider the request made by the exporter, analyse the new circumstances or the new scientific or technical information brought to its attention and give a justified reply within 90 days. Moreover, this rule does not apply to LMOs for direct use as food, as feed or for processing.

Turning to the second potential aspect of conflict between WTO rules and the Biosafety Protocol, the Protocol states that risk assessment should be carried out in a scientifically sound manner in order to identify and evaluate the possible adverse effects of LMOs on the conservation and sustainable use of biological diversity, taking into accounts risks to human health (Article 15). Article 16 deals with mechanisms, measures and strategies to regulate, manage and control the risks identified by risk assessment.

Article 15 requires the importing Party to ensure that risk assessments are the basis for reaching decisions on proposed imports of LMOs for intentional release into the environment. The importing Party may carry out the risk assessment – often on the basis of the information provided by the potential exporter – or request the exporter to do so. If the risk assessment is performed by the importer, it can recover the cost from the potential exporter. Risk assessment is also to be used for LMO-FFPs and is part of the necessary information to be provided to the Biosafety Clearing-House by a Party that takes a final decision regarding domestic use of LMO-FFPs that may be subject to transboundary movement. A developing country Party or a Party with an economy in transition may, in the absence of a domestic regulatory framework, declare through the Biosafety Clearing House that its decisions on the first import of LMO-FFPs will be taken in accordance with a risk assessment as set out in the Protocol and the timeframe for decision-making.

In dealing with the same issue – risk assessment and risk management – the SPS Agreement states that sanitary and phytosanitary measures should be based on an assessment of the risks to human, animal or plant life or health. It is interesting to note that under the Agreement a country can base its measures on the risk assessments carried out by other countries or by international organizations, and may seek additional information from other Member countries or from the industry. Article 5.4 provides that Members, when determining the appropriate level of sanitary and phytosanitary protection (ALOP) they are willing to tolerate, should take into account the objective of minimizing negative trade effects. In dealing with the measures taken to achieve the ALOP, the SPS Agreement puts an obligation on Members to ensure that the chosen measures are not more trade-restrictive than required to achieve the ALOP, taking into account technical and economic feasibility. This means that if there is an alternative measure, equally effective in terms of achieving the appropriate level of protection, that is reasonably available from a technical and economic point of view, that measure should be used. Moreover, Article 2.2 contains the obligation for SPS measures to be "applied only

to the extent necessary to protect human, animal or plant life or health". The SPS Agreement embodies as well the obligation for Members to avoid arbitrary or unjustifiable distinctions in the levels of sanitary and phytosanitary protection they consider to be appropriate in different situations, if such distinctions result in discrimination or disguised restriction on international trade. The objective of this obligation is to achieve consistency in applying the ALOP.

Two aspects of the discipline on risk assessment and risk management respectively developed within the Biosafety Protocol and the WTO framework may then be in tension with each other. First of all, the SPS Agreement includes reference to the restrictive trade impact that a sanitary or phytosanitary measure may have and calls for it to be minimized. In the Biosafety Protocol, this preoccupation is not addressed. Secondly, while the Protocol and the SPS Agreement contain very similar obligations with regard to the Party of import ensuring that its decision is based on a risk assessment, under the Protocol the importing country does not have to finance the underlying scientific studies to demonstrate that the product to be imported meets the level of risk that it has chosen. It may require the exporter to do so. In the case of the SPS Agreement, on the other hand, it is the importing country that usually bears the costs of the risk assessment.

Turning to the third potential aspect of conflict between WTO rules and the Biosafety Protocol, under Article 26 of the Biosafety Protocol, Parties may take into account, when deciding whether and under which conditions to allow the import of LMOs, "socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities". It therefore appears that the Protocol would allow trade-restrictive measures justified by the fact that imports of LMOs might lead to a loss of cultural traditions, knowledge and practices, particularly among indigenous and local communities. Within the SPS framework, risk assessment can, in specific cases, take into account socio-economic considerations. This happens for the assessment of risks to animal or plant life or health, where Members are to take into account relevant economic factors, such as the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks (Article 5.3). These same considerations do not apply to the assessment of risk to human health.[54] However, socio-economic factors may play a role in a Government's decision to be more or less risk-averse, which is one of the reasons why Article 5.5 imposes some discipline on this decision. In an early dispute, a GATT Panel rejected trade restrictions that were justified solely on the grounds that cheap imports would undermine the traditional livelihoods of a certain minority population.[55]

Finally, Article 18 of the Biosafety Protocol sets forth rules related to handling, transport, packaging and identification requirements. Those rules were developed by MOP-1 and will be further elaborated in order to be approved by MOP-2 in 2005. The rules agreed upon with reference to LMOs for food, for feed and for processing, i.e. the genetically engineered crops that represent the bulk of

[54] It is interesting to recall that during the negotiations of the SPS Agreement it was the negotiators from the EU and the Nordic countries who insisted that economic factors could not be considered in assessing risks to human health and life, to avoid public perceptions that governments were somehow putting a price on human health and life.

[55] *Japanese Measures on Imports of Leather*, GATT Panel Report BISD 31S/94, 2 March 1984, p. 44. On the issue of socio-economic considerations see: Mackanzie, R. at all, *An Explanatory Guide to the Cartagena Protocol on Biosafety, supra*, note 46, at 238-239.

international trade in the sector, seem to go beyond the requirements originally included in Article 18.2(a) by urging Governments to require information on the name of the organism and the transformation event or unique identifier code. Compliance with this requirement may prove more cumbersome than simply indicating in the accompanying documentation that the shipment "may contain LMOs", since it implies the establishment of strict systems of identification and segregation. Article 2.1 of the TBT restates the principle of non-discrimination set forth in Article I and Article III of the GATT 1994, as far as imported products and "like" products or domestic origin or originating in any other country are concerned. If GMOs and GM products are considered "like" products in relation to conventional products, then there are no grounds for applying any special treatment to them, including mandatory documentation and identification schemes (see section below).

WTO Agreements that have direct implications for international trade in GMOs

Four WTO Agreements appear to have special relevance for international trade in GMOs: the SPS Agreement, the TBT Agreement, the TRIPS Agreement, and the GATT 1994. As far as the relationship between SPS, TBT and GATT is concerned, once SPS applies, TBT cannot apply, as is stated in Article 1.5 of the TBT Agreement. In the event of conflict between SPS/TBT and GATT, the specific agreement prevails over GATT, according to the General Interpretative Note to Annex 1A to the Marrakesh Agreement Establishing the World Trade Organization. However, the Agreements that represent *lex specialis* as opposed to the GATT do not eclipse it. On the contrary, both Agreements continue to apply to the greatest extent possible, and the more specific agreement (i.e. SPS or TBT) prevails only to the extent that there is a conflict between its provisions and those of the general agreement.

The last proviso in the Preamble of the SPS Agreement establishes that the Agreement aims at elaborating rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b). Moreover, Article 2.4 of the SPS Agreement indicates that measures which conform to the relevant provisions of the SPS Agreement are presumed to be in accordance with the provisions of the GATT 1994, in particular those of Article XX(b). In the case of TBT, the second proviso in the preamble language states that the Agreement is meant "to further the objectives of GATT 1994". In the Asbestos case, the Appellate Body argued that the Agreement does so "through a specialized legal regime that applies solely to a limited class of measures. For these measures the *TBT Agreement* imposes obligations on Members that seem to be *different* from and *additional* to, the obligations imposed on Members under the GATT 1994".[56] This seems to lead to the conclusion that measures should be scrutinized under both the GATT 1994 and the TBT Agreement. Measures that conform to the provisions of the TBT Agreement do not necessarily also conform to those of the GATT, since the two sets of provisions are different.

It is not the purpose of this paper to provide a detailed analysis of the above-mentioned Agreements, but only to analyse those provisions that may be particularly relevant for international trade in GMOs and products thereof.

Concerning the SPS Agreement, its main goal is to prevent domestic sanitary or phytosanitary measures from having unnecessary negative effects on international trade and being misused for protectionist purposes. However, the Agreement fully recognizes the legitimate interest of countries in setting up rules to protect food safety and animal and plant health, and in fact allows countries to give these objectives priority

[56] *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, Report of the Appellate Body, WT/DS135/AB/R, 12 March 2001, at 80. Emphasis as in the original text.

over trade, provided there is a demonstrable scientific basis for their food safety and health requirements.[57] Even though the Agreement does not refer to GMOs explicitly, it can be argued that measures aimed at regulating such trade could reasonably come within the scope of the Agreement, provided that their objectives are consistent with it.[58]

Although the SPS Agreement provides countries with the sovereign right to determine the level of sanitary and phytosanitary protection that they consider appropriate, it also provides that, in doing so, they have to take into account the objective of minimizing negative trade effects (Article 5.4, non mandatory provision). As already mentioned, they have to do the same when selecting the measures that are instrumental in achieving the chosen level of sanitary and phytosanitary protection (Article 5.6, mandatory provision). Moreover, the Agreement includes the obligation for countries to avoid arbitrary or unjustifiable distinctions in the levels of protection they consider to be appropriate in different situations, if such distinctions result in discrimination or disguised restrictions on international trade (Article 5.5). These provisions seem to add some qualifications to the freedom of WTO Members in this field.

As pointed out above, there is limited scope to apply the precautionary principle under the SPS Agreement, contrary to the Biosafety Protocol. The Agreement permits the adoption of SPS measures on a provisional basis as a precautionary step where relevant scientific evidence is insufficient. However, "Members shall seek to obtain the additional information necessary to a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time" (Article 5.7, second sentence).

In the well-known hormone case,[59] related to a ban imposed by the EC on bovine meat and meat products from cattle treated with growth hormones, the role of the precautionary principle in the framework of the SPS Agreement was addressed.

In the view of the European Communities, the precautionary principle is already a general customary rule of international law or at least a general principle of law, the essence of which is that it applies not only in the management of a risk, but also in the assessment thereof.[60] Accordingly, the European Communities submitted that the Panel erred in law in considering that the precautionary principle was only relevant for "provisional measures" under Article 5.7 of the SPS Agreement. The United States rejected the claim of the European Communities that there was a generally accepted principle of international law that may be referred to as the "precautionary principle". In the view of the United States, the EC's invocation of a "precautionary principle" cannot create a risk assessment where there is none, nor can a "principle" create "sufficient scientific evidence" where there is none.[61]

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[57] More specifically, the Agreement covers measures adopted by countries to protect human or animal life from food-borne risks; human health from animal- or plant-carried diseases; animal and plants from pests and diseases; and the territory of a country from the entry, establishment, or spread of pests.

[58] As of 30 July 2003, 82 notifications related to biotech products had been submitted to the WTO secretariat under the notification system established by the SPS Agreement.

[59] *EC Measures Concerning Meat and Meat Products (EC - Hormones)*, Complaint by the United States, WT/DS26/R/USA, (the "US Panel Report") and Complaint by Canada, WT/DS48/R/CAN, (the "Canada Panel Report"), 18 August 1997.

[60] *EC Measures Concerning Meat and Meat Products (EC - Hormones)*, Report of the Appellate Body, WT/DS26/AB/R and WT/DS48/AB/R, 16 January 1998, at 16. The EC did not argue it at the panel stage.

[61] Ibid., at. 43.

The Appellate Body stated that it was unnecessary, and probably imprudent, for it to take a position on the important but abstract question of the status of the precautionary principle in international law. However, it appeared important to note some aspects of the relationship of the precautionary principle with the SPS Agreement: (i) the precautionary principle had not been written into the SPS Agreement as a ground for justifying SPS measures that were otherwise inconsistent with the obligations of Members set out in particular provisions of the Agreement; (ii) the precautionary principle had been incorporated into Article 5.7 of the SPS Agreement, but this provision did not exhaust the relevance of the precautionary principle for SPS; (iii) Governments commonly acted from the perspective of prudence and precaution where risks to irreversible damage to human health were at stake, and this responsible behaviour had to be taken into account when determining whether sufficient scientific evidence existed to warrant the maintenance by a Member of a particular SPS measure; (iv) the precautionary principle did not relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement. The Appellate Body agreed with the finding of the Panel that the precautionary principle did not override the provisions of Articles 5.1 and 5.2 of the SPS Agreement: the risk evaluated in a risk assessment must thus be an ascertainable risk; theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed.[62]

In the hormone case, the Panels and the Appellate Body did not have a chance to interpret Article 5.7 of the SPS Agreement directly, because the EC had not invoked it to justify the measures in dispute. However, Article 5.7 was explicitly addressed in the Japan varietals case.[63] That case was about a complaint by the United States relating to the requirement imposed by Japan for testing and confirming the efficacy of the quarantine treatment for each variety of certain agricultural products. In support of its varietal testing requirement, Japan invoked Article 5.7. According to the Appellate Body, Article 5.7 sets out four cumulative requirements that must be met for adopting and maintaining provisional SPS measures. A country may provisionally adopt an SPS measure if this measure is: (i) imposed in respect of a situation where relevant scientific evidence is insufficient; and (ii) adopted on the basis of available pertinent information. Such a measure may not be maintained unless the country that adopted it: (i) seeks to obtain the additional information necessary for a more objective assessment of risk; and (ii) reviews the measure accordingly within a reasonable period of time.

In the recent Apples case, the Appellate Body confirmed the need for those four cumulative requirements to be met in order for a WTO member country to adopt and maintain provisional SPS measures. Addressing the first criterion, i.e. a situation where "relevant scientific evidence is insufficient", the AB stated that: "'relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement."[64] The Appellate Body clarified that "the application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence. The text of Article 5.7 is clear: it refers to 'cases where relevant scientific evidence is insufficient', not to 'scientific uncertainty'. The

[62] Ibid., at 123 to 125.

[63] *Japan - Measures Affecting Agricultural Products*, WT/DS76/R, 27 October 1998, and WT/DS76/AB/R, 22 February 1999.

[64] *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, 26 November 2003, at 179. The case was about a complaint by the United States concerning certain requirements and prohibitions imposed by Japan with respect to the importation of apple fruit from the United States.

two concepts are not interchangeable."[65] The Appellate Body upheld the Panel ruling that Article 5.7 did not apply in the specific case since the scientific evidence was not "insufficient". This would seem to imply that the present inconclusiveness of scientific evidence related to the actual or potential impact of GMOs on human and animal health and on the environment cannot be regarded as a reason for taking precautionary measures under Article 5.7 of the SPS Agreement. On the other hand, Article 10.6 of the Cartagena Protocol refers to "lack of scientific certainty due to insufficient relevant scientific information and knowledge" as the basis for taking a precautionary step. According to the Protocol, the insufficiency of scientific evidence would lead to scientific uncertainty, which, in turn, would justify a precautionary approach. Article 10.6 addresses the situation where, after carrying out the risk assessment, the Party of import concludes that there is still a lack of certainty about the potential adverse effect of LMOs on biological diversity, as well as the situation where there is insufficient information to carry out a risk assessment. Article 5.7 of the SPS Agreement, on the other hand, seems to apply only in the latter situation.

Labelling and documentation requirements related to food, nutrition claims and concerns, quality and packaging regulations are normally subject to the TBT Agreement. While SPS measures may be imposed only to the extent necessary to protect human, animal or plant health from food-borne risks or from pests or diseases, Governments may introduce TBT regulations when necessary to meet a number of legitimate objectives, including the prevention of deceptive practices, the protection of human health or safety, animal or plant life or health, or the environment. Technical regulations should not create unnecessary obstacles to international trade or be more trade-restrictive than is necessary to fulfill a legitimate objective, taking account of the risks that non-fulfillment would create. Measures should not discriminate between imported products and "like" products of domestic or foreign origin. If GMOs and GM products are considered "like" products in relation to conventional products, then there are no grounds for applying any special treatment to them, including mandatory labelling schemes.

Turning to the GATT 1994, the national treatment principle, which is incorporated into Article III, implies non-discrimination between domestic and imported goods. Translating this principle into the GMO context implies that the importing country is not allowed to apply to foreign products measures more onerous than those applied to like domestic products. In the context of Article III as well, the determination of what constitutes "like products" is a crucial issue, since the national treatment obligations apply only if two products are "like". In assessing whether products are "like", the controversial issue of whether the analysis should be limited to the physical characteristics of the products or should also take into account the process and production methods is still open. The relevant jurisprudence is not conclusive, and authoritative authors are deeply divided on the subject.[66] On the one hand, it has been argued that there is no real support in the text and jurisprudence of the GATT for the product/process distinction[67] and that the distinction is neither warranted nor useful in practice.[68] On the other hand, it has been suggested that there is a textual basis in

[65] Ibid., at 184.

[66] However, it has been stressed that the "trade policy elite has simply accepted the notion of a sharp divergence between measures on products and PPMs as if such a distinction had been written into the GATT all along, and not simply invented in the *Tuna/Dolphin* case": Trebilcock M.J. and R. Howse, *The Regulation of International Trade* (London and New York: Routledge, 1999) at. 413.

[67] Howse, R. and D. Regan, "The Product/Process Distinction - An Illusionary Basis for Disciplining 'Unilateralism' in Trade Policy", *European Journal of International Law* 11, 2000, pp. 249 ff., at 264-268.

[68] Cosbey, A., "The WTO and PPMs: Time to Drop a Taboo", *Bridges* 5 No. 1-3, 2001, pp.11-12.

GATT Article III and the Note ad Article III for the product/process distinction and that the distinction should be retained to prevent protectionist abuses.[69] The product/process distinction is therefore an open issue. Jurisprudence related to Article XX of the GATT 1994, on the other hand, seems to have evolved to interpret Article XX as covering measures that distinguish products on the basis of the production processes.[70] As far as the relationship between Article III and Article XX is concerned, the Appellate Body in the Asbestos case regarded the two articles as complementary and not mutually exclusive.[71]

The general elimination of quantitative restrictions is embodied in Article XI of the GATT 1994, which provides that no prohibitions or restrictions other than duties, taxes or charges shall be instituted or maintained on the importation or exportation of any product.

The obligations of Articles III and XI can be derogated from by using the exceptions set out in Article XX of the GATT 1994. The provisions of the latter which are of special relevance for trade in GMOs are as follows:

> *General Exceptions*
> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrarily or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
> ….
> (b) necessary to protect human, animal or plant life or health;
> …..
> (g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption.
> ….

Article XX gives countries the legal means to balance their trade obligations with important non-trade objectives, such as health protection or the preservation of the environment, which form part of their overall national policies. In the Shrimp case, the Appellate Body, referring to the introductory text of Article XX, stated that "[W]e consider that it embodies the recognition on the part of WTO Members of the need to maintain a balance of rights and obligations between the right of a Member to invoke one or another of the exceptions of Article XX, specified in paragraphs (a) to (j), on the one hand, and the substantive rights of the other Members under the GATT 1994, on the other hand… A balance must be struck between the right of a Member to invoke an exception under Article XX and the duty of that same Member to respect the treaty rights of the other Members".[72] According to the Appellate Body, the purpose of the introductory text of Article XX is "generally the prevention of the abuse of the exceptions of Article XX".[73]

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[69] Jackson, J.H., "Comments on Shrimp/Turtle and the Product/Process Distinction", *European Journal of International Law* 11, 2000, pp. 303-307.

[70] In the *US - Shrimp* case (*United States-Import Prohibition of Certain Shrimp and Shrimp Products,* Appellate Body Report adopted on 12 October 1998, WT/DS58/AB/R), the Appellate Body stated that "It appears to us, however, that conditioning access to a Member's domestic market on whether exporting Members comply with, or adopt, a policy or policies unilaterally prescribed by the importing Member may, to some degree, be a common aspect of measures falling within the scope of one or another of the exceptions (a) to (j) of Article XX.(para 121).

[71] *EC - Asbestos*, at para 115.

[72] *US - Shrimp*, at para. 156.

[73] *US - Shrimp*, at para. 150.

Turning to the last WTO Agreement that has direct relevance for international trade in GMOs, namely the TRIPS Agreement, analysis will again be limited only to those provisions of the Agreement that are directly relevant for GMOs and products thereof.

Strengthened protection of intellectual property rights may make investment by the biotechnology industry more profitable.[74] The TRIPS Agreement, then, may be seen as promoting the adoption of GMOs in the food system. Related to the issue of biotechnology applied to agricultural and food products is the issue of obtaining patents on live plants or animals, including biotechnological inventions and plant varieties. Concerns are being expressed in both developed and developing countries about the economic, social, environmental and ethical impacts of life patenting. Moreover, many developing country Governments are concerned that the control of the nature and distribution of new life forms by transnational corporations may affect their countries' development prospects and food security.

Currently, the TRIPS Agreement does not require that countries grant patents for plants and animals; however, they have to provide for the protection of plant varieties either by patents or by an effective *sui generis* system,[75] or by a mixture of both (Article 27.3(b)). The revision of Article 27.3(b) is part of the "built-in agenda" agreed at the conclusion of the Uruguay Round. In accordance with it, the WTO Council for TRIPS started the revision of Article 27.3(b) in 1999; however, owing to lack of consensus among Members, the revision is still ongoing.

Some developing countries, led by India, have proposed amending the TRIPS Agreement to require patent applicants to disclose the source of origin of the biological resources and associated traditional knowledge, and to provide evidence of prior informed consent and benefit sharing. The African Group has called for Article 27.3(b) to be revised so as to prohibit patenting of plants, animals and micro-organisms, and to classify traditional knowledge as a category of intellectual property rights. Switzerland would like to see these issues discussed outside the WTO and moved to the World Intellectual Property Organization (WIPO). The EC would support mandatory disclosure of origin requirements; such a requirement, however, should not constitute an additional patentability criterion, and failure to disclose should be regulated by civil or administrative law. [76]

While the establishment of the obligation to disclose the source of origin of the biological resources and associated traditional knowledge is highly controversial at the multilateral level, some initiatives have been taken at the national and regional levels.[77] Andean Pact Decision 391 established that any IPRs or other claims to resources shall not be considered valid if they were obtained or used in violation of the terms of a permit for access to biological resources residing in any of the Andean countries, as regulated under that Decision. In the Indian Patent (Second Amendment) Bill 1999, the grounds for rejection of the patent application, as well as revocation of the patent, include non-disclosure or wrongful disclosure of the source of origin of the biological resource or knowledge in the patent application, and prior disclosure of

[74] For a detailed analysis of the issue see: Tansey G., *Trade, intellectual property, food and biodiversity*, Discussion Paper, Quaker Peace & Service, London, February 1999.

[75] A *sui generis* system of protection is an alternative, unique form of intellectual property protection, designed to fit a country's particular context and needs. In the case of plant varieties, it means that countries can make their own rules to protect new plant varieties with some form of intellectual property rights (IPRs), provided that such protection is effective. The Agreement does not define the elements of an effective system.

[76] ICTSD and IISD, Doha Round Briefing Series, *Intellectual Property Rights*, Vol.2 No.5, August 2003.

[77] Correa, C., *Traditional Knowledge and Intellectual Property*, Discussion Paper, Quaker United Nations Office, Geneva, November 2001, at 19.

knowledge, oral or otherwise. Patent applicants must disclose in their patent applications the source of origin of the biological material used in the invention. Moreover, according to section 6 of the Indian Biodiversity Bill, anybody seeking any kind of IPRs on research based upon a biological resource or knowledge obtained from India, needs to obtain the prior approval of the National Biodiversity Authority (NBA) The NBA will impose benefit-sharing conditions. The European Directive on the legal protection of biotechnological inventions refers to the disclosure of information on the origin of biological materials in its preamble.[78]

While most developed countries consider that the model provided by the UPOV[79] system of Plant Breeders' Rights is the most appropriate *sui generis* system to afford protection to plant varieties, developing countries wish to retain flexibility in implementing legislation in this field. The UPOV system produces quite a strong IPR regime for plant varieties mainly geared to industrial breeding, which may not suit all countries. It promotes commercially bred varieties for industrial agricultural systems in which farmers have to pay royalties on such seed and the seed sector becomes an investment opportunity for the chemical and biotechnology industries. The alternative is for countries, especially those characterized by subsistence farming, to develop their own solutions with special legislation protecting plant varieties appropriate to their situation. It should be noted that traditionally there has been no legal protection of plant varieties at the domestic or international levels. Patents and plant breeders' rights were granted progressively to give the private sector the incentive to enter the seed industry. These developments were until recently confined mainly to developed countries. Hardly any developing country had protection of plant variety included in its national legislation before the implementation of the TRIPS Agreement.[80]

Considering that GMOs and GM crops incorporate patented technology and that trade-restrictive measures implemented under the Biosafety Protocol affect those products, it may be argued that those measures may nullify or impair Members' rights under TRIPS.[81] An additional concern is the degree to which patent holders and licensees will be responsible and liable for any adverse consequences of the application of biotechnology for the environment and human well-being. These may cross over into other fields of law, such as corporate governance and limited liability.

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[78] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, Official Journal L 213, 30/07/1998 pp. 13-21. "Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents" at 27 of the Preamble.

[79] Union Internationale pour la Protection des Obtentions Végétales (International Union for the Protection of New Varieties of Plants).

[80] See Cullet Ph., "Protecting rights in plant varieties", Center for International Development at Harvard University, 1999, available at: *http://www.cid.harvard.edu/cidbiotech/comments/comments56.htm.*

[81] A "non violation nullification or impairment" measure is one which, while it does not conflict with the provisions of an agreement, has the effect of nullifying or impairing a "benefit" ensured under a treaty. The rationale of such a provision is to protect the overall balance of concessions reasonably expected when the agreement was reached. This concept finds its roots in trade in goods. Article 64.3 of the TRIPS Agreement, by referring to Article XXIII of the GATT, opens the possibility of applying non-violation complaints in the field of IPRs. However, the extension of the non-violation discipline to IPRs should be agreed by WTO Members by consensus. Most WTO Members are against it.

IV. ACTUAL AND POTENTIAL GM-RELATED TRADE DISPUTES

The Preamble of the Biosafety Protocol states that it shall not be interpreted as implying a change in the rights and obligations of the parties under existing international agreements and that this is not intended to subordinate the Protocol to other international agreements. These provisions may prove not to be very helpful if a conflict arises between countries with divergent interests in the area of agro-biotechnology. Disputes may occur between parties to the Protocol, for instance on the interpretation of the role that the precautionary approach can play in decision-making, or between parties and non-parties on such issues as import restrictions, notification and identification requirements, delays in evaluating requests and authorizing imports, or on special conditions attached to imports, such as mandatory labelling requirements.

WTO law is not very helpful either in this regard. It does not explicitly provide that it is to prevail over pre-existing law, nor does it state that it is without derogation from pre-existing law. It does not include a general conflict clause in respect of future treaties either.[82]

On the basis of the good faith principle, States are presumed to have negotiated all their treaties in good faith, taking into account all their international law obligations. States' obligations should therefore be read together and be considered cumulative. As a consequence, WTO rules should be interpreted with a view to avoiding conflicts between them and the rules included in other international treaties, including the MEAs.[83]

Countries that are parties to a multilateral agreement are expected to solve their possible conflicts within the framework of the agreement they have signed and ratified.[84] The WTO Committee on Trade and Environment (CTE) expressed a preference for trade disputes that arise in connection with a multilateral environmental agreement to be resolved through the mechanisms established by that agreement.[85] However, if a party believes that in a specific circumstance its interests are better protected by WTO rules,[86] it may invoke those rules. In the case of the Biosafety Protocol, a party can argue that the Protocol clearly states that it shall not be interpreted as implying a change in the rights

[82] Pauwelyn, J., *Conflict of Norms in Public International Law – How WTO Law Relates to Other Rules of International Law*, Cambridge Studies in International and Comparative Law, Cambridge University Press, 2003, at 344.

[83] See Marceau G., "Conflicts of Norms and Conflicts of Jurisdiction, The relationship between the WTO Agreement and MEAs and other Treaties", *Journal of World Trade*, December 2001, at pp. 1089 and 1107.

[84] The Biosafety Protocol does not contain specific provisions on the settlement of disputes arising under it, but refers back to the relevant provisions of the CBD (Article 32). Article 27 of the CBD provides for optional recourse to judicial settlement or arbitration, or a conciliation procedure that is mandatory at the request of one of the Parties to a dispute. The newly established Compliance Committee may also provide a forum for the settlement of disputes among Parties to the Protocol.

[85] WTO, Report (1996) of the Committee on Trade and Environment, WT/CTE/1, 12 November 1996, at para 170 ff.

[86] Assuming that all countries involved in the dispute are Members of the WTO.

and obligations of the parties under existing international agreements. A possible conflict between parties may therefore be settled under the WTO dispute settlement mechanism. It flows from Article 23 of the Dispute Settlement Understanding (DSU) that any WTO Member can initiate a case in the WTO if it considers that its rights have been violated.

On the other hand, if a Party to the Biosafety Protocol has an interest in solving a dispute it has with another Party to the Protocol outside the WTO and according to the discipline laid down in the Biosafety Protocol, it may invoke two principles of international law aimed at resolving conflicts in the applicable law: *lex posterior derogat legi priori*, meaning that a later expression of state intent should prevail over an earlier one; and *lex specialis derogat legi generali*, meaning that a special rule is more to the point than a general one and it regulates the matter more effectively than general rules do. These principles may apply when the two conflicting treaties relate to the same subject matter and involve the same parties. The Biosafety Protocol could be said to reflect both a later and more specific expression of state consent than the WTO Agreements.

Finally, a country could take the option of bringing a GMO-related trade dispute before a WTO panel, but ask for its WTO obligations to be interpreted in the light of the Biosafety Protocol. The WTO legal system is linked to the rest of the international legal order and does not operate in "clinical isolation" from existing rules of public international law.[87] First of all, this means that in establishing the relevant facts of a dispute and applying WTO rules to these facts, non-WTO rules may constitute proof of certain factual circumstances. The role that non-WTO rules may play as factual information (though they may not be conclusive) – for instance to prove that some items are widely regarded as dangerous for human health or for the environment or that a specific country is committed to the preservation of a certain natural resource – may be especially important in justifying within a WTO dispute trade restrictions applied pursuant to MEAs, such as the Biosafety Protocol. Secondly, it means that non-WTO rules can be used to interpret WTO law. When interpreting WTO provisions, all international obligations and rights of WTO Members must be taken into account. The existence of the Biosafety Protocol and the fact that the disputing parties have ratified it make the Protocol a useful tool for interpreting WTO Members' obligations, for instance their right to resort to GATT Article XX general exceptions. More importantly, however, the linkages between WTO law and international law may imply that a party may invoke non-WTO rules in defense against a WTO claim. In order to do so, both disputing parties should be bound by the invoked non-WTO rules, e.g. both should have ratified the MEA that is invoked. According to this approach, if a non-WTO rule is invoked, it will be up to the panel and/or the Appellate Body to decide which rule – the WTO or the non-WTO rule – should prevail, in accordance with the relevant conflict rules.

[87] In its very first report (*United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/R, 29 January 1996), the Appellate Body stated that GATT/WTO law is part of international law and acknowledged that the GATT "is not to be read in clinical isolation from public international law" (at 17). In the *Korea – Government Procurement* case (*Korea – Measures Affecting Government Procurement*, WT/DS163, 19 June 2000), the panel stated that the WTO judiciary can fall back on general international law: "Customary international law applies generally to the economic relations between the WTO Members, Such international law applies to the extent that the WTO treaty agreements do not 'contract out' from it" (at 7.96). In the *US-Shrimp* case (*supra*, note 76), the Appellate Body made reference to various international conventions to interpret the term "natural resources" and relied on a non-WTO treaty as a factual reference in its decision that the new US policy was no longer discriminatory in the sense of the chapeau of GATT Art. XX. Joost Pauwelyn concludes "the Appellate Body report on US – Shrimp seems to imply that non-WTO rules can play a role not only as factual reference, but also as valid legal defense" (op. cit, at 465). Moreover: "once such an MEA is concluded, it would be difficult for the Appellate Body to exclude it from the applicable law in case a WTO complaint were brought, for example, against the very trade restrictions imposed or explicitly permitted in the MEA" (op. cit. at 485).

While it is indisputable that the jurisdiction of WTO panels is limited (i.e. claims under WTO-covered agreements only), the issue of applicable law is controversial. Distinguished authors hold opposite views on this crucial issue: some affirm that rules of customary international law, environmental and human rights conventions or bilateral agreements to which disputing parties are bound could be invoked in defence against WTO claims and would be part of the applicable law before the panels and the Appellate Body.[88] Other commentators hold the view that the WTO-covered agreements are the only law applicable in WTO dispute resolution and if panels or the Appellate Body conclude that the WTO provision claimed to have been violated has been superseded by another non-WTO provision, they may decline jurisdiction since no WTO provision seems applicable to the relations between the parties. According to this view, any other solution would go against the fact that panels and the Appellate Body are prohibited from reaching any conclusion that would constitute an amendment to the WTO or that would add to or diminish rights or obligations under the WTO Agreement.[89]

If a dispute occurs between a party and a non-party to the Protocol, the case will most likely be brought to the attention of the WTO Dispute Settlement Body.

The issue of the relationship between the trade rules included in MEAs and WTO rights and obligations, and in particular the issue of which rules would prevail in case the trade provisions of a MEA conflict with WTO rules, has been discussed for several years in various international forums, without any conclusive result.[90] A related unsolved issue is the position on non-parties to a multilateral agreement that may be affected by the trade rules agreed by the parties to a multilateral agreement. The Doha Ministerial Declaration mandated, in para 31(i), negotiations on the relationship between existing WTO rules and specific trade obligation set out in MEAs. WTO Members have agreed in the WTO Committee on Trade and Environment to analyse the "specific trade obligations" of a number of MEAs with a view of examining their interaction with relevant WTO rules. Beyond this factual decision, however, no substantive progress on the issue was made. The topic received almost no attention at the 5th WTO Ministerial Conference in Cancún, and the draft ministerial declaration (not adopted at the end of the meeting) contained a statement only intended to "reaffirm our commitment to these negotiations".[91] The same approach was adopted in the "July package" (document WT/L/579). The text of the General Council's decision on the Doha work programme, agreed on 1 August 2004, reads: "The Council reaffirms Members' commitment to progress in all of these areas of the negotiations [Rules, Trade & Environment and TRIPS] in line with the Doha mandates."

Even though the trade provisions of a multilateral agreement have not yet been challenged before a WTO panel, it may be argued that the Biosafety Protocol is different from other multilateral agreements and that there is a more concrete risk that its WTO compatibility may be challenged. This is because the economic interests involved in international trade in GMOs are huge; public opinion is still very much divided on whether agro-biotechnology is a risk or an opportunity; the United States, which is the single largest producer of GM crops, on one hand has actively participated in the negotiations on the

[88] Pauwelyn, J., *Conflict of Norms in Public International Law – How WTO Law Relates to Other Rules of International Law*, op. cit., *supra*, note 82, at Chapter 8.

[89] Marceau, G., "Conflicts of Norms and Conflicts of Jurisdiction, The relationship between the WTO Agreement and MEAs and other Treaties", op. cit., *supra*, note 83.

[90] According to UNEP, out of 238 MEAs, only 32 contain trade-restrictive provisions.

[91] Draft Cancun Ministerial Text, Second Revision, 13 September 2003.

Protocol but, on the other hand, is not a party to it and is very unlikely to join it (since it has not ratified the CBD), and the Protocol is already being interpreted in divergent ways. According to an analyst,[92] the relationship between MEAs and WTO Agreements has been a peaceful one until now mainly due to the fact that the existing MEAs have a narrow scope, and there exists a widespread consensus, and especially a transatlantic agreement, on the systemic regulatory principles required to deal with the particular issue of concern addressed by the MEAs. On the other hand, a conflict may emerge when an MEA is broad in scope and when there exists regulatory regionalism – precisely the characteristics present in the WTO/Biosafety Protocol relationship.

The inability of the international trade community to solve at the regulatory level the long-standing issue of the relationship between the trade rules included in the MEAs and WTO rights and obligations makes the GMO issue even more complex. Because of its multifaceted implications, this is probably a field where the decision-making process has to remain with Governments (through trade negotiators) and cannot be delegated to the judiciary. To do otherwise would reinforce the increasingly widespread perception that the WTO dispute settlement system is becoming a surrogate to negotiations, since WTO Members are proving unable both to clarify the WTO Agreements and further liberalize international trade through negotiations.[93]

A few weeks before the Biosafety Protocol entered into force, three complaints about EC restrictive measures affecting GMOs and GM crops were officially brought to the attention of the WTO Dispute Settlement Body.[94] More or less at the same time, the EC enacted the new legislation on GMOs and GM food that was described in the section above.

On 7 August 2003, the United States, Canada and Argentina each requested the establishment of a panel on "Measures affecting the approval and marketing of biotech products".[95] According to them, since October 1998 the EC had applied a *de facto* moratorium on the approval of products of agricultural biotechnology. This moratorium had led to (i) the suspension of and failure to consider various applications for approval of agricultural biotechnology products; and (ii) undue delays in finalizing the processing of applications for the approval of such products. The complaining countries also alleged that several EC member States[96] had introduced bans on the importation, marketing or sale of a number of biotech products which had already been approved at Community level, thereby infringing both WTO rules and Community legislation. The approval moratorium and the national marketing and import bans had allegedly restricted imports into the EC of agricultural and food products from the complaining countries.

Further to those complaints, the WTO Dispute Settlement Body established a single

[92] Isaac G.E., "The WTO and the Cartagena Protocol: International Policy Coordination or Conflict?", *Current*, November 4/2003, pp.116-123.

[93] McRae, D., "What is the future of WTO Dispute Settlement?", *Journal of International Economic Law*, 7(1), 2004.

[94] On this issue see: Brack, D., R. Falkner and J. Goll, *The next trade war? GM products, the Cartagena Protocol and the WTO*, The Royal Institute of International Affairs, Sustainable Development Programme, Briefing Paper No. 8, September 2003.

[95] WTO documents: WT/DS291/23; WT/DS292/17; WT/DS293/17 dated August 2003.

[96] Austria, France, Germany, Greece, Italy, Luxembourg and United Kingdom.

panel at its meeting on 29 August 2003. The process of selecting the three panellists proved particularly controversial and, pursuant to paragraph 7 of Article 8 of the DSU, the Director-General of WTO appointed them in early March 2004. Argentina (in respect of the United States' and Canada's complaints), Australia, Brazil, Canada (in respect of the United States' and Argentina's complaints), Chile, China, Colombia, El Salvador, Honduras, Mexico, New Zealand, Norway, Paraguay, Peru, Chinese Taipei, Thailand, Uruguay and the United States (in respect of Canada's and Argentina's complaints) have reserved their right to participate in the Panel proceedings as third parties.[97] The panel's report is expected by mid-2005.

The complaining countries alleged that the measures at issue appeared to be inconsistent with the EC's obligations under the SPS and TBT Agreements, the Agreement on Agriculture and the GATT 1994. More specifically, they alleged violation (some paragraphs or the entirety) of Articles 2, 5, 7 and 8 and Annexes B and C of the SPS Agreement;[98] Articles I, III, X and XI of the GATT 1994;[99] Article 4 of the Agriculture Agreement;[100] and Articles 2 and 5 of the TBT Agreement.[101] Argentina additionally alleged violation of Article 10 of the SPS Agreement and Article 12 of the TBT Agreement, while Canada also alleged violation of Article XXIII 1(b) of the GATT.[102]

A number of provisions included in different WTO Agreements could justify restrictive trade measures imposed by a WTO Member vis-à-vis GMOs or GM products. A Member may invoke the SPS Agreement. This is because measures related to GMOs may have the goal of protecting "human or animal life or health from risks arising from additives, contaminants, toxins or disease-causing organisms in their food, beverages, or feedstuffs" and/or protecting "human life or health from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests". The SPS Agreement also covers measures aimed at protecting the territory of the importing country from other (i.e. other than health) damage arising "from the entry, establishment or spread of pests". The last provision would cover restrictions on

[97] European Communities, *Measures affecting the approval and marketing of biotech products, Constitution of the panel established at the requests of the United States, Canada and Argentina, Note by the Secretariat*, WT/DS291/24, WT/DS292/18 and WT/DS293/18, 5 March 2004.

[98] Article 2 of the SPS Agreement states the basic rights and obligations under the Agreement. Article 5 deals with the assessment of risks and the appropriate level of sanitary or phytosanitary protection and includes the possibility for Members to provisionally adopt SPS measures. Article 7 and Annex B set out the obligations related to transparency, while Article 8 and Annex C deal with control, inspection and approval procedures.

[99] Article I and III include the cornerstone principles of the Most-Favoured Nations (MFN) and of National Treatment (NT). Article X refers to the transparency obligation for Members to publish promptly trade laws and regulations affecting international trade. Article XI refers to the obligation of general elimination of quantitative restrictions.

[100] Article 4 states that Members shall not maintain any of those border measures - such as quantitative import restrictions, import licensing, minimum import prices - which have been required to be converted into customs duties.

[101] Article 2 sets out the rules related to the preparation, adoption and application of technical regulations and includes the concept of "like products". Article 5 spells out the obligations regarding conformity assessment procedures, including that they have to be undertaken and completed as expeditiously as possible.

[102] Article 10 of the SPS Agreements and Article 12 of the TBT Agreement on Special and Differential Treatment refer to the obligation to take into account the special needs of developing countries in the preparation and application of SPS/TBT measures. Article XXIII:1(b) of the GATT 1994 refers to non-violation complains, see *supra*, note 81.

GMOs where the concern is not human or animal health, but that GMOs might spread out of control and become invasive species, or cross-breed with other plants and transfer unwanted genetic material. The critical issue here may be the legal definition of "pest", but any unwanted living organism may be defined as a "pest". This provision of the SPS Agreement seems, therefore, the most directly relevant if the restrictive trade measure at stake is aimed at protecting biodiversity. Measures related to GMOs, in other words, may fall within the spirit, if not the letter, of the SPS Agreement.

The country imposing the trade-restrictive measure has to prove that it is necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence. If the measure is applied on a provisional basis, it must seek to obtain the additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time. There may be some difficulties at present in invoking the SPS Agreement to justify a trade-restrictive measure in respect of GMOs. There is no scientific evidence that clearly identifies the risk that GMOs create for human, animal or plant life or health. If the measure at stake is a trade ban, alternative measures that are less trade-restrictive may be available. If a measure is taken on the basis of the precautionary principle, it has to be reviewed within a reasonable time frame. Moreover, according to recent WTO jurisprudence, the inconclusiveness of scientific evidence cannot in itself justify resort to Article 5.7.

A second option to justify a GM trade-restrictive measure is to invoke the TBT Agreement. Based on its stated objectives, an import ban applying to GMOs or GM products could probably be regarded as a technical regulation falling under the TBT Agreement. According to the jurisprudence in the Asbestos case,[103] a measure which lays down product characteristics – an example of a required product characteristic could be that the food does not contain any material or ingredient that has been subjected to genetic manipulation – is a technical regulation. The requirement that measures not be more trade-restrictive than necessary, and the linked "proportionality test" in respect of the restrictive trade impact of a measure and the risks that non-fulfilment of the stated objectives would create, seem to be relevant in the framework of international trade in biotech products. At the same time, if the stated objective of a measure is the protection of human health or safety, animal or plant life or health, or the environment, the application of the proportionality test would seem to be particularly problematic, considering that there are at present very divergent views on the magnitude of the risk that GMOs might create. On the other hand, some argue that there is no proportionality test included in the TBT Agreement and the issue is only whether the measure chosen is not unnecessarily trade-restrictive, considering the level of protection that a country has chosen. In that case, a country could implement strict technical regulations regarding GMOs, even though the regulations might have a considerable trade-restrictive impact, on condition that they were not more trade-restrictive than necessary.

Another relevant aspect of the TBT Agreement is the concept of "like products". Article 2.1 of the TBT restates the principle of non-discrimination set forth in Article I and Article III of the GATT 1994. If the claimant contends that a technical regulation is incompatible with Article 2.1 of the TBT because it subjects imported genetically modified products to less favourable treatment than conventional products of national or foreign origin, the Panel, in order to determine incompatibility with Article 2.1 of the TBT, would have to establish, *inter alia*, that the

[103] *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, Report of the Appellate Body, *supra*, note 56.

genetically modified and conventional products involved are "like products". In this context, it seems that the issue to consider is whether a genetically engineered product that sufficiently resembles a conventional product in outward characteristics would be considered substantially equivalent to the conventional product. If this were the case, the two products would therefore be regarded as equally safe and should be treated in the same way. The issue of "like products" within the framework of international trade in GMOs has already been brought to the attention of the WTO TBT Committee, but it remains open.

Likewise, the issue of labelling of GMOs and GM crops remains open. Some WTO Members consider that informing consumers through labelling of GM products is a legitimate objective that justifies a trade restriction within the TBT discipline. Others argue that labelling would stigmatise GM products and mislead consumers into thinking that GM products may be unsafe or substantially different from conventional counterparts. Because the legitimacy of mandatory labelling systems relates to the definition of "like" products, it is unlikely to be solved by the TBT Committee. Provisions on information to be included in the accompanying documentation on GMOs and genetically modified commodities have been included in the Biosafety Protocol and further developed by MOP-1, but the problem of the consistency of these provisions with those of the TBT Agreement has not been addressed. The newly enacted EC legislation, which imposes compulsory labelling for all food and food and feed ingredients produced from GMOs, irrespective of whether there is DNA or protein of GM material in the final product, may fall within this gray area of the TBT Agreement. This is again an area where, lacking an agreement among WTO Members, possible clarifications will most likely come from the dispute settlement body.

A third option to justify trade-restrictive measures affecting biotechnology products is to invoke the GATT. In this case the first question to clarify is whether the measure at stake is an import ban (Article XI of GATT) or an internal regulation enforced at the point and time of importation (Article III:4 and Note Ad Article III of GATT). In most cases, in fact, domestic GMO regulatory schemes consist of internal regulations enforced, in the case of imported products, at the point of importation through quantitative restrictions.

The categorization of internal measures, which are externally enforced, as "internal regulations" (Article III) or "quantitative restrictions" on importation (Article XI) has important regulatory implications. While restrictions on importation are prohibited by Article XI:1, Members are permitted by Article III:4 to impose an internal regulation on products imported from other Members provided that it does not discriminate between "like" products. The issue of "likeness" is not at stake in an inquiry under Article XI, while it stands at the heart of the analysis under Article III:4.

If the GM-related trade measure is categorized as an internal regulation, and reviewed under Article III:4 of the GATT, it may be deemed legitimate under that provision, unless it is found to accord to the "like" imported products "less favourable treatment" than it accords to the "like" domestic products. In this case the crucial question, very similar to that under the TBT Agreement, is whether imported genetically modified organisms and products thereof are "like" their domestic conventional counterparts. According to established GATT practice, the four general criteria which provide a framework for analysing the "likeness" of particular products are: (i) physical properties; (ii) end-uses; (iii) consumers' tastes and habits; (iv) and tariff classification.

In the case of GMOs and GM commodities and their conventional substitutes, two of the traditional criteria (i.e. end-use and tariff classification) would point to "likeness", and two (i.e. consumers' perceptions and properties of the products) would point to "non-likeness". The Asbestos case may provide some overall

guidance when addressing this controversial issue. According to the Asbestos jurisprudence, what is of paramount importance to assess "likeness" under Article III:4 of GATT is the competitive relationship between products in the market place. In this case it may be argued that consumers sense GM crops and seeds and their conventional counterparts in a different way (because of the perceived negative health and environmental impacts) and that consumers' perceptions and behaviours in respect of the two sets of items ultimately affect the degree of competitiveness or substitutability of GM crops and seeds and their conventional counterparts in the marketplace. In light of these considerations, it may be difficult to establish that GMOs and their conventional substitutes are "like products".

In the case of processed foods derived from GM materials and their conventional counterparts, "likeness" seems to be confirmed by the application of at least three of the traditional criteria currently applied to determine whether products are "like", namely product characteristics, end-use, and tariff classification. In particular, there is a strong physical similarity between processed foods containing GMOs and GMO-free food products, to the extent that the altered molecular or cellular characteristics of the genetically modified organism contained in the product is usually no longer detectable in the ultimate product. It follows that evidence relating to properties, end-uses and tariff classification indicates that foods containing GM materials and their conventional counterparts are "like".

Assuming that, after careful scrutiny of the factual and legal context in a given dispute, the individual GM-products and conventional products are found to be "like" products, there is a second element that must be established before a measure can be held to be inconsistent with Article III:4: "like" imported products are accorded less favourable treatment than "like" domestic products. Only if "less favourable treatment" is detected, meaning a certain asymmetry between the group of imports as opposed to the group of domestics, can the restrictive trade measure be considered to be in violation of Article III:4. "The term 'less favourable treatment' expresses the general principle, in Article III:1, that internal regulations 'should not be applied…so as to afford protection to domestic production'".[104]

If the measure at stake is found to violate Article XI or Article III:4, it requires justification under Article XX(b) and (g) and the chapeau of Article XX. It is difficult to assess whether or not the measure would be found to come within the scope of Article XX(b) and (g) exceptions. Paragraph (b) requires, *inter alia*, that the measure be "necessary" to protect human, animal or plant life/health. While earlier GATT jurisprudence has interpreted "necessary" as implying a "least-trade-restrictive test", subsequent jurisprudence has not explicitly endorsed that.[105] It appears very difficult, then, to assess how a panel or the Appellate Body would interpret the term "necessary" in a dispute related to a restrictive trade measure affecting GMOs and GM products. Paragraph (g) requires that the measure be aimed at the conservation of exhaustible natural resources. The panel or the Appellate Body would then have to assess whether the release of GMOs into the environment constitutes a challenge to the conservation of exhaustible natural resources, in particular biological diversity. The way in which the panel and Appellate Body will rule would likely depend very much on the specific facts of each case.

[104] Ibid., at 100.

[105] In the *Korean – Beef* case (*Korea - Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161, 169/AB/R, 11 December 2000) the Appellate Body held that "…determination of whether a measure, which is not 'indispensable' may nevertheless be 'necessary' within the contemplation of Article XX(d), involves in every case a process of weighing and balancing a series of factors which prominently include the contribution made by the compliance measure to the enforcement of the law or regulation at issue, the importance of the common interests or values protected by that law or regulation, and the accompanying impact of the law or regulation on imports or exports".

V. CONCLUSIONS

Lacking conclusive scientific evidence on the actual or potential impact of agricultural biotechnology on human and animal health and on the environment, the debate on GMOs continues to be vocal and emotional, and countries continue to hold rather diverging views about the risks and opportunities that agro-biotechnology may bring. Those views are reflected in domestic regulations on the approval, marketing, labelling and documentation requirements for GMOs and GM products that vary substantially from one country to another. The legislation on GMOs and GM products enacted in some regions, and especially in the European Union, is hampering international trade in those products, and it is also claimed to be having indirect negative implications on the transboundary movement of conventional agricultural products.

Countries' attitudes towards agro-biotechnology depend on many factors, but their positions can be classified into three main categories: (i) the position of those countries that have adopted the equivalence principle, have authorized most GM products for production and consumption, and strive for easy and reliable access to foreign markets for their biotechnology exports; (ii) the position of those countries that have mainly adopted the precautionary approach and are imposing strict rules on approval and marketing of GMOs and GM products; and finally (iii) the position of those countries that are still in the first phase of evaluating the risks and benefits that agricultural biotechnology may imply for them, that are striving to develop comprehensive regulatory systems on the issue, and whose main trade-related preoccupation at present is to preventing GM-related regulations and concerns having negative repercussions on their agriculture exports, including exports of conventional products. Many developing countries fall into the third category.

While developed countries have established their national frameworks to deal with agro-biotechnology and biosafety focusing primarily on domestic priorities and strategies, most developing countries are doing so under less flexible circumstances. Instead of enjoying the freedom to assess risks and benefits that agro-biotechnology may bring about and act accordingly, developing countries increasingly seem to be expected to set up their national regulatory schemes based on the requests and expectations of their main trade partners.

As a general rule, domestic regulations should be scrutinized in the light of multilaterally agreed trade rules, if they are likely to have an impact on international trade. The two main legal frameworks applying to trade in agro-biotechnology products are the WTO framework – which is not specific to biotechnology and was actually developed at a time when biotechnology was not an issue – and the Biosafety Protocol which, on the contrary, is a more recent multilateral instrument specifically targeted at GMOs and GM commodities. The two legal frameworks do not seem to be fully consistent with each other. The inability of the international community to decide on how to deal with sectors that are covered by specific multilaterally agreed legal instruments but at the same time are covered by the WTO discipline is *de facto* shifting the responsibility to settle the issue from the decision-making level to the dispute settlement level, from the "legislative" to the "judiciary" branch of the WTO system.

The lack of scientific certainty vis-à-vis the possible impacts of agricultural biotechnology

on health and on the environment and the complexity of the legal framework applying to it – along with the huge economic interests involved and the links that the sector has with human and animal life and health, biodiversity preservation, and ethical and religious concerns – make the whole issue quite prone to disputes. One was indeed brought to the attention of the WTO dispute settlement body in August 2003.

In the event of trade disputes, it is rather uncertain which legal arguments might prevail. They are likely to be different depending on whether GMOs for intentional introduction into the environment, GMOs to be used as food, as feed or for processing, or consumer products derived from GM material are at stake. The relevant WTO provisions may be interpreted in a way supporting the arguments of the claimant, as well as those of the defendant. It is very uncertain what role the Biosafety Protocol may play, the issue of the role of non-WTO law within WTO dispute settlement being controversial. The Protocol may play a role only within its scope, i.e. living organisms for intentional introduction into the environment, living organisms for contained use, and living organisms intended for direct use as food, as feed or for processing, while products thereof are not included. If the WTO Members involved in the dispute are both parties to the Protocol, its provisions may be used as factual evidence, as an instrument that can help in interpreting WTO provisions, or even as the applicable law. However, it will be up to the WTO panels and, possibly, the Appellate Body to decide how much legal weight they wish to give to the provisions of the Protocol. If only one disputing Member is a party to the Protocol, the Protocol could not be used as applicable law, but it may still play a role as proof of certain factual circumstances or as an instrument to interpret WTO treaty terms. However present and possible future disputes are settled, the risk exists that a ruling may be regarded as lacking legitimacy and the dispute settlement body as exceeding the scope of its competence. The ruling may, then, create discontent not only for the country found to be infringing its WTO obligations, but also for civil society at large.

Agro-biotechnology is a particularly challenging issue for developing countries. Their main concern seems to be to find the appropriate balance between pursuing their development objectives and at the same time complying with their multilaterally agreed obligations. The preoccupations that many developing countries may have as exporters of agricultural and food products must be balanced against their role as producers and their responsibility for improving the quantity and quality of agricultural and food products made available to the population, as well as with commitment to environmental preservation. Making these goals mutually supportive is not an easy task, especially for countries that still face major difficulties in dealing with the scientific aspects of biotechnology. Some additional capacity-building efforts on agro-biotechnology and biosafety therefore seem to be required, including efforts to strengthen developing country ability to deal with the international trade dimension of the issue. Efforts may also be needed at the international level to set up a global strategy to deal with new phenomena in a more coherent and systemic manner and avoid *ad hoc* solutions. Bio-engeneering is a recent phenomenon, but the rapid evolution of science and technology will inevitably lead to new scenarios that may be challenging for all countries, but particularly for developing countries.

SELECTED BIBLIOGRAPHY ON INTERNATIONAL TRADE IN AGRO-BIOTECHNOLOGY PRODUCTS

Anderson, K. and Nielsen, C. P. (2004). *Golden Rice and the Looming GMO Trade Debate: Implications for the Poor*, CEPR, Discussion Paper Series No. 4195, January, available at: www.cepr.org/pubs/dps/DP4195.asp.

Antle, J. M. (1999). "Benefits and Costs of Food Safety Regulations", *Food Policy*, vol. 24, pp. 605-623.

Appleton, A. E. (2000). "The Labelling of GMO Products Pursuant to International Trade Rules", *N.Y.U. Environmental Law Journal*, pp. 566-578.

Bailey, R. (2002). *The Looming Trade War Over Plant Biotechnology*, Trade Policy Analysis No. 18, August, Cato Center for Trade Policy Studies, available at: http://www.freetrade.org/pubs/pas/tpa-018.pdf.

Barton, J. H. (1996). "Biotechnology, the Environment, and International Agricultural Trade", *Georgetown International Environmental Law Review*, pp. 95-117.

Baumuller, H. (2003). *Domestic Import Regulations for Genetically Modified Organisms and Their Compatibility with WTO Rules*, Trade Knowledge Network, International Institute for Sustainable Development – International Center for Trade and Sustainable Development, August, available at: http://www.tradeknowledgenetwork.net

Bentley, P.A. (2001). "Re-Assessment of Article XX, Paragraphs (b) and (g) of GATT 1994 in the Light of Growing Consumer and Environmental Concern about Biotechnology", *Fordham International Law Journal*, pp. 107-131.

Berkey, J. O. (1999). "The Regulation of Genetically Modified Foods", ASIL Insights, October, available at: http://www.asil.org/insigh37.htm.

Bernasconi-Osterwalder, N. (2001). "The Relationship Between the Biosafety Protocol and the Rules of the World Trade Organization", in: E. Brown Weiss and J. H. Jackson (eds.), *Reconciling Environment and Trade*, Transnational Publishers.

Boisson De Chazournes, L. and Moise Mbengue, M. (2002). "Le rôle des organes de règlement des différends de l'OMC dans le développement du droit : A propos des OGM", in: J. Bourrinet, S. Maljean-Dubois (eds.), *Le commerce des organismes génétiquement modifiés*, Aix-Marseille, CERIC/La documentation française, pp. 189 ff.

Boisson De Chazournes, L. and Thomas, U.P. et al. (2000). "The Biosafety Protocol: Regulatory Innovation and Emerging Trends", *Revue suisse de droit international et de droit européen*, pp. 513-556.

Brack, D., Falkner, R. and Goll, J. (2003). *The next trade war? GM products, the Cartagena Protocol and the WTO*, The Royal Institute of International Affairs, Sustainable Development Programme, Briefing Paper No. 8, September.

Buckingham, D.E. and Phillips, P.W.B. (2001). "Hot Potato, Hot Potato: Regulating Products of Biotechnology by the International Community", *Journal of World Trade*, pp. 1-31.

Burgiel, S.W. (2002). "The Cartagena Protocol on Biosafety: Taking the Steps from Negotiation to Implementation", *Review of European Community and International Environmental Law*, pp. 53-61.

Busch, M.L. and Howse R. (2003). *A (Genetically Modified) Food Fight*, CD Howe Institute Commentary No. 186, September, available at: http://www.cdhowe.org/english/publications/currentpubs.html

Charnovitz, S. (2000). "The Supervision of Health and Biosafety Regulations by World Trade Rules", *Tulane Environmental Law Journal*, available at: http://www.geocities.com/charnovitz/Tulane.htm.

Cosbey, A. and Burgiel, S. (2000). *The Cartagena Protocol on Biosafety: An Analysis of Results*, IISD Briefing Note, International Institute for Sustainable Development, available at: http://iisd1.iisd.ca/pdf/biosafety.pdf.

Cottier, TH. (2002). "The Implications of the Biosafety Protocol for Trade Law and Policy: Towards Convergence and Integration", in: Bail, C., Falkner R. and Marquard H. (eds.), *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development?*, London, Earthscan and RIIA.

Christoforou, TH. (2004). "The Regulation of Genetically Modified Organisms in the European Union: the Interplay of Science, Law and Politics", *Common Market Law Review*, pp. 637-709.

_____ (2002). "Science, Law and Precaution in Dispute Resolution on Health and Environmental Protection: What Role for Scientific Experts?", in Le Commerce international des organismes génétiquement modifies, Monde européen et international, sous la direction de J. Bourrinet et S. Maljean-Dubois, pp. 213-284.

Daemen, TH. J. (2003). "The European Community's Evolving Precautionary Principle – Comparisons with the United Stats and Ramifications for Doha Round Trade Negotiations", *European Environmental Law Review*, January, pp. 6-19.

Douma, W. TH. (2000). "The Precautionary Principle in the European Union", *Review of European Community and International Environmental Law*, pp. 132- 143.

Echols, M. A. (1998). "Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws", *Columbia Journal of European Law*, pp. 525-543.

_____ (2001). *Food Safety and the WTO. The Interplay of Culture, Science and Technology*, Kluwer Law International, London.

Eggers, B. and MacKenzie, R. (2000). "The Cartagena Protocol on Biosafety", *Journal of International Economic Law*, pp. 525-543.

Giampietro, M. (2002). "The Precautionary Principle and Ecological Hazards of Genetically Modified Organisms", *Ambio*, pp. 466-470, available at: http://www.ambio.kva.se/.

Hagan, P.E. and Weiner, J.B. (2000). "The Cartagena Protocol on Biosafety: New Rules for International Trade in Living Modified Organisms", *Georgetown International Environmental Law Review*, pp. 697 ff.

Hervey, T.K. (2001). "Regulation of Genetically Modified Products in a Multi-Level System of Governance: Science or Citizens?", *Review of European Community and International Environmental Law*, pp. 321-326.

International Agricultural Trade Research Consortium (2001). "The Role of Product Attributes in the Agricultural Negotiations", Commissioned Paper No. 17, May.

Isaac, G.E. (2003). *The WTO and the Cartagena Protocol: International Policy Coordination or Conflict?*, Current – Agriculture, Food & Resource Issues, Number 4, pp. 116-123, available at: www.CAFRI.org.

Isaac, G.E. and Kerr, W.A. (2003). "Genetically Modified Organisms at the World Trade Organization: A Harvest of Trouble", *Journal of World Trade* 37(6).

James, C. (2002). *Report: GM Crop Update 2002*, International Service for the Acquisition of Agri-biotech Applications (ISAAA), available at: http://www.isaaa.org/.

Jazra Bandarra, N. (2002). "Cadre communautaire réglementaire pour les organismes génétiquement modifiés", *Revue du marché commun et de l'Union européenne*, n. 456, pp. 187-194.

Kameri-Mbote, P. (2002). "The Development of Biosafety Regulation in Africa in the Context of the Cartagena Protocol - Legal and Administrative Issues", *Review of European Community and International Environmental Law*, pp. 62-73

Katz, D. (2001). "The Mismatch between the Biosafety Protocol and the Precautionary Principle", *Georgetown International Environmental Law Review*, pp. 949-982.

Kerr, W.A. (1999). "International Trade in Transgenic Food Productivity: A New Focus for Agricultural Trade Disputes", *The World Economy*, 2, pp. 245-259.

Krenzler, H.G. and MacGregor, A. (2000). "GM Food: The Next Major Transatlantic Trade War?", *European Foreign Affairs Review*, pp. 287-316.

MacKenzie, D.J. and McLean Morven A. (2004). "Agricultural Biotechnology: A Primer for Policymakers", in *Agriculture and the WTO – Creating a Trading System for Development*, The World Bank, pp. 237-253.

MacKenzie, R. and Francescon, S. (2000). "The Regulation of Genetically Modified Foods in the European Union: An Overview", *Environmental Law Journal*, pp. 530-555.

MacKenzie, R., Burhenne-Guilmin, F., La Viña, A.G.M. and Werksman, J.D. in cooperation with Ascencio, A., Kinderlerer, J., Kummer, K. and Tapper, R. (2003). *An Explanatory Guide to the Cartagena Protocol on Biosafety*, IUCN, Gland, Switzerland and Cambridge, UK.

Maljean-Dubois, S. (2000). "Biodiversité, biotechnologies, biosécurité: le droit international désarticulé", *Journal du droit international*, pp. 949-996.

Marceau, G. (2001). "Le principe de précaution et les règles de l`Organisation Mondiale du Commerce", in: C. Leben and J. Verhoeven (eds.), *Le principe de précaution et le droit international*, pp. 131-149.

Matthee, M. and Vermesch, D. (2001). "The International Integration of European Precautionary Measures on Biosafety", *European Environmental Law Review*, pp. 183-193.

Murphy, S. D. (2001). "Biotechnology and International Law", *Harvard International Law Journal*, pp. 47-139.

Musselli, I. and Zarrilli, S. (2002). "Non-Trade Concerns and the WTO Jurisprudence in the Asbestos Case: Possible Relevance for International Trade in Genetically Modified Organisms", *Journal of World Intellectual Property*, pp. 373-393.

Nielsen, C.P. and Anderson, K. (2000). *GMOs, Trade Policy and Welfare in Rich and Poor Countries*, CIES Discussion Paper No. 21, Centre for International Economic Studies, University of Adelaide.

Nielsen, C.P., Robinson, S and Thierfelder, K. (2001). "Genetic Engineering and Trade: Panacea or Dilemma for Developing Countries", *World Development*, pp. 1307-1324

Nuffield Council on Bioethics, *Genetically Modified Crops: the Ethical and Social Issues*, available at: www.nuffieldfoundation.org .

Paarlberg, R. (2002). *The Contested Governance of GM Foods: Implications for U.S.-EU Trade and the Developing World*, Working Paper, Weatherhead Center for International Affairs, Harvard University.

Pepa, S.M. (1998). "International Trade and Emerging Genetic Regulatory Regimes", *Law and Policy in International Business*, pp. 415 ff.

Perdikis, N. and Kerr, W.A. (1999). "Can Consumer-Based Demands for Protection Be Incorporated in the WTO? – The Case of Genetically Modified Foods", *Canadian Journal of Agricultural Economics*, pp. 457-465.

Perdikis, N., Kerr, W.A. and Hobbs, J.E. (2000). "Can the WTO/GATT Agreements on Sanitary and Phyto-Sanitary Measures and Technical Barriers to Trade Be Renegotiated to Accommodate Agricultural Biotechnology?", in: W.H. Lesser (ed.), *Transitions in Agbiotech: Economics of Strategy and Policy*, University of Connecticut, Food Marketing Policy Center, available at: http://agecon.lib.umn.edu.

_____ (2001). "Reforming the WTO to Defuse Potential Trade Conflicts in Genetically Modified Goods", *The World Economy*, pp. 379-398.

Phillips, P. W.B. and Kerr, W.A. (2000). "Alternative Paradigms – The WTO versus the Biosafety Protocol on Trade in Genetically Modified Organisms", *Journal of World Trade*, 4, pp. 63-75.

_____ (2002). "Frustrating Competition Through Regulatory Uncertainty – International Trade in the Products of Biotechnology", *World Competition*, 1, pp. 81-99.

Qureshi, A.H. (2000). "The Cartagena Protocol on Biosafety and the WTO – Co-existence or Incoherence?", *International and Comparative Law Quarterly*, pp. 835-855.

Runge, C.F. and Jackson, L.A. (2000). "Labelling, Trade and Genetically Modified Organisms: A Proposed Solution", *Journal of World Trade*, 1, pp. 111-122.

Safrin, S. (2002). "Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements", *American Journal of International Law*, pp. 606-628.

Scott, J. and Vos, E. (2001). "The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO", in: R. Dehousse and C. Joerges (eds.), *Good Governance in an Integrated Market*, Oxford, Oxford University Press.

Sheldon, I. and Josling, T. (2002). *Biotechnology Regulations and the WTO*, Working Paper No. 02.2, International Agricultural Trade Research Consortium, January.

Shoenbaum, TH. J. (2000). "International Trade in Living Modified Organisms: The New Regimes", *International and Comparative Law Quarterly*, pp. 856-866.

Steiner, M.P. (2000). "Food Fight – The Changing Landscape of Genetically Modified Foods and the Law", *Review of European Community and International Environmental Law*, pp. 152- 159.

Teel, J. (2000). "Regulating Genetically Modified Products and Processes: An Overview of Approaches", *Environmental Law Journal*, pp. 649- 703.

Victor, D.G. and Runge, C.F. (2002). "Farming the Genetic Frontier", *Foreign Affairs*, 3, pp. 107-121.

Vogel, D. (1997). "Social Regulations as Trade Barriers", in: P. Nivola (ed.), *Comparative Disadvantages? Social Regulations and the Global Economy*, Washington DC, Brookings Institution Press.

Von Moltke, K. (1999). "The Dilemma of the Precautionary Principle in International Trade", in Bridges Between Trade and Sustainable Development, 3 (6), pp. 3-4, available at: http://www.ictsd.org/.

Wang, X. (2004). "Challenges and Dilemmas in Developing China's National Biosafety Framework", *Journal of World Trade*, pp. 899-913.

Wolff, CH. (2001). *Resolving Possible Conflicts between Domestic and International Biotechnology Regulations and WTO Rules*, ICTSD Workshop on Biotechnology, Biosafety and Trade: Issues for Developing Countries, 18-20 July, available at: http://www.ictsd.org/dlogue/2001-07-19/Wolff.pdf.

Zarrilli, S. with the collaboration of I. Musselli (2004). "The Sanitary and Phytosanitary Agreement, Food Safety Policies, and Product Attributes", in *Agriculture and the WTO – Creating a Trading System for Development*, The World Bank, pp.217-236.

Zarrilli, S. (2000). *International Trade in Genetically Modified Organisms and Multilateral Negotiations – A New Dilemma for Developing Countries*, UNCTAD/DITC/TNCD/1, Geneva, 20 October.

Zedalis, R.J. (2001). "Labelling of Genetically Modified Foods – The Limits of GATT Rules", *Journal of World Trade*, pp. 301-347.

_____ (2002). "GMO Food Measures as Restrictions under GATT Article XI(1)", *European Environmental Law Review*, January, pp. 16-28.

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