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INTERNATIONAL TRADE IN GMOS: LEGAL FRAMEWORKS AND DEVELOPING COUNTRY CONCERNS

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Executive summary

The debate about genetically modified organisms (GMOs) is vocal and passionate. This is probably the consequence of the diverging views among people and Governments of the actual or potential risks and benefits that GMOs and products thereof can bring about. The proliferation of domestic biosafety schemes is likely to further complicate international trade in agro-biotechnology products and to indirectly affect international 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 makes access to seeds more difficult or changes the structure of food production systems. At the multilateral trade level, rules on transboundary movement of GMOs have been agreed upon in a specific legal instrument, the Cartagena Protocol on Biosafety, which recently entered into force. The interaction between this instrument and WTO rules adds challenges to an already complex scenario and might lead to international trade disputes. Developing countries must balance their trade interests with their responsibility to improve the quantity and quality of agricultural and food products made available to the population, as well as with their 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 agro-biotechnology, including risk assessment. Additional capacity-building efforts, including with reference to the international trade dimension of the issue, therefore seem necessary.

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INTRODUCTION

1. 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, modern biotechnology identifies desirable traits more quickly and accurately than conventional plant and livestock breeding and allows gene transfers across species, genera and families, 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. While there is not at present a multilaterally agreed definition of GMOs, the EC has defined a genetically modified organism as follows: "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] This definition, however, cannot be regarded as universally accepted.

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 producers, who can obtain higher yields and/or lower costs. A shift is, however, occurring from the current generation of "agronomic" traits to the next generation of "quality" traits, from which consumers, more than producers, would be able to benefit.

3. 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. Although there is not yet any definite scientific evidence of harm to human beings, animals or the environment, the public is concerned because of a history of revelations of health and environmental dangers in other fields, especially in the chemical sector. Economic preoccupations have also been voiced, the main concern being that a few large firms will enjoy monopoly power on the seed market derived from intellectual property protection. This development may change the nature, structure and ownership of food production systems and could aggravate food security problems that are allegedly caused not so much by food shortages as by inequity, poverty and concentration of food production. 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. Finally, modern biotechnology techniques may raise ethical and religious concerns.

4. Country 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. Assessments of the risks and benefits related to

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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".

[2] This definition is provided in Article 2(2) of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, OJ L 106, 17.04.2001. GMO is not actually a scientific term nor was it coined by scientists. "Transgenic organisms", on the other hand, is a scientific term: it refers only to organisms that have acquired genetic material from other organisms.

agro-biotechnology vary substantially between countries and regions, as do regulatory approaches (e.g. rules on GM approval, marketing, import, labelling, documentation). Diverging domestic requirements may hamper international trade and further complicate an already difficult regulatory system in the area of agricultural products.

I. EXAMPLES OF DOMESTIC LEGISLATION ON AGRO-BIOTECHNOLOGY

5. According to figures from the International Service for the Acquisition of Agri-biotech Applications (ISAAA), the global area of GM crop plantation has grown 40-fold since 1996, and the estimated global GM crop area in 2003 was around 67.7 million hectares, cultivated by seven million farmers in 18 countries. Herbicide-tolerant soybean was the dominant transgenic crop, followed by Bt maize[3] and herbicide-tolerant canola. Six countries accounted for 99 per cent of the global transgenic crop area (United States, 63 per cent of global total; Argentina, 21 per cent; Canada, 6 per cent; Brazil and China, 4 per cent each; and South Africa, 1 per cent). Minor plantings were found in Australia, India, Uruguay, Romania, Mexico, Honduras, Bulgaria, Spain, Germany, Indonesia, the Philippines and Colombia. Almost one-third of the global transgenic crop area in 2003 was in developing countries. In the same year, the global market value of GM crops was estimated to be between US$ 4.5 to US$ 4.75 billion. The market value is based on the sale price of transgenic seed plus any technology fees that apply. [4]

6. Although continuously expanding, GM crop plantings are still confined to a rather small number of countries. Apart from suspected or scientifically proven 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.

7. GMO regulations are based on an assessment of the actual or potential risks that those products may engender. Such an 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 will be 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”.[5] Three basic conditions may thus trigger application of protective measures: uncertainty, risk, and lack of proof of direct causal link.[6]

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. The meat hormones dispute between the EC and the United States/Canada – which shares similarities with the present GMO dispute – well illustrates diverging approaches to

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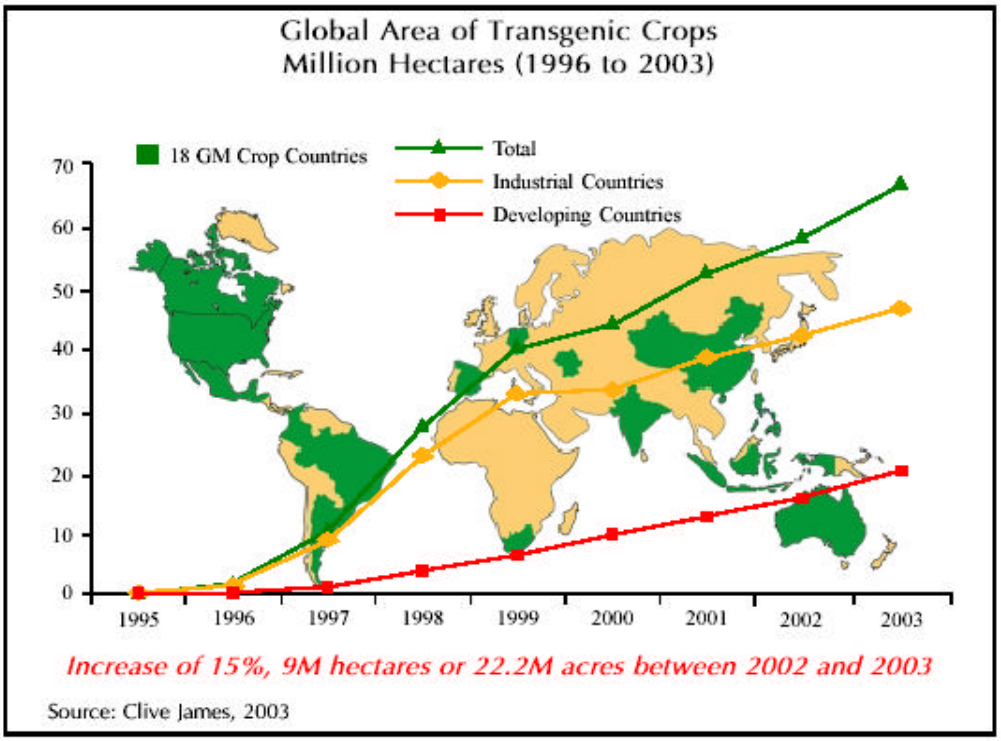
[3] Bt plants produce their own pesticide through a gene borrowed from the bacterium *Bacillus thuringiensis*.

[4] For detailed information and data, see: James, C., *Preview, Global Status of Commercialized Transgenic Crops: 2003*, ISAAA Briefs, No. 30, 2003, available at: www.isaaa.org . ISAAA is a not-for-profit organization with centres based in the Philippines, Kenya and the United States.

[5] 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.

[6] *Ibid*., p. 243.

regulation under uncertainty.[7] It typifies trans-Atlantic differences vis-à-vis the relevance of the precautionary principle in risk assessment.[8]



9. The United States, Canada and Argentina, major agricultural exporters, have applied the conventional risk assessment approach to GMOs substantially, especially during the first years of the agro-biotechnology revolution, and have widely authorized most GM products for production and consumption. They are striving for easy and reliable access to foreign markets for their bio-

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[7] WT/DS26 and WT/DS48 – *European Communities - Measures Affecting Meat and Meat Products (Hormones)*. The Panel dealt with a complaint by the United States and Canada against the European Communities relating to an EC prohibition of imports of meat and meat products derived from cattle to which six specific hormones had been administered for growth promotion purposes.

[8] 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 (EC's appellant's submission, para. 91) 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 (United States' appellee's submission, para. 92). The Appellate Body agreed with the finding of the Panel that the precautionary principle does 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.

engineered products. The international policy conflict over GMOs is fragmenting international markets, thereby decreasing economies of scale; producers of GMOs, however, depend on economies of scale to recoup the considerable R&D 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.[9]

10. 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. Australia and New Zealand have established processes for pre-market approval and implement mandatory labelling of GMOs.

11. Since the early 1990s, the European Communities (EC) have developed and continuously refined a rather complex legislative framework related to GMOs and GM food. Directive 2001/18,[10] which became fully applicable on 17 October 2002 and replaced Directive 90/220EEC,[11] deals with the deliberate release into the environment of GMOs for experimental purposes and with the placing of products on the Community market that consist of or contain GMOs, such as maize, tomatoes, or micro organisms. It pursues the objectives of protecting human health and the environment. To achieve its objectives, the Directive requires a case-by-case evaluation of potential risks to human health and the environment before any GMO or product consisting of or containing GMOs can be placed on the market or in any other way released into the environment within the Community. On the basis of that risk assessment, a market authorization is either granted or refused.

12. The level of appropriate health and environmental protection chosen in the Directive is a level of "no risk". Because the authorization for the release into the environment 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. The Directive introduces a mandatory post-marketing monitoring system of GMOs and traceability at all stages of their being placed on the market. It also establishes an advanced system for directly informing and consulting the general public during the authorization procedure and, finally, it establishes a labelling system.[12]

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[9] 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.; and 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.

[10] *Supra*, note 2. Directive 2001/18 was amended by Regulation 1830/2003. See the EC website on GMOs at: http://www.europa.eu.int/comm/food/fs/gmo/gmo_index_en.html.

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

[12] 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:

13. 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 deals, *inter alia*, with products derived from GMOs but no longer containing any GM material, such as food products like paste or ketchup derived from a GMO tomato.[13] The current relevance of Regulation 258/97, which has been substantially modified by subsequent legislation, is based on the fact that food products from 13 GMOs were approved for marketing while it was in force and eight applications for GM foods are currently at different stages in the authorization procedure. On the other hand, 18 GMOs were authorized under the "horizontal" legislation and 22 applications are still pending. Around the mid-1990s, a number of EC Member States started raising questions on potential adverse effects of GMOs and GM products on health and the environment and raised objections to the placing on the market of new GMOs. As a result of those concerns and the negotiations on the Biosafety Protocol, no new GMOs were approved during the period October 1998 – April 2004. The authorizations that were granted have given rise to disputes within the Community.[14] 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 mechanism.[15]

14. 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. The new Regulations have been in force since 18 April 2004. Regulation 1829/2003,[16] which has substantially modified Regulation 258/97, provides for Community procedures for the authorization and supervision of GM food and feed, and includes specific provisions for their labelling. 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. The process or production method of the GM food or feed is now a relevant factor

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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.

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

[14] Some Member States invoked Article 16, the so-called safeguard clause, of Directive 90/220/EEC to temporarily ban the placing on the market of genetically modified maize and oilseed rape products in their territories. There are currently nine outstanding Article 16 cases involving Austria, Luxembourg, France, Greece, Germany and the United Kingdom. These cases have been examined by the Scientific Committee on Plants, which in all cases deemed that the information submitted by Member States did not justify the bans. The Commission has informed Member States that they should now withdraw their measures under Directive 90/220/EEC and lift the prohibitions. Italy imposed a national safeguard measure under the Novel Food regulation. At present, work is progressing on finalizing a decision aiming at repealing this national safeguard measure.

[15] Three complaints about EC restrictive measures affecting GMOs and GM crops were officially brought to the attention of the WTO Dispute Settlement Body by the United States, Canada and Argentina in August 2003. 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 allegedly restricted imports into the EC of agricultural and food products from the complaining countries and was in violation of EC's obligations under the SPS and TBT Agreements, the Agreement on Agriculture and the GATT 1994. The complaining countries also alleged that several EC member States 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. See WTO documents: WT/DS291/23; WT/DS292/17; WT/DS293/17 dated August 2003. 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.

[16] OJ L 268, 18/10/2003, pp. 1-23.

that justifies labelling. The presence of GM material in conventional food does not have to be labelled if it is below 0.9 per cent and if it can be shown to be adventitious and technically unavoidable. Regulation 1830/2003[17] 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. Traceability is meant to facilitate a withdrawal of food and feed from the market if any unexpected adverse effects were to arise.

15. As expected, following the promulgation of the new regulations, the EC has restarted granting GM authorizations. On 9 May 2004, the European Commission authorized the placing on the market of sweet corn from GM maize, under the novel food legislation. The 10-year authorization covers the specific use of canned or fresh sweet corn for imports, while an authorization for cultivation of Bt maize is pending and has not yet been granted.[18] On 19 July 2004, under Directive 2001/18/EC the European Commission authorized the placing on the market of Monsanto NK603 GM maize for imports 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.[19] It remains to be seen what impact the recent authorizations will have on the current WTO dispute related to the EC moratorium.

16. The United States' regulatory system relative to biotechnology products is rather different from the one in place in the EC. 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:[20] 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.[21] Likewise, new regulations have been formulated under existing laws[22] as needed to address genetically engineered products that have been developed.

17. 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. 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 a recent development, the USDA has declared its intention to update and strengthen its biotechnology regulations for GMOs. Currently, companies creating new transgenic plants must submit an application to the USDA and the 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 broader in

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[17] O.J. L 268, pp. 24-28. See also European Commission Press Release IP/03/1056, *European legislative framework for GMOs is now in place*, 22 July 2003.

[18] 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.

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

[20] United States Federal Register, June 26, 1986, 51 FR 23302.

[21] The Food and Drug Administration (FDA) 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, and the Environmental Protection Agency (EPA) is responsible for development and release for GM plants with pest control properties.

[22] 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).

scope, and will encompass threats to the environment and public health. The USDA will prepare an environmental impact statement to evaluate biotechnology regulations and several possible regulation changes. This will also include a multi-tiered, risk-based permitting system to replace the current permit/notification system, as well as a more flexible process for monitoring.[23]

18. As for the developing countries, the major GM crops approved for commercial release are Bt cotton, which is grown commercially in China, India and Indonesia. China's Bt-cotton planting was officially estimated at 2.8 million hectares in 2003, corresponding to 58 per cent of the global cotton planted area. However, due to seed smuggling, the actual GM-planted area may be much bigger, and it is playing an important role in the return of production in some provinces where acreage had declined.[24] Changes in China's cotton production have the ability to affect both global cotton production and trade in textiles and apparel. 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 (the authorization was 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.

19. 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) R&D, e.g. 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 health and environment risks, minimum distance from organic agriculture or non-GM fields, labelling, post-commercialization monitoring, liability; and (c) import regulations.[25] In setting up domestic legislation, developing countries seem to be paying increasing attention to international trade concerns.

20. 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". 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 on 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 allegedly already taking place because of company practices to replace some

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23 "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

24 MacKenzie, D.J. and M.A. McLean, "Agricultural Biotechnology: A Primer for Policymakers", in *Agriculture and the WTO – Creating a Trading System for Development*, World Bank, 2004, at pp. 238-239.

25 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, available at: http://www.isnar.cgiar.org/ibs/biosafety/regulatory.cfm.

inputs with others (which do not bear the risk of being genetically modified) or to 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.

21. 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 of Zambian food exports by EC countries. The Zimbabwean Government agreed in July 2002 to allow food aid into the country 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.[26] 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.[27] At the 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 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 the GM food restrictions until January 2005) and Angola will accept GM food aid only on condition that the whole 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.[28] 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.[29]

22. 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

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

[27] "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

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

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

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 such a system, 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.[30]

23. Following those recommendations, in May 2004 SADC approved guidelines on handling GM food aid. The guidelines fully endorse the recommendations of the SADC Advisory Committee on Biotechnology and Biosafety.[31]

24. Those 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 on the environment, and to the fact that GM imports may jeopardize exports of conventional agricultural products. These preoccupations, however, must be balanced with Governments' 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.

II. THE MULTILATERAL LEGAL FRAMEWORK

25. Relevant WTO rules concerning international trade in GMOs and products thereof can be found 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. Disciplines regarding transboundary movement of GMOs, however, have also emerged from the Cartagena Protocol on Biosafety. Though most of the rules included in the different legal instruments are consistent with each other, there are a few areas where some discrepancies may be found.

Cartagena Protocol on Biosafety

26. The Cartagena Protocol on Biosafety,[32] which was negotiated under the auspices of the Convention on Biological Diversity, was adopted on 29 January 2000 and entered into force on 11 September 2003. As of 15 August 2004, 107 countries, including the EC, had ratified or acceded to it.[33]

27. 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.

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

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

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

[33] This section of the paper 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. 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.

28. The Protocol distinguishes three categories of LMOs: LMOs for voluntary introduction into the environment (e.g. seeds for planting, live fish for release, micro-organisms for bioremediation); LMOs destined for contained use (LMOs that have limited contact with and impact on the external environment); and LMOs intended for direct use as food or feed, or for processing (LMO-FFPs). The last-named represent the large majority of internationally traded 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. LMOs 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)). 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.

29. The first Meeting of the Parties to the Protocol (MOP-1) was held in Malaysia in February 2004 and ended with the adoption of 10 decisions. Three of them are especially significant for the actual implementation of the Protocol: (a) MOP-1 decided on the documentation that should accompany the three categories of LMOs;[34] (b) some compliance procedures and mechanisms were established and a Compliance Committee was set up to receive cases of non-compliance submitted to it; (c) a working group of experts on liability and redress was set up and it was agreed that an appropriate regime would be developed by 2008. 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 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.[35]

The interface between the Biosafety Protocol and the WTO Agreements

30. It seems there are four aspects of the Protocol that might give rise to some overlaps and tensions with WTO law: (a) the scope for legitimate government action without conclusive scientific

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[34] 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) of the Protocol. 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.

[35] 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.

evidence; (b) risk assessment and risk management; (c) the socio-economic factors which may be taken into account in the decision-making process; and (d) documentation requirements.

31. The precautionary approach is one of the main features of the Protocol. 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". 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. In contrast, the SPS Agreement allows countries to adopt sanitary or phytosanitary measures provisionally when relevant scientific evidence is insufficient – this concept being different from scientific uncertainty – 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 (Art. 5.7).

32. For LMOs destined 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, but 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 or feed or for processing.

33. WTO jurisprudence has addressed the issue of the precautionary principle within the SPS Agreement. In the *Japan varietals* case,[36] the Appellate Body stated that Article 5.7 sets out four cumulative requirements that must be met to adopt and maintain 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.

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

34. The recent *Apples* case[37] seems to be particularly relevant for the analysis of the interface between the WTO rules and those of the Biosafety Protocol. The Appellate Body confirmed the need for the above-mentioned 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."[38] 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 two concepts are not interchangeable."[39] 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 to the latter situation.

35. Turning to the second potential aspect of conflict between WTO rules and the Biosafety Protocol, Article 15 of the Protocol 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, the cost can be recovered from the potential exporter. Risk assessment is also to be used for LMO-FFPs and is among 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 LMOs-FFP will be taken in accordance with a risk assessment as set out in the Protocol and timeframe for decision-making.

36. In dealing with the same issue, the SPS Agreement states that SPS measures should be based on an assessment of the risks to human, animal or plant life or health. Members are free to determine the appropriate level of sanitary and phytosanitary protection (ALOP), but in doing so, they should minimize negative trade effects (Art. 5.4). In dealing with the measures taken to achieve the ALOP, the 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.

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[37] Japan – Measures Affecting the Importation of Apples, WT/DS245/AB/R, 26 November 2003

[38] *Ibid*., at 179.

[39] *Ibid*., at 184.

This means that if there is an alternative measure that is 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. 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.

37. 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 for the Party of import to ensure 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.

38. 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 then 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 (Article 5.3). These same considerations do not apply to the assessment of risk to human health. In an early dispute, a GATT Panel rejected trade restrictions that were solely justified on the grounds that cheap imports would undermine the traditional livelihoods of a certain minority population.[40]

39. Finally, Article 18 of the Biosafety Protocol sets forth rules related to handling, transport, packaging and identification requirements. The rules agreed upon at the first Meeting of the Parties (MOP-1) with reference to LMOs-FFPs seem to mark a step beyond the requirements originally included in Article 18.2(a): they urge Governments to require information on the name of the organism and the transformation event or unique identifier code. Compliance with this requirement is 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. Documentation and labelling requirements related to food, nutrition claims and concerns, quality and packaging regulations are normally subject to the TBT Agreement. Article 2.1 of the TBT restates the principle of non-discrimination set forth in Articles I and III of the GATT 1994, as far as imported products and "like" products of domestic origin or originating in any other country are concerned. In this context, it seems that the issue to consider is whether a genetically

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[40] *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*, IUCN Environmental Policy and Law Paper No. 46, IUCN - The World Conservation Union, 2003, at 238-239.

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.

III. POSSIBLE GM-RELATED TRADE DISPUTES

40. 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 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 the imports, such as mandatory labelling requirements.

41. WTO law is not very helpful either in this regard, since it does not include a conflict clause (i.e. it does not clarify its relationship with pre-existing or future treaties). Principles of international and customary law will therefore apply (see below).

42. 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 multilateral environmental agreements (MEAs).[41]

43. 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.[42] However, if a party believes that in a specific circumstance its interests are better protected by WTO rules,[43] 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 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 market access rights have been violated.

44. On the other hand, if a Party to the Biosafety Protocol has an interest in solving the dispute it has with another Party to the Protocol outside the WTO and according to the discipline laid down in the 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

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[41] 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.

[42] 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.

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

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 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.

45. 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.[44] 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 to justify, within a WTO dispute, trade restrictions taken 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 makes 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, the essential precondition is that both disputing parties are 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.

46. While it is indisputable that the jurisdiction of WTO panels is limited (i.e. claims under WTO covered agreements only), the issue of the 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.[45] 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

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[44] 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. In the US-*Shrimp* case (*United States-Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, 12 October 1998), 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.

[45] 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 Chapter 8.

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.[46]

47. 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, where, as mentioned before, the country party to the Biosafety Protocol may refer to it as a useful tool both for assessing the facts and for interpreting WTO obligations.

48. The issue of the relationship between trade rules included in MEAs and WTO rights and obligations, and in particular the issue of which rules would prevail if the trade provisions of an MEA conflict with WTO rules, has been discussed for several years in various international forums, without any conclusive result. A related unsolved issue is the position on non-parties to a multilateral agreement that may be affected by trade rules agreed by parties to a multilateral agreement.

49. Even though the trade provisions of an MEA have not yet been challenged before a WTO panel, it may be argued that there is a more concrete risk that the compatibility of the Biosafety Protocol and the WTO rules may be questioned. This is because the economic interests involved are huge, because the issue bears important health, environmental and ethical implications, and because of the existence of regulatory regionalism (i.e. a deep transatlantic disagreement on the issue).[47] 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 branch of the WTO system.[48] To do otherwise would reinforce the increasingly widespread perception that the dispute settlement system is becoming a surrogate for negotiations, since WTO Members are proving unable both to clarify the WTO Agreements and to further liberalize international trade through negotiations.[49] Moreover, when very sensitive issues are at stake, the use of judicial dispute settlement may be neither constructive nor likely to promote a country's goals.[50]

IV. CONCLUSIONS

50. Lacking conclusive scientific evidence on the actual or potential impact of agricultural biotechnology on health and on the environment, the GMO debate continues to be vocal and emotional, and countries continue to hold rather diverging views about the risks and opportunities that agro-biotechnology may bring about. Those views are reflected in domestic regulations on GMOs and GM products that vary substantially from one country to another. Diverging rules are hampering international trade in those products and might have indirect negative implications for the transboundary movement of conventional agricultural products.

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[46] Marceau, G., "Conflicts of Norms and Conflicts of Jurisdiction, The relationship between the WTO Agreement and MEAs and other Treaties", op. cit., *supra*, note 41.

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

[48] Cottier, Th. and M. Oesch, "The Paradox of Judicial Review in International Trade Regulation: Towards a Comprehensive Framework", in Thomas Cottier and Petros C. Mavroidis (eds.), *The Role of the Judge in International Trade Regulation: Experience and Lessons from the WTO*, 2003, pp. 287-306.

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

[50] Esserman, S. and R. Howse, "The WTO on Trial", *Foreign Affairs*, January/February 2003.

51. Countries' attitudes on agro-biotechnology depend on many factors, but their positions could be classified into three main categories: (a) the position of those countries that consider transgenic products by and large as equivalent to conventional products, have authorized them for production and consumption, and strive to have easy and reliable access to foreign markets; (b) 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 (c) the position of those countries that are still in the first phase of evaluating the risks and benefits that agro-biotechnology may imply for them, that are striving to develop comprehensive regulatory frameworks on the issue, and whose main trade-related preoccupation at present is to prevent GM regulations and concerns having negative repercussions on their agriculture and food exports, including those of conventional products. Many developing countries fall into the third category.

52. 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 seem to be increasingly expected to set up their national regulatory schemes based on the requests and expectations of their main trade partners.

53. As a general rule, domestic regulations are 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 to 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.

54. The lack of scientific certainty vis-à-vis agricultural biotechnology and the complexity of the legal framework applying to it – along with the formidable economic interests involved and the links that the sector has with health, environmental, ethical and religious concerns – make the whole issue quite prone to disputes. One was indeed recently brought to the attention of the WTO dispute settlement body.

55. In the case of trade disputes, it is rather uncertain which legal arguments may prevail. The relevant WTO provisions may be interpreted in a way supporting the reasons of the claimant, as well as those of the defendant. It is very uncertain which role the Biosafety Protocol may play, since the issue of the function of non-WTO law within the WTO system, including dispute settlement, is still not settled. In any case, the Biosafety 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, feed or for processing, while the products thereof are not included. Whatever way present and possible future disputes are settled, the risk exists that the ruling may be regarded as lacking legitimacy and the WTO panels and Appellate Body as exceeding the scope of their mandate. The ruling may, then, create discontent not only for the country found infringing its WTO obligations, but also for civil society at large.

56. Biotechnology is a particularly challenging issue for developing countries. Their main concern seems to be finding 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 with their role of producers and their responsibility to improve the quantity and quality of agricultural and food products made available to the population, as well as with their 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. Additional capacity-building efforts on agro-biotechnology and biosafety therefore seem to be required, including for strengthening developing countries' 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.

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