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INTERNATIONAL TRADE IN GENETICALLY MODIFIED ORGANISMS AND MULTILATERAL NEGOTIATIONS

A New Dilemma for Developing Countries

by

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Executive summary

1. *In order to be able to export their products, developing countries increasingly have to be able to prove that they comply with the standards and regulations of the importing countries. Standards and regulations are aimed at ensuring,* inter alia, *that domestically produced and imported products are safe, of good quality and have as little a detrimental effect on the environment as possible. For quite a long time developing countries' main concern in this field has been that their trade partners could use, for protectionist purposes, measures intended to protect health, safety and the environment, or to ensure high product quality. Because of this, developing countries have tried to be vigilant regarding the imposition of unnecessarily strict regulations, and have opposed modifications of the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). They have also opposed modifications of Article XX of the General Agreement on Tariffs and Trade (GATT), which deals with general exceptions to GATT obligations. These modifications were proposed by several developed countries to better accommodate non-trade concerns in the multilateral trading system, especially those related to environmental protection.*

2. *However, the situation seems to have become more complex lately. Developing country preoccupations related to market access are still very much present; but these countries are now facing a new challenge related to trade in products whose safety and possible environmental impacts are currently not well known, namely genetically modified organisms (GMOs) and products derived from them. A GMO is an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.[1] Most developing countries have not yet passed legislation in this field and believe that their limited scientific capacities, their recurrent problems with checking products at the border, and their restricted ability to make their own assessment of the risks and benefits involved do not allow them to manage properly the challenges that GMOs pose. They have therefore called for the establishment of international rules in this field. Once it is in force, the Cartagena Protocol on Biosafety, which represents the multilaterally agreed response to these and other non-trade-related concerns, will provide the legal framework for conducting international trade in GMOs, at least among parties to it, although its relationship with the multilateral trade disciplines set out in the World Trade Organization (WTO) agreements is unclear. The Protocol gives quite substantial discretionary power to importing countries with regard to the goods they are willing to import. The trade framework established by it is therefore rather different from the one that developing countries have traditionally supported within the WTO.*

3. *Thus, there are two sets of challenges facing developing countries. The first is to reconcile the preoccupations related to market access with those related to the need to protect human and animal health and the environment from potentially harmful products which could be introduced through international trade. The second is that WTO Members*

[1] This definition is included in EEC Directive 90/220. See footnote 15.

may reach the conclusion that a decision about modifying the multilateral trade rules to better accommodate environment- and health-related concerns cannot be delayed any longer. This could happen because of the magnitude of concerns related to biotechnology, a certain lack of clarity in the Cartagena Protocol and the already existing divergent interpretations of it, and countries' unwillingness to leave the solution of conflicts in this area in the hands of the WTO Panels and Appellate Body.

4. *There are at least four not mutually exclusive forums within the WTO where issues related to trade in biotechnology products could be addressed or have already been addressed, directly or indirectly: the Committee on Sanitary and Phytosanitary Measures, the Committee on Technical Barriers to Trade, the Committee on Trade and Environment, the Committee on Agriculture (negotiations on agriculture started in March 2000, in accordance with Article 20 of the Agreement on Agriculture), and, if a new round of multilateral negotiations is launched, an ad hoc working group established within the WTO. However, the way in which international trade in GMOs is going to be regulated is likely to have an impact extending beyond the specific sector. If the WTO system, for instance, allows in the future a more flexible interpretation of the precautionary principle in order to respond to the health and environmental concerns related to trade in GMOs, the same flexible interpretation will probably apply in other fields, such as trade in conventional agricultural products. If, because of the economic interests involved, an effort is made to clarify the relationship between the trade rules in the Cartagena Protocol and those emerging from specific WTO agreements, the same approach is likely to apply to other multilateral agreements containing trade rules. Each negotiating forum has different characteristics, and discussions may reach different results according to where they are held.*

5. *Discussions on GMOs are also taking place in multilateral forums other than the WTO, such as the Convention on Biological Diversity, the Codex Alimentarius Commission and the Food and Agriculture Organization (FAO). These forums offer some considerable advantages as compared with the WTO: they are specialized and have technical expertise in the issue at stake; and they are forums where developing countries' concerns are usually heard sympathetically. Nevertheless, decisions taken there may be challenged in the WTO if a WTO Member believes that the decisions taken in other forums are affecting its market access rights.*

6. *Developing countries may wish to ready themselves to become active participants in the debate that may start on these issues, so as to ensure that their multifaceted concerns are taken into account and their weaknesses are recognized and addressed.*

Biotechnology: risks and opportunities

7. Biotechnology is a revolutionary technology.[2] It offers humanity the power to change the characteristics of living organisms by transferring the genetic information from one

[2] 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

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 and products derived from them. Changing the characteristics of organisms may provide benefits to society, including new drugs and enhanced plant varieties and food. However, biotechnology does not come without risks and uncertainty. Its potential effects on the environment, human health and food security are being actively debated at the national and international levels. Countries'positions 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, and the investments they have already made in the sector.[3] However, there is a sharp contrast at present between the widespread international acceptance of biotechnology's benefits in pharmaceuticals and industrial products, and the widespread concerns about its possible dangers in agricultural and food production.

8. At present, the perceived benefits of genetically modified crops are better weed and insect control, higher productivity and more flexible crop management. These benefits accrue primarily to farmers and agribusiness, who can obtain higher yields and 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 recently created a strain of genetically altered 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.[4] The impact of biotechnology on food production, post-harvest losses and the nutritional value of food could improve the livelihoods of millions of people.

9. The biotechnology industry reports that among the transgenic products on the market in which beneficial product traits have already been included are the following: Bt crops that are protected against insect damage and reduce pesticide use[5] (these are already used in corn, cotton and potatoes, and will be used in the future in sunflower, soybeans, canola, wheat and

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specific use". The biotechnology industry provides products for human health care, industrial processing, environmental bioremediation, and food and agriculture.

[3] Whereas public funding for agricultural research has stagnated or declined, the biotechnology industry has continued to invest heavily in agricultural research because of the considerable advances made in the area and the strengthening of intellectual property rights for biological material.

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

[5] The modification involves taking genes from a soil bacterium, called *Bacillus thuringiensis*, and making them part of the plants themselves. The Bt plants are toxic only to specific pests.

tomatoes); herbicide-tolerant crops that allow farmers to apply a specific herbicide to control weeds without harm to the crop (these are already used in soybeans, cotton, corn, canola and rice, and will be used in the future in wheat and sugar beet); disease-resistant crops that are armed against destructive viral plant diseases with a plant equivalent of a vaccine (sweet potatoes, cassava, rice, corn, squash, papaya and, in the future, tomatoes and bananas); high-performance cooking oils that create healthier products (sunflowers, peanuts and soybeans); delayed-ripening fruits and vegetables that have superior flavour, colour and texture, are firmer for shipping and stay fresh longer (tomatoes, and in the future raspberries, strawberries, cherries, tomatoes, bananas and pineapples); nutritionally enhanced foods that offer increased levels of nutrients, vitamins and other healthful phytochemicals (protein-enhanced sweet potatoes and rice, high-vitamin-A canola oil, and increased-antioxidant fruits and vegetables).[6] A shift is occurring from the current generation of "agronomic" traits to the next generation of "quality" traits, which are aimed at improved and specialized nutritional food and feed products.

10. However, a number of risks are associated with biotechnology.[7] *Biodiversity protection:* Genetically modified plants may transfer genetic material and associated traits to conventional varieties, developing more aggressive weeds, threatening ecosystems and harming biological diversity. Biodiversity may also be lost, as a result of the displacement of conventional cultivars by a small number of genetically modified cultivars. A number of developing countries could be particularly affected since they are home to a large share of the world's biodiversity. *Food security*: Genetically modified crops may fail to deal with unexpectedly altered climatic conditions. Biotechnology may change the nature, structure and ownership of food production systems. At present, real food security problems are caused, more than by food shortages, by inequity, poverty and concentration of food production. Biotechnology is likely to further consolidate control in the hands of a few large firms. The "terminator technologies," which employ germination control as an intellectual property protection tool requiring farmers to buy new seed every season, have been mainly developed to help transnational agrochemical firms increase their monopoly over seed production and recoup their investment in R&D. *Ethical and religious concerns:* Biotechnology allows scientists to move genetic material across species boundaries and allows, for example, animal genes to be placed in plants. This may raise ethical and religious concerns. The patenting of some aspects of human life and the possibility of human cloning give rise to major preoccupations. *Human and animal life or health:* Genetic modification may change the toxicity, allergenicity or nutritional value of food, and alter antibiotic resistance. *Economic considerations*: Private sector research in agricultural biotechnology has dramatically increased, driven in part by the possibility of profits supported by intellectual property rights. Moreover, private sector industry has become very centralized. What was once an industry in which small seed breeders played a major role has now become a global oligopoly dominated by about five leading transnational corporations. 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,

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[6] See Biotechnology Industry Organization, "Transgenic products on the market", *Guide to Biotechnology*, (website: *http://www.bio.org/food&ag/transgenic_products.html).*

[7] See Stilwell M.T., "Implications for developing countries of proposals to consider trade in genetically modified organisms at the WTO", Center for International Environmental Law, Geneva, 1999.

private science may focus on crops and innovations that are of interest to rich markets and ignore those of interest to poor countries. *Equity considerations*: Private enterprises and research institutes could gain unremunerated control of the genes of plants native to a number of developing countries, use them to produce superior varieties, and then sell the new varieties back to developing countries at high prices. While the concept of "benefit sharing" is included in the Convention on Biological Diversity, it is not addressed in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement).

11. In order to evaluate the risks related to biotechnology, a distinction has been suggested between technology-inherent risks and technology-transcending risks.[8] Technology-inherent risks are those associated with threats to human health and the environment. They could be addressed and minimized by instituting state-of-the-art risk management that takes local ecological conditions into account. Proper risk assessment should be carried out. This would allow Governments, communities and business to make informed decisions about the risks and benefits inherent in using a particular technology to solve a specific problem. Legislation should be developed to ensure the safe production, transfer, handling, use and disposal of GMOs and their products.

12. Technology-transcending risks emanate from the political and social context in which a technology is used. The global economy and the country-specific political and social circumstances play a key role in making biotechnology a risk (e.g. increasing the poverty gap within and between societies, loss of biodiversity, negative impact on the ecosystems) or a benefit for local populations (e.g. improved food security, reduced malnutrition).

13. The above classification of risks, however, may not always prove appropriate for accurately dividing up the ultimate impacts of complex causal chains. For example, the impact of GMOs on biodiversity would fall into both the technology-inherent and the technology-transcending risks. Risks to biodiversity may be caused directly by the modified organisms (through, for instance, the involuntary transfer of genetic material to conventional species) or indirectly (by, for example, interaction with other events, such as changes in agricultural practices or market structure). Similarly, food security may be threatened by "inherent" risks, such as the failure of modified crops to deal with unexpectedly altered climate conditions, and by "transcending" risks, such as oligopoly control of food supply by a few agrochemical and seed companies. The "inherent" and "transcending" risks cut across all areas. It seems difficult, therefore, to divide them clearly and use risk assessment for the former and other techniques for the latter.

The market for GMOs

14. The global area planted with transgenic crops was 1.7 million hectares in 1996, 11 million hectares in 1997 and 27.8 million hectares in 1998; it reached 39.9 million hectares in 1999, with a twentyfold increase between 1996 and 1999. Adoption rates for transgenic crops

[8] See Leisinger K.M., "Disentangling risk issues", in Persley G.J. (ed.), *Biotechnology for Developing-Country Agriculture: Problems and Opportunities*, A 2020 Vision for Food, Agriculture, and the Environment, International Food Policy Research Institute, 1999.

have so far been unprecedented and are the highest for any new technology by agricultural industry standards.[9]

15. In 1999, almost 99 per cent of the global area planted with genetically modified crops was accounted for by three countries: the United States (28.7 million hectares, representing 72 per cent of the global area), Argentina (6.7 million hectares, equivalent to 17 per cent of the global area) and Canada (4.0 million hectares, representing 10 per cent of the global area). The remaining 1 per cent was accounted for by China, Australia and South Africa. Production started in Mexico, Spain, France, Portugal, Romania and Ukraine. Chinaś transgenic crop area increase was the largest relative change in 1999, increasing from less than 0.1 million hectares of insect-resistant cotton in 1998 to approximately 0.3 million hectares in 1999, equivalent to 1 per cent of the global share.

16. As in 1998, the largest increase in transgenic crops in 1999 occurred in the United States, where there was a 8.2 million hectares increase, followed by Argentina with a 2.4 million hectares increase and Canada with a 1.2 million hectares increase.

17. The seven genetically modified crops grown commercially in 1999 were soybean (54 per cent of the global transgenic crop area), corn/maize (28 per cent of the global transgenic crop area), cotton (9 per cent), canola/rapeseed (9 per cent), potato, squash and papaya.

18. The global market for transgenic crops products grew rapidly during the period from 1995 to 1999. Global sales of transgenic crops were estimated at US$ 75 million in 1995. In 1999, they reached an estimated US$ 2.2 billion (a thirtyfold increase). The global market for transgenic crops is projected to reach approximately US$ 3 billion in 2000, US$ 8 billion in 2005 and US$ 25 billion in 2010.

19. However, a proliferation of initiatives at the national and international levels aimed at banning or putting under strict control planting of GMOs and trading in GMOs and GM products, mounting public resistance, refusal by a growing number of food manufacturers and grocery chains to use and sell transgenic products,[10] and an increasing number of questions about liability are causing an inversion of the industry's growth trend in several countries. Stock prices for agricultural biotech companies are falling and exports of transgenic crops are tumbling. American exports of soybeans to the European Union (EU) plummeted from 11 million tons in 1998 to 6 million tons in 1999, while American corn shipped to Europe

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[9] This section is based on: James C. “Preview. Global Review of Commercialized Transgenic Crops: 1999”, International Service for the Acquisition of Agri-biotech Applications, ISAAA Briefs, No. 12, 1999.

[10] An increasing number of producers and retailers have decided not to produce and stock products with GM ingredients - or which cannot be certified as GM-free - in response to mounting concern among consumers. Frito-Lay, the world's largest producer of snack foods, recently announced that it would stop buying genetically modified corn and soybeans. It is following similar moves by a number of other food companies, including Gerber and H.J. Heinz baby foods, the British chains Iceland and Sainsbury’s, Japan’s Asahi Breweries, and the supermarket chains Tesco (United Kingdom) and Migros (Switzerland). Nestlé, the world’s biggest food company, has stopped buying any grain from genetically altered seed for its European operations. Fast-food chains such as McDonald’s and Burger King have declared their intention to stop using GM ingredients. See Analytica Brief, 13 March, 2000: 3, and “Vade retro OGM”, , 2-15 March 2000, No. 616.

dropped from 2 million tons in 1998 to 137,000 tons in 1999, with a combined loss of nearly US$ 1 billion in sales for United States agriculture.[11] United States exports to Europe could be further affected once legislation is passed in the European Union regarding mandatory labelling of animal feed. The Worldwatch Institute and the American Corn Growers Association estimate that GM planting could be reduced by 25 per cent in 2000 as compared with the previous year, since farmers have serious doubts about whether they will be able to sell genetically modified crops. The seed companies and the American Soybean Association dispute this, arguing that plantings in 2000 are likely to be similar to those in 1999. Although reliable data to evaluate these forecasts will become available only by mid-year,[12] there is a small but significant amount of evidence that public resistance to the use of bioengineered foods is affecting United States farmers'planting decisions. According to the April 2000 report of the United States Agricultural Statistics Board, American farmers appear to be reducing plantings of modified corn - from 33 per cent in 1999 to 25 per cent in 2000. Data are less dramatic for modified cotton and soybeans, but there are some indications that, especially for soybeans, farmer's demand for modified seeds may be stagnating, or falling slightly.[13] On the other hand, China has begun a huge push to commercialize genetically modified crops, with around half of its fields expected to be planted with GM rice, tomatoes, sweet peppers, potatoes and cotton in five to ten years. The reasons for this move are reduced pesticide and herbicide requirements and bumper yields from GM crops. Half of the genetically modified seeds used in China have been developed by local scientists: in 2000 China allocated more than US$ 350 million for research into applying biotechnology to agriculture.[14]

The present regulatory framework: selected countries

A. The European Community

20. At the beginning of the 1990s the European Community (EC) introduced an approval system for the deliberate (non-accidental) release into the environment of GMOs ("live 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.[15] This "horizontal" legislation is based on a process-oriented approach, which pays special attention to genetic modification.[16]

21. Any person wishing to undertake the deliberate release of a GMO for research and development purposes must submit a notification to the competent authorities of the country within whose territory the release is to take place. The notification must include a full risk

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[11] See Halweil B., "Portrait of an industry in trouble", Worldwatch News Brief, 17 February 2000 (Internet website: *http://www.worldwatch.org/alerts/000217.html).*

[12] See Oxford Analytica Brief, footnote 10.

[13] See Washington Trade Reports, Vol. VIII, No. 7, 11 April 2000.

[14] See "China sows seeds of GM crop expansion", *Times*, 29 February 2000; "Differences widen on use of modified foods", *Financial Times*, 29 February 2000; and "Genetic engineering: Modified crops take root in China", BBC World Update, 7 June 2000.

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

[16] The other part of the horizontal legislation consists of a Directive on the contained use of genetically modified micro-organisms which focuses on the manufacturing process of GMMs (Council Directive 90/219/EEC, 23 April 1990, OJ L 117, 8 May 1990, pp. 1 ff).

assessment and details of appropriate safety and emergency response measures. The notifier may proceed with the release only when he/she has obtained consent. Since the Directive came into force, over 1,600 such notifications have been received for over 60 species of plants.[17] In the case of applications for placing on the market products containing or consisting of GMOs additional data, including instructions and conditions for use, are required. Consent is given by the competent authorities of the country concerned, but on behalf of all member States, on the basis of a rather long and complex procedure where, in the event of conflict among member States, the final decision has to be taken by the Commission.[18] The following GM varieties have so far been approved for placing on the market under Directive 90/220/EEC: three insect-resistance maizes, one herbicide-tolerant maize, one herbicide-resistant soya bean, one herbicide-resistant swede-rape, one herbicide-resistant tobacco, one herbicide-tolerant chicory; and three varieties of flowers (carnations). However, since June 1999 a de facto moratorium has been in place on GMO approvals as a response to a chorus of demands across Europe for a ban, or at least some restrictions, on planting genetically modified crops and on importing GM commodities and foods. On the basis of Article 16 of the Directive - which allows a member State to provisionally restrict or prohibit the use and sale of an approved product if it has justifiable reasons for considering that the product constitutes a risk to human health or the environment - Austria, Luxembourg, Germany, France and Greece have banned or restricted the use of GM crop varieties.

22. Originally, Directive 90/220/EEC made virtually no provision with regard to labelling. Following a 1997 amendment,[19] however, the EC Commission has made labelling mandatory when a product consists of or contains GMOs. For products consisting of a mixture of GMOs and organisms not genetically modified, the possible presence of GMOs must be indicated.

23. On February 1998 the Commission submitted to the Council a proposal for a Directive amending Directive 90/220/EEC. After the European Parliament had given its opinion, the Commission submitted a new version of its proposal to the Council on March 1999. In December 1999 the Council adopted its common position for a revised Directive.[20] The main innovations of the new Directive are that consent to placing GMOs on the market is limited to

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[17] For further details see the website *http://food.jrc.it/gmo/* maintained by the European Commission.

[18] If the country concerned decides to consent to a proposed release, the dossier is forwarded to the other member countries through the Commission. They can present reasoned objections. If no objections are presented, the competent authority of the country where the authorization procedure was initiated gives its consent, enabling the product to be placed on the market. If objections are presented, the competent authorities of the member States have to try to reach an agreement. If they do not succeed within 60 days, the Commission has to submit a draft of the proposed measures to a committee composed of the representatives of the member States. The Commission can suggest that the GMO should or should not be authorized, but so far the Commission has always been in favour of authorizing the deliberate release. If the committee does not agree with the Commission's draft measure or does not give its opinion, the proposed measures are submitted to the Council. Council decisions can be taken with a qualified majority, but if the Council does not reach consensus within three months, it is up to the Commission to take the final decision. For an analysis of Directive 90/220, see Douma W.Th. and Matthee M., "Towards new EC rules on the release of genetically modified organisms", *Review of European Community & International Environmental Law, RECIEL*, Vol. 8, Issue 2, 1999, pp. 152 ff.

[19] Commission Directive 97/35/EC, 18 June 1997, OJ L 169, 27 June 1997, pp. 73 ff.

[20] EC Council, Common Position (EC) No. 12/2000, adopted by the Council on 9 December 1999, OJ C 64, 6 March 2000, pp. 1 ff.

a fixed period (renewable), and that a system of compulsory monitoring after GMOs have been placed on the market has been introduced in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment. The Directive makes reference to the precautionary principle and to the need to respect ethical principles; it includes public information and consultation. It provides for a common methodology to assess the risks associated with the release of GMOs and a mechanism allowing their release to be modified, suspended or terminated where new information becomes available on the risks of such release. The new text makes it clear that products containing and/or consisting of GMOs covered by the Directive cannot be imported into the EC if they do not comply with its provisions.

24. The European Parliament approved a number of amendments to the revised text of the Directive on 12 April 2000. There is a call for environmental risk assessment to be strengthened and for the Directive to be further amended and clarified in the light of the Biosafety Protocol. An amendment was also adopted that would require the prior consent of third countries that are importing GMOs. The year 2005 was set as a definitive date for phasing out the use of GMOs that are resistant to antibiotics. The European Commission hopes that this new legal instrument will increase consumers' confidence in the regulatory system. Although the Directive contains rigorous approval and monitoring rules for GMOs, biotechnology companies are supporting it in the hope that it will help to end the de facto moratorium on registration of new modified products in the EU.

25. In addition to "horizontal" legislation, the EC has adopted a number of "vertical" Directives and Regulations. This "vertical" legislation is product-oriented, and deals with specific aspects or products resulting from genetic modification. The introduction of the vertical legislation has altered the hitherto purely process-oriented nature of EC legislation on GMOs.

26. Legislation related to novel foods and novel food ingredients is part of the "vertical" regulatory approach.[21] 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[22] are subject to a single safety assessment through a Community procedure before they are placed on the EU market. Companies wishing to market a novel food in the EU are required to submit an application to the competent authority in the member State where they intend to market their product first. A copy of the application should be sent to the EC Commission. For food and food ingredients containing GMOs, a specific environmental risk assessment has to be provided. The competent authority completes an initial safety assessment and forwards it to the Commission. The Commission then copies this assessment to other member States for their comments. If the initial assessment is favourable and no objections are raised by other member States, the product can be marketed. The competent authority may ask for more data or research at any time during this assessment. The competent authorities in other member States may also

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

[22] 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.

choose to raise objections or concerns. If objections are raised, or if the initial member State considers that an additional assessment is required, the application will be referred to the EC Standing Committee for Foodstuffs for final agreement, with the EC Scientific Committee for Food being consulted as necessary. If no agreement is reached there, the matter will be referred to the Council of Ministers. The Regulation allows member States to temporarily suspend or restrict the trade in and use of a novel food and food ingredient in their territories if a country, on the basis of new information or the reassessment of existing information, has grounds for considering that the novel food or ingredient endangers human health or the environment (Article 12).

27. The Novel Foods Regulation incorporates specific labelling rules for products developed through biotechnology. It provides for mandatory labelling and requires that consumers be informed of differences between a new product and existing equivalent products.[23]

28. The procedure for authorizing the placing on the market of novel foods is expected to be clarified and made more transparent. The European Commission is likely to adopt by the end of 2000 an implementing regulation to clarify the procedures laid down in the Novel Foods Regulation. It will also present a proposal to improve this Regulation in accordance with the revised Directive for the deliberate release of GMOs into the environment. Furthermore, the labelling provisions will be completed and harmonized.[24]

29. On 21 October 1999, legislation to further strengthen GM labelling was agreed.[25] In the new rules,[26] which came into force on 10 April 2000, labelling requirements have been extended to include foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms. Regulation No. 49/2000 allows a *de minimis* labelling threshold of 1 per cent (of each ingredient individually considered) for the accidental content of genetically modified material in non-GM products. The aim of the threshold is to solve the problem faced by operators who have tried to avoid GMOs but who, owing to accidental contamination, still find themselves with a low percentage of modified material in their products.

30. In conclusion, products authorized under the Novel Foods Regulation which either contain or comprise GMOs (e.g. a plant, part of a plant or the processed plant where there is

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[23] The label has to provide the final consumers with information on (a) any characteristic of food property which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient; (b) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population; (c) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns; and (d) the presence of an organism genetically modified by techniques of genetic modification, the non-exhaustive list of which is laid down in Directive 90/220/EEC (Article 8).

[24] See Communication by the European Communities, *White Paper on Food Security*, COM(1999) 719 final, 12 January 2000.

[25] See European Commission, Press Release, "Commission proposes de minimis threshold and labelling rules website: http://*europa.eu.int/comm/dg03/press/1999/IP99783.htm.*

[26]Commission Regulation (EC) No. 50/2000, 10 January 2000, OJ L 006, 11 January 2000, pp. 15 ff., and Commission Regulation (EC) No. 49/2000 of 10 January 2000, OJ L 006, 11 January 2000, pp. 13 ff.

still genetic material present, such as a sweet corn which can be eaten directly or a genetically modified tomato) must be labelled. Products derived from GMOs and authorized under the Novel Foods Regulation must be labelled if they are no longer equivalent to an existing foodstuff or food ingredient (e.g. oil from a GM maize or a tomato paste, where the processing refines the product so that DNA is no longer present). Non-GM foods adventitiously contaminated must be labelled when contamination, at the level of the ingredient, is greater than 1 per cent.

31. In January 2000, the Commission presented a proposal for a Directive that will include a requirement for animal feeds to be labelled.[27] The Directive will amend previous legislation on the marketing of compound feeding stuffs aimed, as regards labelling, at ensuring that stock farmers are informed of the composition and use of feeding stuffs. In the aftermath of the BSE (bovine spongiform encephalopathy) crisis and the events in 1999 relating to oils and additives contaminated by dioxin, the EC member States have expressed their dissatisfaction with the existing labelling provisions and stressed the importance of detailed qualitative and quantitative information on the labels of compound feeding stuffs. The Commission's proposal imposes a compulsory declaration of all the food materials, as well as their amount in the compound feeding stuffs, listed on a label or in the accompanying document. Member States are also looking at the need for labelling of the presence or absence in animal feed of material derived from GM material.

32. Since there are currently no specific regulations in the EU covering "GM-free" labelling, some EU member States, such as the United Kingdom, are pressing for the development of a comprehensive discipline at a European level on it.[28]

33. European consumers are increasingly showing an interest in "organic" products - whose market is growing exponentially - as a reaction to the multiple scandals where food safety has been at stake, but also as a way to protect themselves against involuntary consumption of genetically modified food, and to protect the environment. In the European Union, it is reported that 100,000 farmers and food processors are producing organic food. There are 2.5 million hectares under organic cultivation. While this amount represents less than 2 per cent of the global cultivated area, it has tripled in the last four years.[29]

B. Japan

34. Following European moves on GMOs, the Japanese Government recently introduced mandatory labelling requirements for final products containing GMOs in response to consumers' concerns. A committee in charge of developing rules for labelling was established

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[27] Commission of the European Communities, Proposal for a European Parliament and Council Directive amending Directive 79/373/EEC on the marketing of compound feeding stuffs, COM(1999) 744 final, 2000/0015 (COD), 7 January 2000.

[28] See Genetic Modifications Issues (GM): GM Food Labelling (website of the United Kingdom Cabinet Office Genetic Modification (GM) Issues, *http://www.gm-info.gov.uk/1999/gmfoodlabel.htm).*

[29] See "Europe sees potential in organic foods", Reuters, 9 March 2000 and "L'euphorie de l'agriculture *Le Figaro*, 2 April 2000.

in 1997 under the auspices of the Ministry of Agriculture, Forestry and Fishery (MAFF). The public was encouraged to comment on the draft legislation and the committee received more than 10,000 submissions. The labelling system will apply to a variety of food products, most of them included in the Japanese traditional diet, which contain genetically modified ingredients, such as modified corn, soybeans, potatoes and rapeseeds. Labelling standards were issued in April 2000 and compliance with them is likely to become mandatory by April 2001. The labelling system is supposed to give information to consumers to allow them to make an informed choice.

35. Where the presence of genetically modified inputs is not proved, but the producers cannot exclude that some GM materials have been used, this has to be indicated on the label. A voluntary "GM-free" labelling system has already been implemented.

36. The MAFF started inspections of imported GM products at major ports in the autumn of 1999. There are currently 22 GMOs which are officially recognized as "safety-proven." The inspections are carried out to ensure the safety of the "safety-proven" GM products and to separate them from non-approved GM products. Inspected products may be denied entry if it is found that they are not on the GMO approved list.

37. On 20 January 2000, the MAFF circulated the official definition of organic farm products and organic processed foods made from agricultural products in order to stop the proliferation of "organic" labels based on producers' own definitions. GM products are among the products that cannot be labelled "organic." The new system will enter into effect on 1 October 2000.[30]

C. United States

38. Biotech crops have been sold in the United States since 1996 and are already planted on millions of acres. They account for about a half of the nation's soybeans and cotton, a third of all corn, and smaller proportions of canola, potatoes and squash. The Government has approved some 50 varieties of genetically modified crops. Genetically modified soybeans and corn can be found in hundreds of processed foods.

39. On 3 May 2000 the Clinton administration released a plan that would increase federal oversight of genetically modified foods and make details of that oversight more available to the public in an effort to increase consumer confidence in GM foods. In particular, the new proposal is the result of an effort by the Food and Drug Administration (FDA), which is a part of the Department of Health and Human Services, to solicit the public's views on its policies for handling GM foods. In response to its call for comments and hearings in October 1999, the FDA heard testimony from several hundred interested parties and received more than 30,000 written comments. These comments came from pharmaceutical and biotechnology companies,

[30] See MAFF Update, No. 345, 4 February 2000, website: *http://www.maff.go.jp/mud/345.html*.

seed companies, agricultural groups, food producers and processors, marketers, consumer groups, environmentalists, and others.[31]

40. Under the proposal, biotech companies would have to notify the FDA four months before marketing a new genetically modified food, providing the agency and the public with the research results that affirm the new foods safety. Until now, the process has been voluntary. Moreover, the FDA intends to create a regulatory mechanism by which foods could for the first time be voluntarily labelled as either genetically modified or free of gene-altered ingredients.

41. One of the significant developments in the proposal is the greater involvement in the regulatory process of the Agricultural Department (USDA) and the Environment Protection Agency (EPA). The USDA would become directly involved in validating new scientific tests aimed at detecting the presence of gene-altered ingredients. The EPA would conduct a six-month review of its environmental regulations dealing with testing, monitoring and approving the use of genetically engineered crops.

42. The growing consumer resistance to GM food has apparently changed the food and agriculture industries' views about government regulation. Whereas industry groups have previously resisted attempts to introduce new regulatory procedures, they now seem to believe that a stronger, clearer government approach may reassure the consumer that the products are independently deemed to be safe. The biotech industry, which in the past has strongly opposed labelling because it could stigmatize or could imply the superiority of foods not containing GM ingredients over genetically engineered foods, is now more willing to accept labelling as a necessary instrument to combat consumer scepticism. The industry may decide to couple its support for voluntary labels with greater efforts to make consumers aware of the benefits of GM foods. The Biotechnology Industry Organization, for instance, has begun a major television and print media advertising campaign extolling the benefits of biotechnology in food and medicine.

43. On 2 May 2000, 13 State Governors[32] announced that they would begin a campaign to improve the public image of genetically modified foods by informing consumers about the science of genetically modified foods. They declared that they were going to do so because of the economic challenges for farmers and of the need to enhance the value of crops so that farming would yield good profits. Also, they stressed that their initiative was related to environmental concerns concerning the quality of water and air resulting from heavy reliance on herbicides and fertilizers.[33]

44. In contrast to the food industrys positive reaction, the proposal by the Clinton administration has not elicited an enthusiastic reaction from consumer groups, which have

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[31] The paragraphs related to the 3 May 2000 proposal are based on "U.S. to add oversight on biotech food", *Washington Post* online, 3 May 2000, website: *www.washingtonpost.com/wp-dyn/articles/A56999-2000May2.html*, and on information provided by the team of Washington Trade Reports.

[32] The States in question are Delaware, Idaho, Illinois, Indiana, Iowa, Michigan, Missouri, Nebraska, Nevada, North Carolina, North Dakota, Washington and Wisconsin.

[33] See "13 governors will promote genetically altered foods", *St. Louis Post-Dispatch*, 3 May 2000.

charged that the plan falls short of what consumers need, especially in the field of mandatory labelling of GM foods.

45. Interested parties will have opportunities to submit written comments on the proposal and hearings are likely to be held until the end of 2000. Because of the complexity of the issues and the large number of comments expected, the FDA will most likely have to adjust the proposal before it is ready to move to the final-rule stage. The process is expected to be long and to continue after the end of the Clinton administration (20 January 2001).

46. A bill requiring the labelling of all foods that contain a genetically modified entity was introduced to the United States Congress in November 1999 (Kucinich bill, H.R.3377). As of 15 April 2000, the bill had 51 co-sponsors. However, the prospects of its moving forward in Congress before the end of the 106th Congress (on about 8 October 2000) are quite remote. Even though a total of 51 co-sponsors is a respectable number, no one on the co-sponsor list is close to the United States agriculture industry. Secondly, like all bills, H.R.3377 has to be "referred" to one or more committees of jurisdiction. In this case, those two committees are the House Agriculture Committee and the House Commerce Committee. Currently, neither committee has plans to take up the GMO issue in general, let alone the Kucinich measure in particular. In the committees'views the issue is so new and undeveloped that Congress should not be eager to rush in to legislate. On March 2000 Mr. Kucinich introduced additional legislation (H.R. 3883), directing the FDA to overhaul its procedures for reviewing the safety of genetically engineered foods. In the Senate, Senator Barbara Boxer (Democrat, California) introduced her GMO food-labelling bill on 22 February 2000 (S.2080). She has attracted no co-sponsors so far. There is great reluctance to start legislating on GMO issues in the Senate, for the same reasons as in the House of Representatives.

47. In conclusion, there does not appear to be any eagerness in Congress to take up GMO legislation in the year 2000. The Congress is definitely interested, but it has not been able to resolve many of the issues yet. In those circumstances, it is reluctant to act, even though farmers are requesting a definitive direction from the Government. The issue is regarded as being of paramount importance in the United States.[34]

48. On 8 March 2000, the FDA released its proposed final rule for "organic" foods. The proposal marks the Government's second attempt to define "organic" food after the first such effort failed amid controversy two years ago. After months of review of more than 2,000 comments received in response to its earlier proposal, the FDA appears to be adopting a rather strict standard. Any food labelled "organic" would have to have been produced without the use of many fertilizer types, including processed sewage sludge, could not be irradiated for pest control, and could not have been developed using genetic modifications of any sort. There is a growing assumption in the United States that organic agricultural products may be commanding a higher price than conventionally produced goods. By contrast, bioengineered products may be selling at a discount, compared with conventional agricultural products, despite possible higher costs associated with segregating, storing, transporting and labelling modified crops.[35]

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[34] Information provided by the team of Washington Trade Reports.

[35] See Washington Trade Reports, Vol. VIII, No. 7, 11 April 2000.

D. Other countries' initiatives

49. The Australia-New Zealand Food Authority (ANZFA) has developed standards for genetically modified foods which came into effect on 13 May 1999. They require a pre-market safety assessment to be carried out by ANZFA before such foods can be sold. They also require labelling of foods which are substantially different from their conventional counterparts. Recently the Australian and New Zealand Health Ministers agreed that the labelling requirements should be extended to all GM foods for the purpose of consumer information. A draft standard and a draft protocol intended to provide guidance on the practical implementation of the new labelling system have been released for public comment. The Ministers expect to finalize the details of the extension of the system by July 2000.[36]

50. In New Zealand, the field tests and release of GMOs take place under the 1996 Hazardous Substances and New Organisms Act. The Environmental Risk Management Authority decides on the development, production, import and release of GMOs in the country. Risk management decisions are made on the basis of scientific evidence and take account of environmental, health, social and economic considerations, as well as of the multilateral commitments entered into by New Zealand.[37]

51. In Canada, the Canadian Council of Grocery Distributors, representing about 80 per cent of Canadian food industry retailers, agreed in September 1999 to develop a voluntary GM food labelling regime in partnership with the Canadian General Standards Board and a variety of stakeholders from industry, environmental groups, consumer groups and academia. The label will indicate whether a specific food has been produced through genetic modification. The committee established for this purpose is developing general principles and models for voluntary declarations, procedures required to verify the truthfulness of these declarations, principles of a certification mechanism, and definitions that are clear and concise. A draft standard is expected to be completed before the end of 2000. This initiative is largely in response to consumer demand for more information on GM foods. The Canadian Government is supporting this approach and considers it to be consistent with its international trade obligations.[38]

52. In Switzerland, approval of a bill presented by the Federal Council in January 2000, which would authorize the voluntary release of GMOs into the environment under certain conditions, seems to be going to face obstacles, since a broad alliance including the Farmers' Association, environmental groups and consumer associations is opposing it and proposing a 10-year moratorium on the release of GMO into the environment. According to the Farmers' Association, there are two reasons for not planting modified seeds in Switzerland: consumers

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[36] The OECD and UNIDO have jointly developed a database on regulatory developments in the field of biotechnology. The information can be accessed through the following websites: www.binas.unido.org/binas (for UNIDO member countries) and www.oecd.org/ehs/country.htm (for OECD member countries).

[37] Information provided by the Ministry of Agriculture and Forestry of New Zealand.

[38] See WTO, Communication from Canada. The Development of a Voluntary Standard for the Labelling of Foods Derived from Biotechnology, G/TBT/W/134, 23 May 2000.

are against them; and it is the transnational companies, not the farmers, that are currently benefiting from biotechnology. [39]

53. In 1994, Thailandṣ legislation on plant quarantine was expanded to cover GMOs. Since then, the release into the environment and the import of genetically modified seeds and crops have been subject to a strict approval system. The Thai authorities have so far approved only the release into the environment of GMOs for experimental purposes. Imports of GM soya and maize, however, have been derestricted and do not need to go through the approval process. In response to consumers' concern, the Thai Food and Drug Administration is considering imposing a labelling system for all products using GMOs, starting in 2001. Discussions are being held about whether the system should be mandatory or voluntary and about how much GMO content in a product should warrant labelling. A precondition for the implementation of the proposed labelling system will obviously be to equip the authorities concerned with the technology needed for testing GM products.[40]

54. The Republic of Korea passed legislation in March 2000 regarding mandatory labelling of genetically modified soybeans, corn and soybean sprouts. It will enter into force in 2001.[41]

55. In Sri Lanka, the National Food Advisory Committee is considering the possibility of imposing a ban on the import of GMOs and GM foods, as it lacks precise information about the long-term effects of these new products. The list of foods that may be banned is being studied, while the Sri Lankan authorities are also considering other less trade-restrictive options.[42]

56. In March 2000, the Mexican Senate unanimously approved a reform of the General Health Law so that transgenic foods, whether produced nationally or outside Mexico, carry a label that identifies them as such and specifies the type of genetic modification which has taken place. The bill must still be approved by the Mexican Chamber of Deputies.[43]

The multilateral solutions

57. At present, international trade in GMOs 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 SPS and TBT Agreements and in GATT 1994. However, disciplines regarding trade in GMOs are also emerging from specific multilateral agreements being negotiated outside the purely trade context, such as the recently agreed Cartagena Protocol on Biosafety, or may be developed in the future by adhoc groups, such as the proposed WTO Working Party on Biotechnology. Intergovernmental organizations that have specific expertise in the field are carrying out technical work in key areas, such as the risk analysis of food derived from biotechnology or

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[39] See "Le projet du Conseil fédéral sur les OGM court à la défaite" and " S'adapter au marché? Les paysans prennent au mot les partisans du génie génétique", *Le Temps*, 28 April 2000.

[40] Information provided by the National Science and Technology Development Agency of Thailand.

[41] WTO, G/TBT/Notif.00/49, 1 February 2000.

[42] See "Sri Lanka: Government bans genetically engineered foods", *South-North Development Monitor*, 14 April 2000, and information provided by Sri Lanka's Permanent Mission in Geneva.

[43] See "Trade: Mexico Senate approves transgenic product labelling", *SUNS*, 4 April 2000.

the methodology to identify food derived from biotechnology. Other organizations are providing a forum for discussion to respond to the interests and concerns of their member countries. The rules included in different legal instruments and the conclusions reached in different forums may not be fully consistent with each other and may give rise to conflicts between GMO-exporting countries and potential importers.

A. The Cartagena Protocol on Biosafety

58. The Cartagena Protocol on Biosafety,[44] which was negotiated under the auspices of the Convention on Biological Diversity (Rio de Janeiro, 1992), was adopted on 29 January 2000 after four years of negotiations. It will enter into force 90 days after the 50th instrument of ratification is received. The Protocol was opened for signature at the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity (Nairobi, 15 - 26 May 2000) and 64 countries, plus the European Community, signed it. It will be available for signature for one year, beginning 5 June 2000.

59. The Protocol provides rules for the safe transfer, handling, use and disposal 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. The use of the term "living modified organism" instead of "genetically modified organism" was supported by some delegations that felt that it was a more precise definition. The United States, on the other hand, strongly supported the use of the term "living modified organism" to stress that the use of genetic engineering resulted in products which were no more risky than those obtained through other means of modifying living entities. 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)).

60. The proposal for provisions in the field of the safe transfer, handling and use of LMOs within the Convention on Biological Diversity (CBD) came first from an expert group that was established during the negotiations on the CBD. However, there was neither time nor a wholehearted willingness to develop such provisions and include them into the Convention, and it was therefore agreed that specific provisions on biosafety would be negotiated at a later stage and included in a protocol. Malaysia and Ethiopia, on behalf of the African Group, were the most vocal advocates of the idea of developing a Protocol on Biosafety, and were supported by most developing countries, the Nordic countries and environmental groups.[45]

61. During the long and complex negotiations on the Protocol, five main negotiating groups emerged. The *Like-Minded Group* consisted of the large majority of developing countries (with the exception of the developing countries members of the Miami Group and the Compromise Group). The emphasis of developing countries was on their lack of capacity

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

[45] The paragraphs on the negotiating history of the Biosafety Protocol draw on Gupta A., "Framing 'biosafety' in an international context", ENRP Discussion Paper E-99-10, Kennedy School of Government, Harvard University, 1999; and Cosbey A. and Burgiel S., "The Cartagena Protocol on Biosafety: An analysis of results", IISD Briefing Note, International Institute for Sustainable Development, 1999.

to assess and manage the hazards that GMOs may pose to biodiversity and to human health. They made it clear that, given the lack of a regulatory framework for biosafety in most developing countries, they risked becoming the testing grounds for release of GMOs produced in the developed countries. Thus, they called for internationally mandated information-sharing obligations to be put in place for all kinds of LMOs. The Like-Minded Group therefore supported a wide coverage by the Protocol, a strong formulation and implementation of the precautionary principle, the inclusion of the requirement that those exporting LMOs should provide information to allow importing countries the possibility of informed consent, a comprehensive identification and documentation of LMOs shipments, and the possibility of taking into account human health and socioeconomic considerations in decision-making. The *Miami Group* included the main exporters of genetically modified seeds and crops, and the principal holders of the related technology: Argentina, Australia, Canada, Chile, the United States and Uruguay. Although Argentina, Chile and Uruguay were producers and exporters of GM seeds and crops, they were not in a position to developed new GMOs. The main aims of the group were to narrow the scope of the Protocol by keeping genetically modified commodities out of it, to limit the possibility of referring to the precautionary principle and socioeconomic considerations in decision-making, and to apply the strict system of Advance Informed Agreement (AIA) only to LMOs intended for introduction into the environment. The *European Union (EU)* negotiators, who were facing food-safety scandals at home and were under scrutiny and pressure from consumers' organizations and environmental groups with serious concerns about GMOs' safety, strove for a strong protocol which would include risks to human health, cover genetically modified commodities, include strong language on the precautionary principle, and make reference to the principle of non-discrimination between domestically produced and imported items. Moreover, the EU was in the process of developing and implementing legislation in this field and was therefore striving for the conclusion of a multilateral instrument under which its existing legislation could be accommodated. The *Compromise Group* included Japan, Mexico, the Republic of Korea, Singapore, Switzerland and New Zealand. Although the group had a common position on the inclusion of the precautionary principle and on wide coverage by the Protocol, its main aim was to bridge the major differences between the other groups. In fact, it played a key role in building the final consensus on the text of the Protocol. The *Central and Eastern European bloc of countries (CEE)* had a position in between that of the EU and the Like-Minded Group. Its main aim during the negotiations was to contribute to a text that would be practical and applicable. Two non-State coalitions had a strong presence during the negotiations: the Global Industry Coalition, consisting of over 2,200 agricultural, food and pharmaceutical firms, which had a position almost identical to that of the Miami Group; and an international coalition of consumer safety and green groups, which supported the Like-Minded Groups' perspective.

62. One of the central points of contention during the negotiations 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 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, science would be the only objective and standardizable basis for the decision-making process as regards biosafety. To rely on the precautionary principle, on the contrary, would open the Protocol to abuses and

trade protectionism. Moreover, the Miami Group argued that the precautionary approach was inconsistent with WTO rules, in particular with those spelt out in the SPS Agreement.

63. The EU, the Like-Minded Group, and 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. They wanted flexibility in decision-making and regarded it as paramount to the predictability that would result from an approach mainly based on "sound

64. The final text of the Protocol, which is obviously a "compromise text," includes elements from the different negotiating groups; it seems, however, to go more in the direction of the EU's and the Like-Minded Group's approach. It reflects the complexity of the issues discussed and the effort to translate environmental and trade requirements into international binding obligations.

65. One of the main features of the Protocol is the system of Advance Informed Agreement. The AIA covers seeds for planting, live fish for release, micro-organisms for bioremediation, and other LMOs which are "intentionally introduced" into the environment.[46] It provides that the exporter must provide, through notification, detailed information on the product exported to the competent national authority of the country of import in advance of the first shipment. Information must include the modification introduced, the technique used and the resulting characteristics of the LMO, the regulatory status of the LMO in the country of export (e.g. whether it is prohibited, subject to other restrictions, or has been approved for general release), and the contact details of the importer and the exporter. The notification has to be accompanied by a risk assessment report. Within 90 days of notification, the importing country has to inform the notifier either that it will have to wait for written consent, or that it can proceed to export. If the importing country indicates that written consent will have to be awaited, it has 270 days from the date of notification to decide whether to approve the import (adding conditions as appropriate), prohibit it, request additional information or extend the deadline for response. This decision has to be notified also to the Biosafety Clearing-House (based on the Internet).[47] Failure by the importing country to communicate its decision does not imply consent. Countries of import must give reasons of their decisions, except for unconditional approval. Decisions must be based on available scientific evidence and on risk assessment; however, importing countries can invoke the precautionary principle provisions. The country of export must bear the financial responsibility for risk assessment if the country of import so requires.

66. LMOs intended for release into the environment must be accompanied by documentation that identifies them as LMOs, specifies the relevant traits/characteristics, provides information on safe handling, storage, transport and use, and specifies the name and

[46] According to Article 7.2 of the Protocol, LMOs for intentional introduction into the environment are all LMOs other than those intended for direct use as food or feed, or for processing.

[47] Alternative ways will have to be found to make information available to those countries which do not yet have full access to the Internet.

address of the importer and the exporter. A declaration that the movement is in conformity with the requirements of the Protocol is also needed. In the future, the Conference of the Parties to the Protocol will consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices.

67. The AIA system, however, covers only a small percentage of traded LMOs, since LMOs for direct use as food or feed or for processing are subject to a different and less strict notification procedure. Four types of LMOs are also excluded from the AIA system, namely most pharmaceuticals for humans, LMOs in transit, LMOs destined for "contained use",[48] and LMOs which have been declared safe by a meeting of the Parties to the Biosafety Protocol. Consumer products derived from LMOs are not covered by the Protocol.

68. For LMOs for direct use as food or feed or for processing (i.e. commodities, identified as LMO-FFPs in the Protocol), imports are based on an advanced information procedure and take place according to domestic legislation. Importers have to announce their decision regarding domestic use of LMO-FFPs to the Biosafety Clearing-House. Decisions should be based on a risk assessment. Developing countries and countries with economies in transition may indicate their need for financial and technical assistance and capacity building with respect to LMO-FFPs. Although the Protocol spells out two different procedures depending on the final use of the LMOs (for voluntary introduction into the environment, or for food, feed or processing), it is actually rather difficult to separate them into two categories, considering that it may happen that grains imported as food or feed or for processing are used as seeds, being significantly less expensive than proper seeds.

69. Shipments of commodities for food, feed or processing containing LMOs will have to carry documentation specifying the possible presence of LMOs and indicate that the products are not intended for intentional introduction into the environment. The details of this procedure remain to be worked out, and are supposed to be settled within two years after the Protocol enters into force. The "soft" rules agreed upon were welcomed by the Miami Group, which had argued that strict requirements on documentation and identification would imply segregation of crops and be unfeasible. On the other hand, the fact that some countries have passed legislation on mandatory labelling for GMOs and GM crops is already imposing segregation. The category of LMO-FFPs includes the large majority of traded LMOs, such as modified corn, soya, wheat, rapeseeds, tomatoes and cotton.

70. The Protocol permits the countries of import to take a precautionary approach; this means that lack of scientific certainty due to insufficient information on the potential negative effects of LMOs on biodiversity, taking also into account risks for human health, will not prevent the receiving country from taking decisions regarding shipments of LMOs. This principle applies to LMOs for intentional introduction into the environment, as well as to those for direct use as food or feed or for processing. The precautionary approach is one of the main features of the Protocol and reference is made to it in the Preamble, in Article 1 ("Objective"), and in Articles 10 and 11. It allows importing countries to ban imports because of lack of

[48] According to Article 3(b) of the Protocol, " 'contained use' means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment".

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 for reaching 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.

71. 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. 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[49] 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.

72. It seems that there are already some rather divergent interpretations of the Protocol. According to a United States press release, Mr. Loy, Secretary of State for Global Affairs, said that "the agreement emphasizes that regulatory decisions must be based on science." In a Fact Sheet published by the United States Department of State on 16 February 2000, it is stated that "The language [on the precautionary approach] acknowledges the role that precaution may serve during decision making. However, the language does not replace science-based decision-making, nor does it authorize decisions contrary to a country's WTO

[50] In a meeting held in March 2000 in Geneva immediately after the first 2000 meeting of the WTO Committee on Trade and Environment (CTE), representatives of the United States declared that according to their interpretation the Protocol is subordinated to the WTO Agreements. On the other hand, Ms. Wallstrom, the EU Environment Commissioner, said at the conclusion of the negotiations that "the Protocol in general...and the inclusion of the precautionary principle in particular...represented a victory for consumers."

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[49] It is interesting to note that under the SPS 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.

[50] See United States Department of State, Office of the Spokesman, Fact Sheet, "The Cartagena Protocol on

73. 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 recital 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.

74. Usually, countries which are parties to a multilateral agreement are supposed to solve their possible conflicts within the framework of the agreement they have signed and ratified. However, in the case of the Biosafety Protocol, if a party believes that in a specific circumstance its interests are better protected by WTO rules, it may invoke those rules, arguing 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 that any WTO Member can initiate a case in the WTO if it considers that its market access rights have been violated. The United States Department of Agriculture, for example, observed that "The Protocol preserves countries' rights under other international agreements, including the WTO...The Protocol does not undermine an exporting country's right to challenge, under the WTO, an unwarranted decision of an importing country not to accept a bio-engineered product."[51] The issue then is which WTO violation would be alleged by the exporting country and which defence is admissible. If the justification of the trade-restrictive measure is not safety, the SPS Agreement is not applicable and not violated. The exporting country could therefore claim violation of Article XI of GATT or Article 2.2 of the TBT Agreement, and the importing country could justify its trade-restrictive measure by using the exceptions of Article XX of GATT, particularly paragraphs (b) and (g). On the other hand, a country which has an interest in solving a dispute according to the discipline laid down in the Biosafety Protocol may invoke the fact that the Protocol represents *lex specialis*, which has priority over *lex generalis* (WTO agreements). It may also refer to the principle that later in time prevails. Finally, it could ask for its WTO obligations to be interpreted in the light of the Protocol. 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. It will be up to the panels and, possibly, the Appellate Body to decide how much legal weight they wish to give to the provisions of the Protocol. Even though the Appellate Body stated in two disputes[52] that the

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[51] See US Department of Agriculture, Foreign Agricultural Service Fact Sheet, "International Protocol on Biosafety: What it Means for Agriculture", February 2000 (website: *http://www.usia.gov/topical/ global/ biosafe/00021402.htm).*

[52] In the *Gasoline* case (*United States-Standards for Reformulated and Conventional Gasoline*, Appellate Body Report adopted on 20 May 1996, WT/DS2/9) the Appellate Body cited Article 3.2 of the Dispute Settlement Understanding, which requires Panels and the Appellate Body to use "customary rules of interpretation" to interpret the provisions of the WTO Agreements. The Appellate Body linked the WTO legal system to the rest of international legal order and imposed on Panels and WTO Members the obligation to interpret the WTO Agreements in accordance with customary rules of interpretation of public international law. In the *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 made reference to various international conventions to interpret the term "natural resources". Therefore, non-WTO treaties, practices,

WTO legal system does not operate in "clinical isolation" from existing rules of public international law, it would be difficult to predict which principles and rules would apply to a specific dispute.

75. The issue of the consistency between the trade rules included in multilateral agreements and WTO rights and obligations, and the position on non-parties to a multilateral agreement which may be affected by the trade rules agreed by the parties to a multilateral agreement has been discussed for several years in various international forums, without any conclusive result. Even though the trade provisions of a multilateral agreement have not yet been challenged before a dispute settlement 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 biotechnology is a risk or an opportunity; the main player, the United States, on one hand has actively participated in the negotiations of the Protocol as member of the Miami Group, but, on the other hand, is not a party to the CBD Convention; and the Protocol is already being interpreted in divergent ways.

76. The United States Trade Representative has raised the possibility that the United States may consider a possible dispute settlement case in the WTO against the EU for its failure to approve biotechnology varieties of corn. In a related development, the United States is seeking to unblock corn exports to the EU, which were halted because of its moratorium on approving new biotechnology varieties, with a new proposal whereby United States laboratories would be certified to conduct certain tests. These would ensure that United States shipments would not contain any unapproved varieties of genetically modified corn. The proposal requires that pre-shipment tests in the United States not be duplicated by subsequent tests in the EU, thus freeing exporters from the risk that their shipments would be blocked at the port of entry. The proposal is apparently viewed by the European authorities as a positive sign of cooperation on a contentious issue, although it is too early for the EU to approve the plan. On the other hand, industry sources in the United States said that the proposal, even if it were to meet with EU approval, would be problematic, because of the degree to which it would require segregation of unapproved varieties of GM corn from approved GM varieties and from conventional corn.[53]

B. The WTO Agreements which have implications for international trade in GMOs

77. Four WTO Agreements appear to have special relevance for international trade in GMOs: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), the Agreement on Technical Barriers to Trade (TBT), the Agreement on Trade-Related Aspects

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customs and general principles of law may be relevant in the interpretation of WTO provisions and can become quite influential in defining the parameters and the content of WTO obligations. For a detailed discussion on this topic see Marceau G., "A call for coherence in international law: Praises for the prohibition against 'clinical isolation' in WTO Dispute Settlement", *Journal of World Trade*, October 1999, pp. 87 ff.

[53] See "Barshefsky hints at considering possible biotech case Against EU", *Inside US Trade*, Vol. 18, No. 24, 16 June 2000.

of Intellectual Property Rights (TRIPS), and the General Agreement on Tariffs and Trade 1994 (GATT).

78. The main goal of the SPS Agreement is to prevent domestic SPS measures from having unnecessary negative effects on international trade and being misused for protectionist purposes. 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; and animal and plants from pests and diseases. Therefore, the specific aims of SPS measures are to ensure food safety and to prevent the spread of diseases among animals and plants. Although the WTO SPS Committee has not so far been requested to address issues related to trade in GMOs, it can be argued that measures aimed at regulating such a trade could reasonably come within the scope of the Agreement. This is because measures related to GMOs may have the goal of protecting "human or animal life from food-borne risks" or protecting "plants from pests and diseases" (in view of the lack of scientific certainty about the impact of GMOs on the environment, avoiding the transfer of genetic material and associated traits from engineered varieties to conventional varieties could be regarded as similar to protecting plants from pests and diseases). In other words, measures related to GMOs may fall within the spirit, if not the letter, of the SPS Agreement. There is, however, no consensus on this assumption.

79. Article 2.2 of the SPS Agreement states that "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5." The Agreement permits the adoption of SPS measures on a provisional basis as a precautionary step in cases where there is an immediate risk of the spread of disease but where the 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). Countries must establish SPS measures on the basis of an appropriate assessment of the actual risks involved. The procedures and decisions used by a country in assessing the risk to food safety or animal or plant health must be made available to other countries upon request.

80. The Agreement, then, maintains the sovereign right of any Government to provide the level of health protection it deems appropriate; however, it expects countries, *inter alia*, to base their SPS measures on scientific evidence and on an appropriate risk assessment.

81. In the well-known *hormone* case,[54] 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.

82. The EC invoked the precautionary principle[55] in support of its claim that its measures were based on a risk assessment. Its basic submission was that the precautionary principle was

[54] *EC Measures Concerning Meat and Meat Products (Hormones)*, Complaint by the United States, WT/DS26/R, 18 August 1997; Complaint by Canada, WT/DS48/R, 18 August 1997.

or had become a "general customary rule of international law" or at least a "general principle of

Referring more specifically to Article 5.1 and 5.2 of the SPS Agreement, the EC reached the conclusion that since applying the precautionary principle meant that it was not necessary for all scientists around the world to agree on the possibility and magnitude of the risk, or for all or most of the WTO Members to perceive and evaluate the risk in the same way, its measures (an import ban) were precautionary in nature and satisfied the requirements of Article 2.2 and 2.3 of the Agreement, as well as the requirements of paragraphs 1 to 6 of Article 5. According to the United States, on the other hand, the precautionary principle did not represent customary international law: it was more an approach than a principle. For Canada, the precautionary approach or concept was "an emerging principle of law", but had not yet been incorporated into the corpus of public international law. The Panels concluded that 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 and that it did not by itself, and without a clear textual directive to that effect, relieve a panel of 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[56] 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. The Appellate Body upheld the Panels' conclusions that the precautionary principle would not override the explicit wording of Article 5.1 and 5.2 and stressed that it 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.

83. In the *hormone* case the Panels and the Appellate Body did not have a chance to interpret directly Article 5.7 of the SPS Agreement, because the EC had not invoked it to justify the measures in dispute. However, Article 5.7 of that Agreement was explicitly addressed in the *Japan varietals* case.[57] The 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 information 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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[55] The formulation of the precautionary principle contained in Principle 15 of the Rio Declaration of 1992 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".

[56] WT/DS26/AB/R, WT/DS48/AB/R, 16 January 1998.

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

84. It seems, therefore, that the WTO jurisprudence is proposing a rather narrow interpretation of Article 5.7 the SPS Agreement: by stressing the need for countries to comply with four specific requirements in order to be able to invoke the right to adopt and maintain provisional measures, and by stating that the precautionary principle would not override the need for countries to base their SPS measures on a risk assessment - and, in general, by avoiding the expression of any view on the status of the precautionary principle in public international law. However, the Appellate Body also stated that Article 5.7 did not exhaust the precautionary principle for SPS. It seems that the central role of scientific evidence and risk assessment as the necessary bases for taking and maintaining SPS measures is reconfirmed. While the precautionary principle may be invoked to justify time-limited measures, it does not represent a long-term alternative to risk assessment and scientific evidence.

85. Labelling 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. Both the SPS and TBT Agreements encourage the use of international standards. However, under the SPS Agreement the only reasons accepted for not using such standards for food safety and animal/plant health protection are scientific arguments resulting from an assessment of the potential health risks. In contrast, under the TBT Agreement Governments may decide that international standards are not appropriate for other reasons, including fundamental technological problems or geographical factors.[58] It seems, therefore, that the TBT Agreement places less emphasis than the SPS Agreement on the need to justify measures on the basis of scientific considerations. However, technical regulations should not be more trade-restrictive than is necessary to fulfil a legitimate objective, taking account of the risks that non-fulfilment would create. 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 GMOs. 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.

86. It has not yet been determined whether an import ban applying to GMOs or GM products could be regarded as a technical regulation falling under the TBT Agreement.

[58] See WTO, "Understanding the WTO Agreement on Sanitary and Phytosanitary (SPS) Measures", May 1998 (Internet website: *http://www.WTO.org/wto/goods/spsund.htm*).

Similarly, it is not clear whether the general exceptions of Article XX of GATT could be invoked to justify measures otherwise inconsistent with the TBT Agreement.

87. Another relevant aspect of the TBT Agreement is the concept of "like products". If GMOs and GM products are considered "like products" in relation to conventional products, there are no grounds for applying any special treatment to them.

88. It seems that there are two important issues to consider. The first one is whether "like products" are determined by a "substantial equivalence" test. Under such a test, a genetically engineered food that sufficiently resembles a conventional food product in outward characteristics would be considered substantially equivalent to the conventional product, and the two products would therefore be regarded as equally safe and should be treated in the same way. "Substantial equivalence" has been promoted within the framework of the activities of the Codex Alimentarius Commission by a group of GMO-exporting countries. However, the EU and many developing countries have not supported the use of the substantial equivalence test, considering it unscientific and too narrow. They have taken the position that GM and non-GM products are physically dissimilar. This physical difference arises because, as a result of modification to develop different characteristics, GM-products contain DNA and/or proteins that their conventional counterparts do not contain. That being the case, a national labelling scheme that requires only GM products to be labelled could not be found to contravene the TBT Agreement's non-discrimination requirements that prohibit WTO Members from distinguishing among like products. Genetic modification could be regarded as a "product-related process and production methods" (product-related PPMs). The TBT Agreement allows countries to distinguish products on the basis of PPMs that are reflected in the final product characteristics. This interpretation of TBT rules, however, could be threatened if the substantial equivalence test is adopted by the Codex Alimentarius Commission as an international standard. A second issue that may be worth addressing, if "like products" is not determined by a "substantial equivalence" test, is which other test could be used.[59]

89. The issue of "like products" within the framework of international trade in GMOs has already been brought to the attention of the TBT Committee. The starting point for the discussions was the complaints made by a number of GMO-exporting countries about EC Regulation No. 1139/98,[60] which prescribes specific labelling requirements for food and food ingredients produced from genetically modified soya beans or genetically modified maize. In the EC's view, food and food ingredients containing DNA or proteins resulting from genetic modification are not equivalent to their conventional counterparts and consequently have to be subject to labelling requirements with a view to providing relevant information to consumers. In the exporting countries' view, the EC Regulation was going to negatively affect trade and set an unfortunate example for future regulation of food and agricultural products. The basis of the exporting countries' position was that food or food ingredients developed through genetic engineering or modification did not differ as a class in composition, quality or safety

[59] See Stilwell, footnote 7.

[60] Regulation (EC) No. 1139/98, 26 May 1998, OJ L 159, 3 June 1998, pp. 4 ff.

from products produced by other methods of breeding. Moreover, they believed that excessive labelling tended to confuse, rather than inform, consumers.[61]

90. The issue of labelling of GMOs and GM crops remains open within the WTO. Because it relates to concepts which are complex and controversial, such as 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 of GMOs and genetically modified commodities have been included in the Biosafety Protocol. However, the problem of the consistency of these provisions with those of the TBT Agreement has not been addressed.

91. A number of notifications concerning agricultural and food products derived from modern biotechnology were made under the TBT and SPS Agreements, utilizing the transparency provisions included in both Agreements. A total of 48 notifications were made between 1 January 1995 and 10 June 2000 (which include a revision and some identical measures notified by more than one country and/or under both Agreements). The notifications were made by a number of developed countries (the United States, Japan, Canada, New Zealand, Australia, Switzerland, the EU, Norway, Germany and the Netherlands), some developing countries (Mexico, Colombia, the Republic of Korea and Malaysia), and by a country in transition (the Czech Republic).[62] Increasingly, Members are undertaking efforts to implement national rules for products derived from biotechnology: 11 notifications have already been submitted in 2000, compared with 4 in 1995. It is interesting to note that the EU has notified its draft regulations under the TBT Agreement, invoking labelling-related issues in respect of their objective and rationale. The United States has notified its draft regulations under the SPS Agreement.

92. If uncertainties exist about the scope for applying the SPS and TBT Agreements to international trade in GMOs, the multilateral rules that undoubtedly apply to it are Articles III, XI, and XX of GATT.

93. 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".

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[61] WTO, Committee on Technical Barriers to Trade, Communication from the European Community, Reply by the European Commission to the comments by the United States and Canada on Notification 97.766, G/TBT/W/78, 27 August 1998; and WTO, Committee on Technical Barriers to Trade, Communication from the United States, European Council Regulation No. 1139/98 – Compulsory Indication of the Labelling of Certain Foodstuffs from Genetically Modified Organisms, G/TBT/W/94, 16 October 1998. The TBT Committee discussed this topic in the meetings held on 15 September 1998, 11 June 1999 and 1 October 1999.

[62] WTO, Committee on Sanitary and Phytosanitary Measures, Submission by the United States – National Regulatory Measures Related to Trade in Agricultural and Food Products Modified by Modern Biotechnology, G/SPS/GEN/186, 21 June 2000.

94. The general elimination of quantitative restrictions is embodied in Article XI, 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.

95. The obligations of Articles III and XI can be derogated from by using the exceptions set out in Article XX. 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 resources if such measures are made effective in conjunction with restrictions on domestic production or consumption.
> ….

96. 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[63] 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".[64] 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."[65]

97. A country which bans imports of GMOs or GM products may be infringing its trade obligations; it can, however, invoke a number of provisions to justify its trade-restrictive measure. It may invoke the SPS Agreement. In this case, it has to prove that the measure 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 are some difficulties at present in invoking the SPS Agreement to justify a trade-

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[63] Appellate Body Report on United States-Import Prohibition of Certain Shrimp and Shrimp Products, adopted on 12 October 1998, WT/DS58/AB/R.
[64] *Shrimp*, at para. 156.
[65] *Shrimp*, at para. 150.

restrictive measure in respect of GMOs. GMO-related measures come within the spirit but not the letter of the Agreement. There is no scientific evidence that clearly identifies the level of risk that GMOs create for human, animal or plant life or health. If a measure is taken on the basis of the precautionary principle, it has to be reviewed within a reasonable time frame. A second option is to justify a GM trade-restrictive measure under the TBT Agreement. Some difficulties also arise in this case. First of all, it is unclear whether an import ban can be regarded as a technical regulation. Secondly, it is unclear whether GMOs can be considered different from conventional products or whether they are "like products". Even though several considerations lead to the conclusion that genetically modified products and conventional products are dissimilar, no consensus has been reached on this issue. The third option is to invoke Article XX of GATT. In this case, the country implementing the trade-restrictive measure has to prove not only that its measure is consistent with the specific exception invoked (paragraphs (b) or (g)), but also that it complies with the requirements of the introductory text of Article XX, i.e. that it does not constitute unjustifiable or arbitrary discrimination between countries where the same conditions prevail and does not constitute a disguised restriction on international trade.

98. Strengthened protection of intellectual property rights may make investment by the biotechnology industry more profitable.[66] 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. Life patenting raises concerns about consumer rights, biodiversity conservation, environmental protection, sustainability of agriculture, indigenous rights, scientific and academic freedom, and, ultimately, the economic development of many developing countries dependent on new technologies. 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.

99. 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,[67] 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 that agenda, 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 going on in 2000. Most developed countries see it as a review of

[66] The analysis of IPRs is based on Tansey G., "Trade, intellectual property, food and biodiversity", Discussion Paper, Quaker Peace & Service, London, February 1999.

[67] 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.

implementation, while most developing countries see it as a review of the provisions themselves which could lead to a revision of the text.

100. While most developed countries consider that the model provided by the UPOV[68] 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 a quite strong IPRs regime for plant varieties mainly geared to industrial breeding, which may not suit all countries. It promotes commercially bread 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. For instance, developing countries could establish non-monopoly rights that allow different property rights to coexist, in recognition of the fact that a variety of actors participate in plant variety management and that they may have claims to the same innovations or knowledge. 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 progressively granted 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.[69]

101. Considering that patenting is linked to the development and introduction of GM plants, it can be argued that a country needs first to establish appropriate biosafety rules and control systems before considering the implementation of patent regimes that could encourage the development and release of these plants.

C. The Third WTO Ministerial Conference and its preparatory process

102. Most developing countries went to the Third Ministerial Conference of the World Trade Organization (Seattle, 30 November - 3 December 1999) with the idea that, in the field of biotechnology, the status quo would most likely be the best option. They opposed the view that environmental considerations should permeate the whole trade debate and remained hostile to the position that environmental concerns should be given greater weight within the WTO framework.[70] Also, they also felt that by keeping the GMOs issue out of the negotiations and by avoiding the setting up of new multilateral rules in this field, they would have the time to develop regulatory frameworks to address the issue.

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

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

[70] See, for example, WTO, Submission from India, General Council – Preparations for the 1999 Ministerial Conference – Discussion on Paragraph 9a(iii) of the Geneva Ministerial Declaration, WT/GC/W/151, 8 March 1999: "The trade and environment interface issue is a complex one and in our assessment the existing WTO provisions are more than adequate to deal with genuine and bona fide environmental concerns. The real solution for the problem, if any, lies with international institutions dealing with multilateral environmental agreements."

103. GMO-exporting countries were hoping that some decisions would be taken at the Seattle Conference that would facilitate their future exports of GMOs and GM crops. In particular, they intended to tackle the problem of national GMO approvals (having in mind the very slow approval process in the EC and the de facto moratorium), reconfirm that scientific evidence should be the basis of any measure meant to protect human and animal health and the environment, characterize GM products and conventional products as "like products," and, eventually, launch the idea that a new set of rules should be developed to deal with trade in GMOs.

104. In particular, there were two sets of issues related to GMOs that different countries wished to tackle. The holders of the technology to produce GMOs wanted the WTO system to produce new disciplines on GMOs which would limit the regulatory capacity of countries in this field. A condition for reaching this goal was to ensure that a decision would be taken at the multilateral level in favour of a speedy and reliable system of approval of new GMOs in all countries. For those countries that were producers and exporters of GMOs, but not holders of the relevant technology, the main concern was to safeguard existing market access opportunities. While the first group of countries was in favour of including the issue of international trade in GMOs in the negotiations on agriculture, the latter was against this option, being concerned that this would move the focus of the negotiations from market access to biotechnology. As a compromise solution, some countries put forward proposals related to biotechnology and international trade during the preparatory process of the Seattle Conference.

105. The United States asked for the WTO "to address disciplines to ensure trade in biotechnology products is based on transparent, predictable and timely processes."[71] Through this proposal, the United States tried to achieve several goals: to ensure rapid exports of biotechnology products by limiting the time frame for the importing countries to take a decision about imports (timely processes); to allow GMO-exporting countries to provide inputs into the decision-making process of other countries at an early stage and therefore able to influence the policy development of other nations, in particular that of countries lacking scientific and technical capacity (transparent processes); and to consider GM products "like products" in relation to conventional products on the basis of a "substantial equivalence" test (predictable processes).

106. Canada suggested that there be established "a Working Party on biotechnology in the WTO with a fact finding mandate to consider adequacy and effectiveness of existing rules as well as the capacity of WTO Members to implement these rules effectively. One year after its establishment, the WP would report on its findings to the Steering Body (to be established at Seattle) and provide any conclusions it considered appropriate."[72] Canada's wish, therefore, was to discuss biotechnology and international trade not only in the context of agriculture.

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[71] WTO, Communication from the United States – Preparations for the 1999 Ministerial Conference – Negotiations on Agriculture – Measures Affecting Trade in Agricultural Biotechnology Products, WT/GC/W/288, 4 August 1999.

[72] WTO, Communication from Canada – Preparations for the 1999 Ministerial Conference – Proposal for Establishment of a Working Party on Biotechnology in WTO, WT/GC/W/359, 12 October 1999.

Moreover, Canada wanted to maintain flexibility about the use of the findings of the Working Party, i.e. the establishment of the Working Party would not automatically imply that biotechnology would be included in the negotiations on agriculture.

107. Japan suggested that the WTO "establish an appropriate forum to address new issues, including GMOs. Such a forum would hold discussions from a broad perspective in order to analyze the current situation of GMOs, to examine the issues which need to be addressed, and to consider their relationship with existing WTO Agreements." This could be "a sub-group of an independent negotiating group on agriculture to identify topics on food-related matters of GMOs." Such a group should *inter alia* consider whether the relevant WTO agreements, such as SPS, TBT and TRIPS, are capable of responding to GMO-related matters; what is the current situation of Members with regard to their evaluation of the safety of GMOs and the labelling of food containing GMOs; and what would be the appropriate way for the WTO to deal with the contents and outcomes of discussions in other international forums.[73]

108. Under pressure from the promoters and from other GMO-exporting countries, these proposals were incorporated into the Draft Ministerial Declaration of 19 October 1999 in two parts. Paragraph 71, under the heading "Other elements of work programme", reads: "We agree to establish a Working Party on Biotechnology. The Working Party shall have a fact-finding mandate to consider the adequacy and effectiveness of existing rules as well as the capacity of WTO members to implement these rules. It is appropriate for this Group to deliberate within an X period of time."

109. Under the heading "Negotiations mandated at Marrakesh. Agriculture", Paragraph 29 (vi) refers to "improvements in the rules and disciplines as appropriate, including with respect to…disciplines to ensure that trade in products of agricultural biotechnology is based on

110. In Seattle, there was an initial discussion on these proposals. The United States confirmed that its aim was not to give the WTO the role of assessing the scientific basis of Members' decisions on whether or not to allow certain products in their markets, but rather to give it a role with respect to the process by which countries approve bioengineered agricultural products. The European Commission attempted to bridge its differences with the United States in this field by endorsing the creation of a working group in biotechnology, on condition that such a group would have a fact-finding rather than a negotiating mandate and would be part of a comprehensive package on environment-related issues. Also, it reconfirmed that it would not relinquish its rights to ban agricultural and food products on safety grounds. However, the Commission lacked the specific mandate to make this concession and the EU environment and trade ministers reversed its positions and opposed discussion on biotechnology in the WTO. There may have been several reasons for this position: the fear that the creation of a WTO working group would jeopardize the successful conclusion of the negotiations on the Biosafety Protocol; the conviction that the WTO was not the most adequate forum for developing a multilateral approach to biotechnology issues; and the fear that if a specific mandate were given to the WTO, trade considerations would have precedence

[73] WTO, Communication from Japan – Preparations for the 1999 Ministerial Conference – Proposal of Japan on Genetically Modified Organisms (GMOs), WT/GC/W/365, 12 October 1999.

over environmental concerns. After the EU ministers opposed the Commission's initial position, the Commission declared that it would accept a working group on biotechnology only if all countries pledged to work in good faith to conclude the biosafety talks and agreed a broad negotiating agenda in the WTO which would include environmental and consumer issues.

111. Following the failure of the Seattle Conference, the future status of the proposals submitted during the preparatory process has not been clarified. However, whatever the decision that is taken about their legal status, they reflect countries' concerns which did not have a chance to be addressed during the ministerial conference, but which are still present. In the specific area of biotechnology and GMOs, the launching of the new negotiations on agriculture in March 2000 has provided a forum where these issues could be discussed; some GMO-producing and exporting countries have already proposed that this topic be included in the negotiations. It is very doubtful, however, whether this forum will prove to be the most appropriate place for holding discussions on biotechnology-related issues. It will probably be very difficult for developing countries to obtain positive overall results from the negotiations on agriculture if the issue of biotechnology looms too large and attracts too much attention from delegations. The successful conclusion of the Biosafety Protocol will most probably have an impact on the positions that countries held during the Seattle preparatory process and at the Conference itself.

D. The initiatives taken by the Codex Alimentarius Commission and the Food and Agriculture Organization

112. The Codex Alimentarius Commission established in June 1999 an Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology to develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnologies or traits introduced into foods by biotechnological methods. The expectation of the global community is that the Task Force will reach an agreement on the modalities of the safety assessment of food derived from biotechnology within a period of four years. The Task Force held its first session from 14 to 17 March 2000. During the meeting, many delegations and observer organizations identified safety and nutrition assessment of foods derived from biotechnology as the main priority area of work.[74]

113. The Task Force decided that it would proceed with the elaboration of two major texts: (i) a set of broad general principles for risk analysis of foods derived from biotechnology, including science-based decision-making, pre-market assessment, post-market monitoring and transparency; and (ii) specific guidance on the risk assessment of foods derived from biotechnology, including matters such as food safety and nutrition, substantial equivalence, non-intentional effects and potential long-term health effects. A Working Group chaired by Japan was charged with the task of elaborating those texts.

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[74] Joint FAO/WHO Food Standard Programme, *Report of the First Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology*, Chiba, Japan, 14-17 March 2000, ALINOR 01/34. The report will be considered by the 24th Session of the Codex Alimentarius Commission (Geneva, 2-7 July 2001).

114. In addition, the Task Force agreed that a list of available analytical methods, including those for the detection or identification of foods or food ingredients derived from biotechnology, should be prepared, and that it should indicate the performance criteria of each method and the status of its validation. A Working Group chaired by Germany is in charge of compiling the list.

115. The Codex Committee on Food Labelling is considering the adoption of an international standard for GMO labelling.

116. In 1996, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) held an Expert Consultation and recommended that developing countries be provided with assistance and education regarding approaches to the safety assessment of foods and food components produced by genetic modification. At the first meeting of the Task Force, FAO and WHO reaffirmed their support for technical assistance to developing countries.

117. FAO published a statement on the occasion of the first meeting of the Task Force.[75] It stressed that genetic engineering provides powerful tools for the sustainable development of agriculture, forestry and fisheries and can be of significant help in meeting the food needs of a growing and increasingly urbanized population. In the case of GMOs, however, FAO called for a science-based evaluation that would objectively determine the benefits and risks of each individual GMO and address the legitimate concerns regarding the biosafety of each product and process prior to its release. FAO noted that investment in biotechnological research tends to be concentrated in the private sector and oriented towards agriculture in higher-income countries where there is purchasing power for its products. In view of the potential contribution of biotechnologies for increasing food supply and overcoming food insecurity and vulnerability, FAO called for efforts to be made to ensure that developing countries in general, and resource-poor farmers in particular, benefit more from biotechnological research while continuing to have access to a diversity of sources of genetic material. FAO proposed that this need be addressed through increased public funding and dialogue between the public and private sectors.

118. On 28 June 2000, the Director-General of FAO acknowledged in an interview that conventional crops could feed the 800 million hungry people in the world if only they were fairly distributed across the developing world. He predicted, however, that a shortage of land available for cultivation would make it impossible to feed a global population expected to peak at 9 billion people without recourse to genetically engineered plants and animals. In addition, he stressed that there is a need to take all necessary precautions to protect human health and the environment. He said he believed that consensus on GM food standards could be achieved, despite a division of opinion. The FAO, he added, is setting up a special "ethics committee," with input from philosophers and religious representatives, to investigate human factors related to GM agriculture.[76]

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[75] See "FAO stresses potential of biotechnology but calls for caution", FAO Press Release 00/17.

[76] See "World needs GM crops, says UN food chief", *Financial Times,* 28 June 2000.

119. In July 1999, the Codex Alimentarius Commission approved international guidelines for the production, processing, labelling and marketing of organically produced food. The guidelines define the nature of organic food production and will prevent claims that could mislead consumers about the quality of a product or the way it is produced. The final objective is to provide the consumer with a choice while giving assurances that organic agricultural standards have been met.[77]

E. The initiatives taken by the OECD

120. Biotechnology, genetically modified crops and other aspects of food safety have rapidly become issues of major interest to the member countries of the Organisation for Economic Co-operation and Development (OECD). OECD has a number of projects related to biosafety, such as the Working Group for the Harmonization of Regulatory Oversight in Biotechnology, the Working Party on Biotechnology, and the Task Force for the Safety of Novel Foods and Feeds. Currently, it is preparing a response to a request received from the G8 Heads of State and Government in June 1999 for a study to be undertaken on the implications of biotechnology and other aspects of food safety".[78] OECD has planned five elements in response to the G8: a report on the safety assessment of novel foods; a report on related environmental issues; a compendium describing national and international food safety systems; the results of an OECD consultation with non-governmental organizations held on 20 November 1999; and the results of the OECD Conference on "GM and Food Safety: Facts, Uncertainties and Assessment" (Edinburgh, 28 February – 1 March 2000). [79]

The precautionary principle

121. The precautionary principle started to appear in multilateral agreements in the mid-1980s. Reference was made to it in the 1985 Vienna Convention for the Protection of the Ozone Layer and the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer. The text of the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) did not explicitly invoke the principle, however, the Conference of the Parties explicitly endorsed it in 1994. The use of the principle increased further in the 1990s, when the United Nations Conference on Environment and Development (UNCED)

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[77] See "The Codex Alimentarius Commission approves guidelines for organic food and sets up taskforces on standards for foods derived from biotechnology, animal feeding and fruit juices", FAO Press Release 99/41.

[78] "Biotechnology offers great opportunities but also represents significant challenges and has given rise to public debate on its implications. Ministers stressed the importance of safeguarding human health and the environment while enabling people to enjoy the benefits that flow from advances in biotechnology. Scientific research is essential to the process. The OECD should continue to examine the various dimensions of this issue, including in the discussion at the forthcoming CSTP (Committee on Science and Technology Policy) ministerial meeting and in other fora." Communiqué of the OECD Council meeting at Ministerial level, paragraph 9, May 1999. "Because trade is increasingly global, the consequences of developments in biotechnology must be dealt with at the national and international levels in all the appropriate fora. We are committed to a science-based, rules-based approach to addressing these issues."
of State and Government meeting, paragraph 11, Cologne, June 1999.

[79] See Inter-Agency Network for Safety in Biotechnology (IANB), *Safety in Biotechnology – IANB Newsletter*, No. 1, 19 April 2000, and *OECD Work on Biotechnology and Other Aspects of Food Safety*, Note by the Secretary-General, C(99)148/REV4, 15 November 1999.

significantly enlarged the consensus on it. Principle 15 of the Rio Declaration was adopted.[80] In addition, UNCED delegates invoked the principle in the United Nations Framework Convention on Climate Change, in the Convention on Biological Diversity and in Agenda 21. As already mentioned, the precautionary principle is one of the central features of the Cartagena Protocol.[81]

122. By 1990, the precautionary principle was also appearing in regional declarations and treaties. The 1991 Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa calls for the implementation of the precautionary principle. In Europe, the principle was included in the 1992 Convention for the Protection of the Marine Environment of the North-East Atlantic, in the 1992 Convention on the Protection and Use of Transboundary Watercourses and Lakes, and in the 1992 Convention on the Protection of the Marine Environment of the Baltic Sea Area. The precautionary principle was written into the Maastricht Treaty in 1992 as the basis for EU action on the environment.

123. Since 1992, the precautionary principle has also been reflected in the domestic legislation and case law of an increasing number of countries. According to most commentators, it originated in the municipal environmental policy of the Federal Republic of Germany, where it materialized in the concepts that environmental hazards must be avoided before they occur, and that governmental authorities can order measures or act themselves, even in the face of uncertainty. In Colombia, Law No. 99 (approved in 1993) incorporates the precautionary principle as fundamental to the country's environmental policy. In 1988, Costa Rica passed Law No. 7788 to conserve biodiversity, to foster the sustainable use of natural resources and to distribute in an equitable fashion the benefits and costs derived from biodiversity. The precautionary criterion is one of the criteria for implementing the law. In Australia the precautionary principle has been incorporated into nearly all recent federal environmental policies and strategies. In addition, Australiaś judiciary has recognized the principle in a number of environmental cases. Canada has adopted the precautionary approach in legislation and intergovernmental agreements and it has appeared in Canadian case law. Several of Canadaś provinces have adopted the precautionary principle in their environmental legislation. The precautionary approach is reflected, at least implicitly, in numerous domestic environmental laws in the United States, including the Endangered Species Act, the National Environmental Policy Act, the Clean Air Act, the Federal Food, Drug and Cosmetic Act, the Clean Water Act and the Oil Pollution Act. The United States, however, has consistently maintained that the precautionary approach is not a rule of customary law; thus, although it arguably adopts a precautionary approach in several environmental laws, it does not do so out of a sense of international obligation.

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[80] In the Rio Declaration's formulation, the principle has several elements. The threshold for triggering the principle is that there are identifiable threats of serious or irreversible damage. Where such threats exist, Governments are free to take preventive cost-effective measures. Governments may also refuse to take such measures, but not on the ground that there is a lack of scientific certainty. Other than reference to cost-effective measures, Principle 15 places no conditions or restrictions on the preventive measures a Government chooses.

[81] For a recent analysis of the precautionary principle in international trade, see Ward H., “Science and Precaution in the Trading System”, Royal Institute of International Affairs and the International Institute for Sustainable Development, 1999.

124. In the *Vellore Citizens Welfare Forum versus Union of India &ORS*, the Indian Supreme Court adopted the precautionary principle in addressing pollution caused by tanneries and concluded that it was an essential element of sustainable development. Also, the Court found that the precautionary principle was part of the law of India, at least in part because the rules of customary international law, presumably including the precautionary principle, are deemed to be incorporated into domestic law if they are not contrary to domestic law. In *Shehla Zia versus WAPDA*, the Pakistani Supreme Court reviewed the challenge by a citizens' group to the proposed construction of an electric grid station. On the basis of the precautionary principle as expressed in international law and the Pakistan Constitution, the Court prohibited construction of the grid station until further studies could clarify its potential impact.[82]

125. On 2 February 2000, the EC Commission adopted a Communication [83] on the use of the precautionary principle as a complement to the Biosafety Protocol and the White Paper on Food Security. The stated objectives of the Communication are to inform all interested parties about how the Commission intends to apply the principle; establish guidelines for its application; provide input to the ongoing debate on this issue both at EU and international level; build a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully; and avoid unwarranted recourse to the precautionary principle as a disguised form of protectionism.

126. According to the Communication, the Commission considers that the precautionary principle has a scope far wider than the environmental field and also covers the protection of human, animal and plant health. It provides a basis for action when science is unable to give a clear answer, but when there are reasonable grounds for concern that potential hazards may affect the environment or human, animal or plant health in a way inconsistent with the high level of protection chosen by the EU. Decision makers need to be aware of the degree of uncertainty surrounding the results of the evaluation of the available scientific information; however, determining what is an acceptable level of risk is, in the Commission's view, an eminently political responsibility. Measures based on the precautionary principle should be, *inter alia*, proportional to the chosen level of protection; non-discriminatory in their application; consistent with similar measures already taken; based on the examination of the potential benefits and costs of action or lack of action; subject to review, in the light of new scientific data; and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment. The Commission makes it clear that examining costs and benefits of action and lack of action is not simply an economic cost-benefit analysis: it includes non-economic considerations, such as the efficacy of possible options and their acceptability to the public. In the conduct of such an examination, the protection of health takes precedence over economic considerations.

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[82] The analysis of the precautionary principle in regional and national legislation and in case law is based on Stilwell M.T., "The precautionary principle in international and domestic law", mimeo, 2000.

[83] Commission of the European Communities, *Communication from the Commission on the Precautionary Principle*, Brussels, 2 February 2000, COM(2000) 1 final.

127. The Environment Commissioner, who presented the White Paper on Food Security at a plenary session of the European Parliament, admitted that the use of the precautionary principle by the EU could trigger further trade friction with the United States, but said that disputes could be worked out.[84]

128. During the Seattle preparatory process, the EU addressed the issue of the precautionary principle and suggested that WTO Members focus on, *inter alia*, "reviewing if a clarification of the relationship between multilateral trade rules and core environmental principles, notably the precautionary principle, is needed." It added that "it is necessary to ensure the right balance between prompt, proportional action, where justified, and the avoidance of unjustified precaution, bearing in mind that the basic concept of the precautionary principle is already present in the WTO in several key provisions, such as the SPS and TBT Agreements."[85]

129. The reference in multilateral, regional and national legal texts to the precautionary principle does not make it less controversial in the context of international trade: although the precautionary principle has been included in a number of crucial legal instruments dealing with the environment, its status within the framework of the international trading system is still unclear.

130. The WTO SPS Committee discussed the precautionary principle at its first meeting in 2000 (15 - 16 March), when the EU introduced its Communication on the principle. Both the developed and the developing countries that participated in the debate voiced their concerns about the Communication and stressed that the SPS Agreement already contained rules for dealing with cases where emergency measures were needed but related scientific evidence was not fully available. They stated that a broad application of the precautionary principle in international trade would lead to a situation of unpredictability in relation to market access, which would jeopardize the results of the Uruguay Round. Moreover, the implementation of precautionary measures without a strict time frame would encourage inefficiency and slow down scientific research. Countries that expressed themselves in the SPS Committee against a broad interpretation of the precautionary principle include those that had taken up a position against it during the Biosafety Protocol negotiations, as well as some of those that were in favour of it within the Biosafety Protocol framework.

Conclusions

131. As *exporters*, developing countries have traditionally been concerned that developed countries would use measures for health, environment or consumer protection as tools to protect their domestic industry with a consequent risk for developing country market access opportunities.

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[84] See "EC's precautionary principle seeks proportionate, unbiased risk analysis", *International Trade Reporter*, 2 February 2000, Vol. 17, No. 6.

[85] WTO, Communication from the European Communities, Preparations for the 1999 Ministerial Conference – EC Approach to Trade and Environment in the New WTO Round, WT/GC/W/194, 1 June 1999.

132. As *importers*, developing countries are facing a different risk in the biotechnology field - that of importing and utilizing products which may prove to be harmful for human health or the environment. The limited capacity of most developing countries to check products at the border and make their own assessment of the risks and benefits involved, and the lack of domestic legislation in this field, make their concern serious.

133. If, as *exporters*, developing countries have pleaded against any modification of the existing multilateral trade rules that would allow more flexibility to use trade-restrictive measures for the protection of human or animal life and health or the environment, as potential *importers* of GMOs, most developing countries have requested the flexibility to decide whether to accept or refuse products whose effects on health and the environment are not yet fully known.

134. In practical terms, these different preoccupations have been reflected in the fact that developing countries have requested TBT and SPS measures to be based, as far as possible, on international standards and scientific evidence, have supported a narrow interpretation of the precautionary principle within the WTO Agreements, and rejected developed country proposals for modifying Article XX of GATT. On the other hand, most developing countries have taken a strong position in favour of flexibility in decision-making within the Biosafety Protocol and have struggled to make the precautionary approach one of the key features of the Protocol.

135. These conflicting positions are not a sign of a lack of understanding of the issues at stake, but show how difficult it is for countries - especially countries with scarce financial and technical resources and competing needs - to take an unequivocal position in an international trade scenario which is becoming increasingly complex.

136. Biotechnology may be an area where developing countries do not have a particular interest in negotiating further, especially within the WTO, since in any negotiations they would be likely to face several risks. Introducing GMOs into the WTO may bring the trade and environment communities into conflict and allow the GMO - exporting countries to develop new disciplines which could undermine the Biosafety Protocol. On the other hand, it may allow some countries to develop new rules on the precautionary principle that extend far beyond the GM products that developing countries are concerned about, thus undermining their market access for conventional products.

137. There are forums outside the WTO where GMO-related issues have been addressed and could be addressed further, such as the CBD/Biosafety Protocol or the FAO. Scientific, legal and tactical considerations would justify choosing to hold discussions on GMOs there. Countries are represented in these forums by delegates with specific expertise in the sector. The Biosafety Protocol is targeted at GMOs, whereas WTO Agreements - such as the TBT and SPS Agreements - apply across the board. Developing countries are usually more able to make their voice heard in the CBD or FAO context than in the WTO. Discussions held in these forums can be very productive, but the conclusions reached may be challenged on the basis of their WTO consistency.

138. There are also several forums within the WTO where issues related to trade in biotechnology products and, more specifically, GMOs could be addressed or have already been addressed, directly or indirectly. Each forum has its own characteristics and discussions may have different results according to where they take place. The SPS and TBT Committees are technical committees with a rather well defined mandate and relatively little room for trade-offs, even though the TBT Agreement is at present going through its second triennial review. The Committee on Trade and Environment is a forum where non-trade concerns are given special attention. The Committee on Agriculture, where agricultural negotiations are ongoing, is the forum that offers at present the widest margin of manoeuvre and the broadest opportunities for trade-offs. However, it may also be a risky forum for developing countries. GMO-producing and exporting countries may exchange concessions in the field of biotechnology for concessions in other fields, such as export subsidies, and this could lead to a situation which would go against developing country interests in the sector. Moreover, too great a focus on biotechnology would divert attention from the issues that are of most relevance to developing countries, namely tariff reductions and dismantling of subsidies, and jeopardize the global outcomes of the negotiations. Furthermore, it could be argued that trade in GMOs is an horizontal issue that has implications extending beyond agriculture and that the Committee on Agriculture is therefore not the most appropriate forum in which to discuss it. An ad hoc working group within the WTO could contribute to enhancing the understanding of the issue; however, working groups have often been the first step towards the negotiation of new trade rules.

139. If the question of international trade in GMOs and products derived from them is brought to the WTO, two possible scenarios could be envisaged.

Scenario 1

140. Since some powerful trading partners strongly support changes in the WTO system in order to better accommodate their non-trade-related concerns, and in view of the pressure put on the system by very vocal consumer and environmental groups, the multilateral trading system may become more flexible by allowing countries to make use of restrictive trade measures to protect their markets from products which may have detrimental effects on human, animal or plant life and health or on the environment. Negotiations may therefore start in the WTO to modify Article XX of GATT and, possibly, Article 5.7 of the SPS Agreement.

141. A wholesale change to the SPS Agreement and to Article XX of GATT affecting not only trade in GMOs but also trade in non-GM crops and food products would be a risky option for developing countries since it could jeopardize their existing market access opportunities. On the other hand, it would be unnecessary for them when seeking to protect domestic health and safety in the field of GMOs, since they could use the Biosafety Protocol for that purpose.

142. Nevertheless, if trade rules are changed in the way described above, the developing country attitude could be that technical and financial assistance should be provided to them to ensure that they will be able to comply with the new and stricter requirements which will be likely to be implemented by the importing countries. Full implementation by developed

countries of the provisions on technical cooperation and special and differential treatment contained in the SPS and TBT Agreements should be encouraged. The market access opportunities of developing countries should be preserved and the balance of rights and obligations emerging from the Uruguay Round should not be changed. This option may be risky: strict requirements will be implemented, but technical and financial cooperation may not follow, as the experience with best endeavour clauses has shown. However, developing countries have also to keep in mind that retailers and consumers may refuse products which do not comply with strict standards; therefore, enhanced capacities to produce quality and safe products are, in the long run, the most promising alternative.

143. This option implies building up knowledge, skills and capabilities in developing countries. Strengthening domestic capacities in this domain would have positive spillover effects, as it would also help developing countries, *as importers*, to reliably identify the kind of products they wish to allow into their markets. From a position where, owing to the lack of capacity to assess the potential risks and benefits related to genetically modified products, they are sceptical about importing and using them, they could move to a position where, on the basis of increased scientific capacities and of their own assessment of the potential risks and benefits involved, they would block the entry of those products that are actually or potentially detrimental to domestic health and safety, taking into account local conditions, while letting in those products which may prove to be beneficial for addressing serious domestic problems, such as food security, public health or environmental protection. In other words, strengthening developing country ability to deal with scientific issues in the agricultural field would improve their capacities as *exporters* as well as *importers*, and, in the future, as *producers*. Developing countries may benefit from biotechnology if they are able to deal with it and participate in its development.

Scenario 2

144. Legal uncertainty is already affecting international trade flows in GMOs and products derived from them, and the economic interests of GMO-exporting countries, primarily the United States and Canada, are being affected. Transnational corporations which have made significant investments in biotechnology are already putting pressure on their Governments to ensure that the multilateral trading system includes as few limitations as possible on the transborder movement of biotechnology products. As a result of the pressure exerted by key trading partners and by manufacture's lobbies, the existing Uruguay Round Agreements remain unchanged.

145. The attitude of the developing countries could be that the present trade scenario presents difficulties for them, since they have to cope with new phenomena, such as biotechnology, and they lack the expertise to do so. Therefore, they need technical and financial cooperation to build policy and technical capacities in the new fields. An international fund, sponsored by public and private contributions and run under the auspices of the CBD secretariat, the FAO or the Codex Alimentarius Commission, could be set up to finance technical training in biotechnology applied to agriculture and make it possible for developing countries to assess the risk and benefits of biotechnology products. On the basis of such an assessment, they would decide which products to import or which seed to sow, and,

eventually, which technology to develop to address their own agricultural and food security problems. The FAO/WHO offer to provide support to developing countries in the safety assessment of foods and food components produced by genetic modification could be a starting point. Technical cooperation offered by those developing countries that have already acquired some expertise in the field of biotechnology to the other developing countries that are still in the process of familiarizing themselves with this new phenomenon would also be an important contribution towards capacity building.

146. The *status quo* option is less risky than the first one from a trade point of view (in order to be able to implement WTO-consistent trade-restrictive measures to pursue health- or environment-related objectives, countries will have to comply with the strict requirements of Article XX of GATT and Article 5.7 of the SPS Agreement). However, it may be more risky from the point of view of domestic health and environmental protection, if the competent international organizations and the developed countries do not provide the cooperation requested. The Biosafety Protocol, however, contains specific provisions related to technical cooperation and these should also be utilized.

147. If the *status quo* prevails, the chances of having numerous trade disputes brought to the WTO dispute settlement system are quite high. This is because the issue of the relationship between the trade rules included in specific multilateral agreements and WTO rights and obligations has not yet been solved. The WTO Panels and the Appellate Body will provide solutions on a case-by-case basis. Developing countries face some difficulties in this field: to be party to a dispute settlement case is time-consuming and very costly, especially if they have to rely on foreign lawyers. Moreover, if a specific dispute is solved in a certain way, it does not mean that a similar case will be settled on exactly the same terms. Therefore, it is necessary to be constantly vigilant about the evolution of WTO jurisprudence. These are additional considerations to be taken into account.