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Domestic Import Regulations for Genetically Modified Organisms and their Compatibility with WTO Rules

Some Key Issues

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CONTENT

Introduction

While the estimated global area of transgenic or genetically modified (GM) crops continues to grow, the vast majority of acreage (99 per cent) remains confined to just four countries, namely the United States (68 per cent) followed by Argentina (22 per cent), Canada (6 per cent) and China (3 per cent), with minor plantings (<1 per cent) found in South Africa, Australia, Mexico, Bulgaria, Uruguay, Romania, Spain, Indonesia and Germany (James 2001; ISAAA 2002). In most developing countries it is still not legal to plant GM crops on a commercial basis, largely due to hold-ups in the approval process (Paarlberg 2002). Even countries that have in the past moved rapidly on the adoption of genetically modified organisms (GMOs), including China and Argentina, are now slowing down the approval processes. While the regulatory blockages are usually justified on biosafety grounds, trade concerns appear to play an increasing role with countries fearing export losses in markets such as the EU, Japan and Korea where the import regulations for GMOs continue to be tightened. The ongoing trade dispute between the U.S. and the EU over the EU's continued *de facto* moratorium on the approval of new GMOs is also adding to the prevailing uncertainty in the international commodities market.

In this context, the first part of this paper will outline regulations affecting the import of GMOs and GMO products in selected countries, including import restrictions, risk assessment provisions and labelling requirements. While most of the attention will focus on some of the major OECD countries, including the EU, the U.S. and Australia/New Zealand, the paper will also review regulations in key developing countries in Asia, Latin America and Africa. The second part will look at possible conflicts between national import regulations and WTO rules, in particular regarding the current and proposed EU regulations. To this end, the section will briefly outline the relevant WTO agreements; assess the trade-restrictiveness of mandatory traceability and labelling requirements; evaluate whether GMO regulations covering substantially equivalent GM products might be discriminatory; look at the role of precaution as a justification for an import ban on GMOs; and briefly discuss the Cartagena Protocol on Biosafety and how its provisions might impact on a possible dispute at the WTO.

1 Review of selected Domestic Import Regulations for GMOs

1.1 European Union

Community legislation related to the importation of GMOs has been in place since the early 1990s. The 1990 EU "Council Directive on the deliberate release into the environment of genetically modified organisms" (*90/220/EEC)* established Europe-wide procedures for the deliberate release of GMOs in member states.[1] The 1990 Directive thereby aimed to protect consumer health and the environment, while creating a unified market for biotechnology. The 1990 Directive allowed a member state to refuse the release of GMOs in its territory even if consent has been given under the Directive (Article 16) if the country has "justifiable reasons" to believe that an approved product "constitutes a risk to human health or the environment".[2] A revised version of the

[1] EU Council Directive on the deliberate release into the environment of genetically modified organisms (*90/220/EEC)*. http://biosafety.ihe.be/GB/Dir.Eur.GB/Del.Rel./90.220/TC.html on 31 Aug 03.

[2] This article was used by Austria and Luxembourg in 1997 to ban the import and cultivation of GM insect resistant maize. While the European Commission asked Austria and Luxembourg to lift their bans, no formal decision was reached under the Directive as to whether the bans should be allowed to remain in place. Nine Article 16 cases are currently underway involving Austria, Luxembourg, France, Greece, Germany and UK. Eight cases have been examined by the Scientific Committee on Plants, which in all cases deemed that the information submitted by Member States did not justify their bans. (Mackenzie & Francescon 2000; European Commission 2002)

Directive (*2001/18/EC*) was adopted in March 2001 by the European Parliament and the Council of Ministers and entered into force on 17 October 2002.[3]

Applications for the approval of GMOs for release into the environment or placing on the market must be accompanied by a full risk assessment which should identify and evaluate potential negative effects of the GMO, either direct or indirect, immediate or delayed, taking also into account the cumulative and long-term effects on human health and the environment. While a risk assessment was already required under the 1990 Directive, the procedure has been strengthened in the revised 2001 Directive by introducing mandatory information to the public, including information on notifications, assessments and releases of GMOs, and general rules on mandatory labelling and traceability at all steps of market placement. The new Directive furthermore includes mandatory monitoring requirements for long-term effects associated with the interaction with other GMOs and the environment.

Approval of GMOs for environmental release
Under the 1990 and 2001 Directives, applications for the release of GMOs into the environment are assessed by the member state where the product is first placed onto the market. If approved and if no objections are raised by other member states, the product can be marketed throughout the EU. If objections are raised, the decision will be taken at the Community level, based on a risk assessment conducted by the Scientific Committees on Plants or Food. In contrast to the 1990 Directive, approval under the 2001 Directive is granted for only 10 years after which period authorizations are renewable. The amended Directive also requires the phasing out of antibiotic resistance marker genes for GMOs placed on the market by 31 December 2004 and for experimental GMOs possibly by 31 December 2008.[4]

On 25 July 2001, the European Commission put forward two legislative proposals on GMOs, a Regulation on GM food and feed (*COM 2001 - 425 final*, European Commission 2001a) and a Regulation on traceability and labelling of GMOs and products produced from GMOs (*COM 2001 - 1821 final*, European Commission 2001b). The regulations were adopted by the European Parliament and the European Council of Ministers in July 2003 with certain amendments.[5] Under the new regulations, the authorization process for GMOs for release into the environment and GM food or feed has been simplified with a "one door one key" procedure, i.e. a single risk assessment and a single application are required to obtain approval for the deliberate release of GMOs into the environment and for use in food or feed (European Commission 2003). Scientific risk assessments will be conducted by the newly established European Food Authority. The Commission will then draft a proposal for granting or refusing authorization, which will be submitted for approval by member states within a Regulatory Committee. The new regulations will enter into force 20 days after their publication (September/October 2003) with a six month compliance period.

Approval and labelling of GMOs for use in food and feed

[3] EU Directive *2001/18/EC* of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (*2001/18/EEC*). http://biosafety.ihe.be/GB/Dir.Eur.GB/Del.Rel./2001_18/2001_18_TC.html on 31 Aug 03.
[4] Antibiotic resistance marker genes (ARMG) are inserted in the modified organism to identify genetically transformed plants, i.e. only plants with the ARMG will grow on material that contains antibiotics. Some fear that ARMGs may be transferred into bacteria in the stomach, thereby making potentially harmful bacteria resistant to antibiotics. (Donaldson & May 1999)
[5] Amendments include, *inter alia*, language to allow EU member states to impose "appropriate measures" to avoid the unintended presence of GMOs in other products ("co-existence"). The European Commission has released Guidelines for the development of national strategies and best practices to ensure the co-existence of GM crops with conventional and organic farming.

The 1997 Regulation *(EC) 258/97* on novel foods and novel food ingredients set up a similar process for the authorization of novel foods - including food products containing, consisting or produced from GMOs - as that set out in the 1990 and 2001 Directives for the approval of GMOs for environmental release.[6] However, the full authorization procedure was not required for foods derived from, but no longer containing, GMOs which are 'substantially equivalent' to existing foods regarding composition, nutritional value, metabolism, intended use and the level of undesirable substances (see Box 2 on substantial equivalence). Companies simply needed to notify the Commission when placing such products on the market together with a scientific justification that the product is indeed substantially equivalent. Under the new labelling and traceability regulations, this simplified procedure has been abandoned.

Since the entry into force of the 1997 Novel Foods Regulation, labelling of foods and food ingredients, which contain or consist of a GMO, is mandatory, including GM seed varieties. Foods derived from, but no longer containing, GMOs, which are substantially equivalent, do not need to be labelled. Since January 2000, additives and flavourings have to be labelled if DNA or protein of GMO origin is present in the final product (Regulation *(EC) 50/2000*). Besides, Regulation *(EC) 49/2000* introduces a 1 per cent *de minimis* threshold for adventitious contamination, i.e. conventional foods where the amount of GM material accidentally introduced lies below 1 per cent, do not need to be labelled.

While traceability requirements were already included in general terms in the 2001 Directive, the new regulations further elaborate on these provisions. In particular, the 2001 Directive requires operators to transmit and retain specified information for GMOs, including their unique codes, at all stages of the placing on the market.[7] With regard to labelling, the new regulations extend the current labelling requirements to all GM food or feed, irrespective of whether the GM material can still be detected. Thus, all pre-packaged products on the market consisting of, or containing, GMOs must be labelled as 'containing GMOs', while products, including bulk quantities, that are not packaged and the use of a label is not possible, must be accompanied by the relevant information. The labelling threshold is 0.9 per cent below which GM products are exempt from labelling. The threshold for the accidental presence of unauthorized GM material is 0.5 per cent, provided that the GMOs have been judged as safe for human health and the environment by the relevant Scientific Committees or the European Food Authority. With these provisions, the new regulations, together with the revised 2001 Directive, have established what the Commission has described as the "world's most stringent" rules on controlling and monitoring the release of GMOs (BW, 31 July 2001 and 11 December 2002).

As of August 2003, the commercial release of 18 GMOs into the environment has been authorized in the EU since the 1990 Directive entered into force. At the EC Environment Council meeting in June 1999, five member states - i.e. Denmark, Greece, France, Italy and Luxembourg - called for the suspension of new authorizations pending the adoption of rules ensuring labelling and traceability of GMOs and GMO-derived products (EC Environment Council 1999). Seven other Member States - i.e. Austria, Belgium, Finland, Germany, Netherlands, Spain and Sweden - declared their intention to take "a thoroughly precautionary approach" to the authorization of new GMOs and "not to authorize the placing on the market of any GMOs until it is demonstrated that there is no adverse effect on the environment and human health". As a result of this *de facto* moratorium, no new GMOs have been approved since October 1998 with 13 applications pending (European

[6] Regulation *(EC) No 258/97* Of The European Parliament And Of The Council of 27 January 1997 concerning novel foods and novel food ingredients. http://biosafety.ihe.be/GB/Dir.Eur.GB/FF/258_97/258_97.html on 31 Aug 03.

[7] Regarding products derived from GMOs, the Directive requires operators to inform the next operators in the production and distribution chain that the product was derived from GMOs, but does not require the unique code(s) to be transmitted.

Commission 2003). The European Commission has repeatedly stated that the *de facto* moratorium would be lifted once the regulations entered into force, but no new GMOs have been approved to date. Regarding GM food, 16 products can be legally marketed in the EU. These include one variety of soybean and one of maize authorized under the 1990 Directive, and processed foods derived from, *inter alia*, seven GM oilseed rape, four GM maize and oil from two GM cottonseeds, which have been notified as substantially equivalent under the 1997 Novel Foods Regulation (European Commission 2003). Ten applications are currently pending.

1.2 USA

In the United States, GMOs are regulated through existing legislation, which is implemented by three federal agencies:

- Department of Agriculture (USDA)'s Animal and Plant Health Inspection Service which regulates the development and field testing on most GMOs,
- Environmental Protection Agency (EPA), which oversees the development and release of GM plants with pest control properties, and
- Food and Drug Administration (FDA), which is responsible for the safety of food and feeds.

Currently, no mandatory risk assessment requirements exist in the U.S. for GMOs. In 1992, the U.S. FDA released its *Statement of Policy: Foods Derived from New Plant Varieties*, which provides guidance to industry on scientific and regulatory issues related to bioengineered foods, including questions to be answered by developers of foods from new plant varieties to ensure that the new products are safe and comply with applicable legal requirements (U.S. FDA 1995). The document furthermore encourages continuation of the general practice of the food industry to consult with the agency about the safety of new foods, including bioengineered foods. In addition, the FDA released its proposed rule on *Premarket Notice Concerning Bioengineered Foods* in January 2001 which would require GM food producers to notify the FDA at least 120 days prior to the commercial distribution of plant-derived bioengineered foods intended for human or animal consumption (U.S. FDA 2001a). The notification would need to be accompanied by information on, *inter alia*, the method of development; any newly inserted antibiotic resistance marker gene; and the substances introduced into or modified in the food, including safety considerations associated with them. Information submitted to the FDA and its response would be posted in the agency's electronic reading room unless deemed confidential.

The 1992 policy does not establish special labelling requirements for bioengineered foods as a class of foods. This is based on the assumption that bioengineered foods do not differ from other foods in any meaningful or uniform way, or pose any different or greater safety concern than foods developed through traditional plant breeding. Instead, the FDA issued a *Draft Guidance for Industry Voluntary Labelling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering* in January 2001 to assist manufacturers who wish to voluntarily label their foods (human and animal) as being made with or without bioengineering or the use of bioengineered ingredients in order to ensure that labelling is truthful and not misleading (U.S. FDA 2001b).

While currently no mandatory labelling requirements exist at the national level, Congressman Dennis J. Kucinich (Democrats) introduced five bills in the U.S. House of Representatives in May 2002, which would provide a comprehensive regulatory framework for all GM plans, animals, bacteria and other organisms. The bills include the *Genetically Engineered Food Right to Know Act* (2002), which would require food companies to label all foods containing or produced with GM

materials (H.R.4814).[8] The draft Act has been endorsed by the Sierra Club, the National Farmers Organization, the Centre for Food Safety, the Organic Trade Organization, the American Corn Growers Association and the Campaign to Label Genetically Engineered Foods.

Efforts have also been underway in some states to introduce such regulations, notably in California and Oregon (BTB 11 July 2002). In particular, a Californian proposal (California State Senate 2002), which would require all transgenic fish and shellfish to be labelled, passed the first vote in the Senate Health & Human Services Committee, making it the first labelling bill for GM foods that has passed a major policy committee in the U.S.. Consumers in Oregon had hoped that they could replicate the precedent set in California. On 5 July 2002, the consumer organization Oregon Concerned Citizens for Safe Foods handed in over 100,000 signatures to the Oregon Secretary of State office for a ballot initiative in November 2002 on GM food labelling.[9] Specifically, the proposal suggested that food derived or processed from genetically engineered materials are labelled by the Oregon Department of Agriculture (OCCSF 2002). While the Oregon initiative was defeated by more than 70 per cent of voters, many see the State as a fertile testing ground, which has in the past already played an important role in shaping consumer attitudes and setting standards with regard to organic food.

The first GM food product went on sale in the U.S. in 1994. Since then, 54 GM foods have been approved (as of 11 October 2002, U.S. FDA 2002). Today, the U.S. is the largest producer of GM, accounting for 68 per cent of planted hectares in 2001 (ISAAA 2002).

1.3 Australia / New Zealand

The Australian *Gene Technology Act* was passed in December 2000 to regulate all 'dealings' with GMOs (e.g. research, manufacture, production, commercial release and import) together with associated Acts (the *Gene Technology (Consequential Amendments) Act 2000* and the *Gene Technology (Licence Charges) Act 2000).*[10] The legislation is the Commonwealth's component of a new national scheme for the regulation of GMOs that will include legislation in every Australian jurisdiction (i.e. States and Territories).

The Act established the *Gene Technology Regulator* (GTR), an independent statutory office holder charged, *inter alia*, with administering the legislation (including the approval of GMOs), providing information and advice to other regulatory agencies, promoting the harmonization of risk assessment, and monitoring and enforcing the legislation. The Act furthermore establishes three key committees, including the *Gene Technology Technical Advisory Committee* - comprising 18 members (experts in relevant scientific fields including risk assessment, public health, ecology and a layperson) appointed by the former Minister for Health and Aged Care - to provide scientific advice to the GTR and/or the Ministerial Council. Applications for release of GMOs need to be submitted to the GTR accompanied by all information detailed in the regulations, including information on potential negative impacts on health and the environment. Based on the information provided by the applicant and other relevant bodies, the GTR will prepare a comprehensive risk assessment and risk management plan. All approved GMOs will be included in the GMO Register.

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[8] Also introduced were the G*enetically Engineered Food Safety Act*, the *Genetically Engineered Crop and Animal Farmer Protection Act*, the *Genetically Engineered Organism Liability Act* and the Re*al Solutions to World Hunger Act*. The draft Acts are searchable at http://thomas.loc.gov/home/c107query.html (on 31 Aug 03).

[9] Ballot initiatives give direct legislative power to the voters to enact new laws, change existing laws or amend the Oregon Constitution. In this case, the number of signatures is sufficient to place an initiative measure on the ballot that would amend the Oregon Constitution.

[10] Australia *Gene Technology Act 2000;* http://scaletext.law.gov.au/html/pasteact/3/3428/top.htm on 31 Aug 03.

In New Zealand, the environmental release of GMOs is governed by the *Hazardous Substances and New Organisms Act 1996*. No GMO has so far been approved under the Act and a moratorium has been put in place until 31 October 2003 (MfE 2003).

Standard A18 *Foods Produced using Gene Technology* (1999) in the Australian *Food Standards Code* (Standard 1.5.2 in the joint Australia New Zealand *Food Standards Code*) regulates the sale of food produced using gene technology in Australia and New Zealand (ANZFA 1999). In July 2000, Health Ministers of the Australian States and Territories, The Australian Commonwealth and New Zealand agreed to amend the standard to include mandatory labelling requirements for GM foods. In particular, the Standard requires all foods produced using gene technology to be assessed regarding safety for human consumption and approved before sale and use. The safety assessment is carried out by the Australia New Zealand Food Authority and is based on the Authority's approved safety assessment criteria.

The Standard furthermore requires all GM food and ingredients to be labelled where they contain novel DNA and/or novel protein in the final food, or have altered characteristics. [11] Exempt from these requirements are highly refined foods (e.g. oil made with GM ingredients), most processing aids and food additives, flavours present in a concentration less than or equal to 0.1 per cent, and food prepared at point of sale. Any one ingredient in the food is allowed to contain up to one per cent GM material if introduced accidentally. While not explicitly including traceability requirements, compliance with the Standard likely requires verifiable documentation regarding the GM status of the food to be transmitted from growers, processors, suppliers and importers to manufacturers and retailers along the supply chain (FSANZ 2001). Following the amended Standard's entry into force in December 2001, Australia and New Zealand now have some of the strictest labelling requirements in the world.

Numerous field trials of GM plants are currently being carried out in Australia, but only four plants have so far been approved for commercial release i.e. a violet carnation, a carnation with improved vase life, Bt cotton and transgenic canola. A number of GM food products are also being imported to Australia for sale, including soybeans, canola oil, corn, cotton, potatoes and sugar beet, as at August 2001 (FSANZ 2001). Several Australia states, however, have instituted moratoria for the commercial release of certain GMOs, including GM canola, which has been blocked from commercial release in South Australia, Victoria, Western Australia and New South Wales. The state of Western Australia has instituted a general moratorium on the release of GM crops (ENS 2003).

1.4 Asia

In Asia, the only major GM crops approved for commercial release are GM cotton, which is grown commercially in China, India and Indonesia, and GM corn, recently approved in the Philippines. To date, no Asian government has given official permission to plant soybeans or rice (Paarlberg 2002). While China had initially moved quickly on the approval of GM crops for environmental and commercial releases, the approval process has slowed considerably since 2000 and strict regulations have been implemented for GMO imports (Paarlberg 2002). Several other countries in the region have also made efforts to control imports of GMOs. Korea's Ministry of Agriculture & Forestry requires mandatory labelling for certain genetically modified "raw materials", including GM soybean, corn and beans sprouts as of 1 March 2001 and GM potatoes as of 1 March 2002. The threshold for accidental presence of GMOs is three per cent. In this case, a certificate is required to prove that the GMOs have been separately cultivated, harvested, stored and distributed (MAF 2002). In 2001, Thailand banned all GM field experiments and has restricted GM imports, most

[11] "Altered characteristics" is understood to mean that when compared to conventional foods, the GM food is different with respect to composition or nutritional values, anti-nutritional factors or natural toxicants, factors know to cause allergic responses, and its intended use

recently in February 2002 when the country banned the import of 37 more GM plants in addition to the 40 already listed. Efforts are also underway to implement labelling regulations for a number of soy and corn products.[12] Malaysia, while investing heavily in the development of GM crops since the 1980s, is also holding back on the commercial release of GM crops. On 1 May 2001, Sri Lanka's Health Ministry imposed import restrictions requiring 21 categories of food imports to be free of GM products. The ban was later suspended following a request by the WTO that the country should give its trading partners 60 days to prepare for the restrictions, before it was finally postponed indefinitely (Reuters 2001).

China

Based on the *Regulations on Safety Control of Agricultural GMOs* issued on 23 May 2001 by the State Council, the Chinese Ministry of Agriculture on 5 January 2002 issued three sets of Implementation Regulations related to the safety assessment, import and labelling of agricultural GMOs[13], which set up a complicated and lengthy approval procedure involving numerous certificates and agencies.[14]

Safety Assessment: The *Regulations on Safety Assessment* defines four safety classes ranging from 'no danger' to 'high degree of danger'. Safety evaluations of agricultural GMOs are carried out by the Agricultural GMO Safety Committee, established under the Ministry of Agriculture. In addition, the Agricultural GMO Safety Administration Office, also under the Ministry of Agriculture, is responsible for administering the safety evaluation of agricultural GMOs. The decision on whether to approve an agricultural GMO is taken by the Ministry of Agriculture. Safety assessments are carried out twice a year (in March and September), a process that can take up to five months.

Importation: Depending on the intended use of a GMO (e.g. research, environmental release, use in production, use as raw material etc.), different documentation requirements and testing procedures apply as set out in the *Regulations on Safety of Import*. For agricultural GMOs for production (including GM planting seeds, breeding livestock, poultry and fish fry), importers must first obtain an approval to enter the country. Once imported, the GMO must go through three stages of testing (medium test, environmental release and productive test) and must pass a safety evaluation at each stage to obtain approval. Only when this testing procedure has been completed, will the Ministry of Agriculture issue a safety certificate, which the foreign company can then use to complete the remaining approval procedures. For agricultural GMOs for use as raw materials, import and safety evaluation applications need to be submitted to the Agricultural GMO Safety Administration Office at the same time, along with other relevant documents (as specified in the Regulations) when applying for a safety certificate. For all agricultural GMOs, the Ministry of Agriculture will decide on whether or not to approve the GMO within 270 days after receiving the application.

Labelling: The Agriculture Ministry requires that certain agricultural GMOs are labelled, including products derived from, but no longer containing, GMOs, as set out in the *Regulations on Labelling of Agricultural GMOs*. Currently, labelling is required for soybeans and corn (including their seeds, powder, oil and meal); rapeseed, oil and meal; cotton seed; and tomatoes, tomato seed and tomato

[12] Notification by Thailand's Food and Drug Administration to the SPS Committee. G/SPS/N/THA/71. 5 October 2002. Searchable at http://docsonline.wto.org

[13] i.e. animals, plants, microorganisms and their products whose genetic structures have been modified by genetic engineering technology for the use of agricultural production or processing

[14] Note that the following outline of China's GMO regulations is based on unofficial translations of the relevant regulations. Consequently, names of agencies and regulations might differ from other translations. The translations are available at http://binas.unido.org/binas/country.php3?id=5. The regulations were notified to the WTO SPS Committee on 19 April 2002 (G/SPS/N/CHN/P/136, G/SPS/N/CHN/P/137, G/SPS/N/CHN/P/138, G/SPS/N/CHN/P/139; searchable at http://docsonline.wto.org/).

mark, but the Agriculture Ministry reserves the right to adjust this list. A decision will be made within 30 days (BTB 21 March 2002).

The Regulations were set to enter into force on 20 March 2002, but were temporarily waived until 20 December 2002 (under *Circular of the Ministry of Agriculture No 190*).[15] In the interim period, traders need to apply for a provisional certificate from the Agricultural GMO Safety Administration Office, once the application for the safety certificate of the GMO in question has been submitted and approval is pending. The application should include valid safety evaluation documents issued by the competent authorities of the exporting country or a third country. While the application is being processed, importers of the agricultural GMO may apply for labelling approval (following the procedure as described above). The provisional certificate and the labelling approval will be granted within 30 days of the application. After a slow start, China began issuing the first temporary certificates in April 2002. The interim regulations were extended twice - first until September 2003 and subsequently until April 2004 - with the added requirement that applications for preliminary safety approvals will need to be accompanied by a safety certificate from the country of origin rather than from a third country as under the previous temporary rules.

Regulations for the approval and labelling of GM foods are set out in the *Administrative measures on Hygiene of GMO Foodstuffs*, adopted on 11 December 2001 by the Ministry of Health. Under these regulations, all foods and food additives made from animals, plants and microorganism whose genome composition is modified through biotechnology need to undergo a safety assessment, carried out by the GMO Food Expert Commission established by the Health Ministry. These GMOs include GM animals, plants and microroganisms; products made thereof; and food and food additives processed by using products directly made from GM animals, plants and microorganisms. GM foods should not be inferior to their conventional counterparts with respect to safety and nutritional quality. Approval or rejection of the application will be issued within six months after receiving the application. Any food products, including raw and processed foods, must be labelled.

China is developing the largest plant biotechnology capacity outside of North America (Huan *et al* 2002). Between 1997 and 2000, 45 GM plant applications for field trials were approved, 65 for environmental release and 31 for commercialization. The only GM crop widely adopted on a commercial basis is insect-resistant GM cotton, with approval also given for minor food and horticultural crops, including tomato, sweet pepper and petunia. However, since late 2000 the approval process has slowed down significantly, including for GM corn and soybeans. This shift has been attributed to changes in the international commercial market for GM products, in particular preferences for GM-free corn and soy in the EU, Japan and Korea (Paarlberg 2002).

India

In 1989, the Indian Ministry of Environment & Forests established rules for the manufacture, use, import, export and storage of hazardous micro-organisms, genetically engineered organisms or cells (MEF 1989). The overall responsibility for the application of Biosafety guidelines and regulations rests with the Department of Biotechnology (DBT) under the Ministry of Science and Technology. In addition, the rules set up various competent authorities to implement the regulations. These include, inter alia, the Review Committee on Genetic Manipulation (RCGM) in the DBT, which is charged with monitoring the safety-related aspects of research and other activities involving GMOs. The Committee is furthermore instructed to lay down procedures restricting or prohibiting production, sale, importation and use of GMOs as listed in the Schedule attached to the rules. The Genetic Engineering Approval Committee (GEAC) under the Department of Environment, Forests and Wildlife is responsible for the approval of environmental releases of GMOs and GMO

[15] Notification by China's Ministry of Agriculture to the SPS Committee. G/SPS/N/CHN/P/14O. 19 April 2002. Searchable at http://docsonline.wto.org/.

products, including field trials, as well as other R&D efforts involving GMOs. Field trials are monitored by the Monitoring and Evaluation Committee of the DBT.

The *Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts* (1994, revised in 1998) approved by the RCGM cover areas of recombinant DNA research on plants including the development of transgenic plants and their growth in soil for molecular and field evaluation (DBT 1998). The guidelines also deal with import and shipment of GM plants (for research use only). Clearance for import of transgenic material for research purposes is provided by the RCGM, which will issue an import certificate after looking into the documents related to the safety of the material and the national need.

While no labelling scheme for GMOs exists as such, GMOs do need to be labelled, whether importer or domestically approved, due to the conditions on the approvals granted by the GEAC on each application for environmental release. Each approval may have different labelling requirements, depending on what is being approved and for what purpose.[16]

Field trials are underway in India for tobacco, rice, mustard / rape seed, potato, brassica / mustard, tomato, brinjal, cauliflower, cabbage, cotton, chilli, bell pepper (BINAS n.d.). The country had not approved the commercial planting of any GM crops until March 2002 when the GEAC finally approved the commercial production of three varieties of GM cotton amid widespread protests by anti-GM activists (Paarlberg 2002). Since its approval, Bt cotton continues to attract much controversy. In a report tabled in the Indian Parliament in April 2003, the Agriculture Ministry's Standing Parliamentary Committee raised serious doubts regarding the crop's efficacy, concluding that Bt cotton appeared to perform "only marginally" better than conventional varieties, both in terms of productivity and resistance to bollworm infection (BTB 1 May 2003).

Japan

The Ministry for Agriculture, Forestry and Fishery (MAFF) issued *Guidelines for Application of rDNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries* in April 1989 (reissued partly revised in April 1992, April 1995, and August 1995) to establish basic requirements concerning the appropriate application of GMOs in agriculture, forestry, fisheries, the food industry and other related industries (MAFF 1989). The guidelines require all recombinant DNA (rDNA) organisms (crop plants, micro-organisms, and small laboratory animals) to which new properties have been introduced using rDNA technology to undergo a safety evaluation, which should be submitted for the MAFF for approval. This applies even if safety assessments have been completed abroad to account for differences in propagating and environmental conditions. Feed and feed additives are subject to separate rules also issued by the MAFF.

The Ministry of Health and Welfare (now Ministry of Health, Labour and Welfare, MHLW) has been assessing the safety of foods and food additives produced by recombinant DNA techniques based on the *Guideline for Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques* since 1991. Under the amended *Standardized Regulation on Foods, Food Additives and other Related Products*, any foods and food additives produced by recombinant DNA techniques are subject to a mandatory assessment of their safety as food items by the MHLW. Any such foods or food additives without a safety assessment shall be neither imported nor sold in Japan.

Under the amended *Law Concerning Standardization and Proper Labelling of Agriculture and Forestry Products*, MAFF requires mandatory labelling of GM agricultural products as listed in the *Labelling Standard for Genetically Modified Foods* as of 1 April 2001 (MAFF 2001). The list currently includes soybeans (including green soybeans and soybean sprouts), corn, potato, rapeseed and

[16] Personal communication, Atul Kaushik, 4 October 2002.

cottonseed, but might be adapted as appropriate. Labelling of processed food is also required (as listed in the Standard) in which rDNA or the resulting protein still exist even after processing. Food products must be labelled as 'genetically modified' and must specify whether GM products were segregated from non-modified products during production, distribution or processing. In addition, the MHLW has requested the Food Safety Investigation Council to discuss the necessity for labelling of foods and food additives produced by rDNA techniques (MHLW n.d.). Discussions at the Subcommittee on Food Labelling are still underway to decide appropriate measures for the labelling under the *Food Sanitation Law*.

As of May 2003, 24 plants have been approved by MAFF, while 55 GM foods and 12 GM food additives have undergone safety assessment by the MHLW as of 1 July 2003 (MAFF 2003; MHLW 2003). Imports of corn from the US had dropped significantly following the StarLink crisis when StarLink corn, which is not approved in Japan for food or feed, was found in U.S. corn imports in October 2000.

Philippines

In April 2002, the Philippine government adopted regulations for the environmental release of GM plant and plant products, and the importation of GMOs for food, feed and processing by 1 July 2003. Under the Administrative Order No. 08 (Series 2002) entitled *Rules and Regulations on the Importation and Release into the Environment of Plants and Plant Products Derived from the use of Modern Biotechnology*, all GM plant and plant products will have to undergo safety tests by the regulatory bodies of the Department of Agriculture, including the Bureau of Plant Industry (BPI) as the main regulatory agency.[17] The BPI will require a risk assessment by an independent Scientific Technical Review Panel created by BPI, which will assess potential risks to plant, humans and the environment. The regulations include the concept of 'substantial equivalence' as a point of departure for the risk assessment.

The government was to prepare a list by 30 June 2003 of approved GM commodities allowed into the country (BTB 21 March 2002). After that date, any imported GMO not included on the list require a permit. Conditions for receiving a permit differ depending on the intended use of the GMOs. Thus, any GMO released for propagation requires a permit from the BPI; be shown to not pose significant environmental risk based on field studies conducted in the Philippines; pass food and/or feed safety studies to show that the GMO does pose significant risks to human or animal health; and, in cases of pest-protected plants, be registered with the Fertilizer Pesticide Authority (FPA). Importation for direct use as food or feed or for processing is only allowed for GMOs whose importation has been authorized by the BPI; that have been authorized for commercial distribution in the country of origins; and that do not pose a significant threat to human and animal health regardless of intended use.

In December 2002, BPI approved the first biotechnology crop (insect-protected GM corn) for commercial release in the Philippines (Monsanto 2002). The distribution of GM corn in May/June 2003 was accompanied by anti-GMO protests that tried to halt the crop's release (BTB 1 May 2003).

1.5 Latin America

In Latin America, Argentina, as the world's second largest producer of GMOs after the U.S., is by far the biggest player regarding the commercialization of GM crops. In contrast, several other important agricultural states in the region, including Brazil, have yet to officially approve the commercialization of GM crops, even though illegal planting of GMOs is thought to be widespread in some areas. Even in Argentina, authorities began to hold back on the release of new GM crops

[17] Administrative Order No. 08 (Series 2002), http://www.da.gov.ph/agrilaws/AO2002/Transgenics.PDF on 31 Aug 03.

that have not yet been approved in the EU. Concerns have also repeatedly been raised in Mexico regarding the importation GM corn. These concerns were further fuelled by findings that Mexican native varieties of corn grown in remote regions of Mexico have been contaminated by transgenic DNA. Bolivia imposed a ban on the import of GMOs in January 2001, which was revoked in October 2001 despite assurances by the Bolivian government in August that it would not lift the ban, allegedly due to pressure by the Argentinean soy corporate sector (FOEI 2001).

Argentina

In 1991, the National Advisory Commission on Agricultural Biotechnology (CONABIA) - a consultative and technical support service - was set up to advise the Secretary for Agriculture, Livestock and Fisheries (today Secretary of Agriculture, Livestock, Fisheries and Foods, SAGPyA) on the design and administration of regulations for introducing and releasing genetically-engineered plant materials into the environment. CONABIA comprises public and private sector representatives working in agricultural biotechnology.

Argentine GMO-related regulations are based on identified characteristics and risks of biotechnological products, rather than on the process by which they are produced (Argentina 2000). In other words, they are aimed at transgenic products according to their proposed usage, taking into account only those aspects of procedures employed for their development, which might pose a threat to the environment, agricultural production or public health. Resolutions nº 656 (30 July 1992) and nº 289 (9 May 1997) set out the requirements, which must be met in order to permit the release of GMOs into the environment; these are taken into account by CONABIA when evaluating each application.[18] These regulations are also incorporated into the general regulatory framework governing the agricultural sector, i.e. existing regulations in Argentina in connection with plant and seed protection and new phytogenetic products. Evaluation of applications and the subsequent monitoring of trials are the responsibility of the SAGPyA. Once authorization for release into the environment has been granted, a "flexibilization" licence may be applied for (Resolution nº 131, 1990, of the SAGPyA). Granting of the "flexibilization" licence means that future releases into the environment require only presentation of information regarding: sown area, sowing date, release site and harvest date. CONABIA will recommend only inspections of harvests and of the final disposal of material.

In order to obtain the appropriate marketing licence, varieties must also comply with requirements stipulated by the National Service of Health and Agrofood Quality (SENASA) regarding human and animal consumption. The safety assessment is based on the concept of "substantial equivalence" (as a starting point rather than an evaluation in itself, see below). A technical permit is also required from the National Directorate for Agrofood Markets, a department of this Ministry, relating to potential marketing of GMOs.[19] Finally, varieties must also comply with the conditions laid down by the National Seed Institute (INASE) for registration in the National Crop Register and for tax purposes. There are currently no requirements for mandatory labelling of GMOs.

Argentina is the world's second largest producers of GM crops, accounting for 22 per cent of planted hectares in 2001 (ISAAA 2002). A total of 495 licences for release of GMOs into the environment were granted from 1991 to 2001 (CONABIA 2002). Almost half of the licenses where granted for maize, while the rest included sunflower, alfalfa, potato, cotton, soy and wheat, most of which are genetically engineered for pest-resistance or herbicide- tolerance. However, since the 1998 release of GM crops, which has not yet been approved in the EU, has slowed following concerns that bulk shipments of GMOs to Europe might be rejected due to biosafety concerns (Paarlberg 2002).

[18] The Argentine regulations can be found at http://www.sagpya.mecon.gov.ar/0-0/
[19] For further information, see http://www.senasa.gov.ar/

Brazil

In 1995, Brazil enacted the *Brazilian Biosafety Law* (Law Number 8974), establishing guidelines for the safe use of genetic engineering techniques and the environmental release of GMOs.[20] The Law, which applies to all GMOs whether used for release into the environment or for human or animal food processing, prohibits the entry of GMOs into Brazil without prior approval. Técnica Nacional de Biossegurança (CTNBio), which is part of the Executive Secretariat of the Ministry of Science and Technology, was set up as the responsible agency for establishing standards and regulations for activities and projects involving GMOs, and for issuing a conclusive technical opinion on the release of any GMO into the environment. As a result of the judicial problems surrounding Monsanto's soybeans (see below), the *Biosafety Law* has been amended to give CTNBio final power for approving the release and food use of GMOs. Responsibility for the registration, transportation, marketing, handling, and release of products containing GMOs or derivatives had previously rested with the Ministry of Health; the Ministry of the Environment, Water Resources, and Legal Amazonia; or the Ministry of Agriculture, Supply, and Agrarian Reform, based on the opinion issued by CTNBio (Oda *et al* 1999).

In July 2001, the Brazilian government issued a Federal Decree (No 3.871), which requires all packaged food with a GMO content of more than four per cent to be labelled by 2002 (Lopes & Sampaio forthcoming). While the decree was scheduled to enter into force on 31 December 2001, it was never implemented. Instead, the Brazilian government published another Decree (No 4.680) in April 2003, which also requires labelling for all foods or food ingredients, but with a stricter labelling threshold of one per cent. The decree also mandates the labelling of animals fed with GM grains and products prepared with these animals. The Decree, however, does not apply to the 2003 harvest of GM soybeans and its derivatives. Argentina has lodged a complaint with Mercosur officials, alleging that the new labelling rules constitute non-tariff barriers to Argentina's products sold in Brazil.

As the world's second largest soy producer accounting for 20 per cent of global supply, Brazil is the only major agricultural exporting country that does not use GM technology. A number of GM corn varieties are allowed to be imported into Brazil for use in feed, but no GM foods have been approved for sale so far. Only one GM crop - Monsanto's Roundup Ready soybeans - has been approved for commercial release by CTNBio. However, in 1999, a lower court issued an injunction on the commercial planting of the soybeans in Brazil, following opposition by Brazilian consumer groups. Appellate Court rulings in June and September 2000 denied requests to cancel the injunction. As a result of this "judicial moratorium" on the commercial planting of GM soybeans, government approval of the commercial release of GMOs has been put on hold. The case is now being assessed by a panel of three judges who had been asked to decide on the case by early 2002. As of August 2003, the decision is still pending (Lopes & Sampaio forthcoming). However, despite the moratorium, illegally planted GMO soy is becoming increasingly widespread, in particular in Brazil's South due to smuggling of seeds from Argentina. The share of GM soy is now thought to amount to as much as 80 per cent of the total crop in some areas, leading many traders to avoid Southern ports. Some have expressed concerns that this trend might endanger exports to key markets, including the EU and China.

Mexico

The *Draft Official Mexican Standard NOM-056-FITO-1995* sets out the phytosanitary requirements for the transport within Mexico and the import of organisms manipulated by genetic engineering, and for the establishment of filed tests for such organisms (CIBIOGEM 2002). The Standard was

[20] *Brazilian Biosafety Law*, Law Number 8974, 5 January 1995. http://www.ctnbio.gov.br/ctnbio/legis/leis/leis.htm on 31 Aug 03.

developed and is administered by the General Directorate of Plant Health (DGSV) - under the Secretariat of Agriculture, Livestock, and Rural Development (SAGARPA) - and ensures compliance with biosafety regulations during field trial. The Directorate bases its decisions to grant permits on the opinion of the national Biosafety Committee on Agriculture, set up in 1989 as a consulting body to the DGSV. In addition, the Intersectoral Commission for Biosafety and Genetically Modified Organisms (CIBIOGEM) was established in 1999 to develop GMO-related policies.

In April 2003, the Mexican Senate passed new legislation designed to implement the Cartagena Protocol on Biosafety (BINAS 2003). The legislation would allow the limited release of GM crops, requiring GM seeds to be declared risk-free before they are released for human consumption or commercial planting. The legislation would also require GM products to be labelled in an effort to ensure consumer information on nutritional characteristics, composition and advantages of GM crops. To this end, the legislation sets out general criteria that the labels must be truthful, objective, clear, understandable and useful for the consumer. The legislation is based on a precautionary approach, which "serves as a parameter to assume precautionary decisions, in case of lack of scientific certainty of the magnitude of the possible adverse effects that the GMOs could cause to biological diversity and to the human health".

Regarding GM foods, the Mexican *Health Act* requires all biotechnology products or their derivatives, which are intended for human consumption, to be notified to the Secretariat of Health. In March 2000, the Mexican Senate passed an addition to Article 282 of the *Health Act* that would require that all genetically modified or transgenic foods be labelled with the phrase "Transgenic Food" or "Food made from transgenic product" and, in both cases, indicate the gene that was added (CIBIOGEM 2002).

Field testing for genetically modified crops has been underway in Mexico since 1988. By May 2000, 151 release permits had been issued, including for transgenic maize, tomatoes, cotton, soybean and squash (Alvarez-Morales 2000, La insignia 2002). Traits most widely tested include insect resistance, herbicide tolerance and virus resistance. In recent months, much attention has focused on the discovery of transgenic DNA contamination of native maize varieties despite a ban imposed on 1998 on the planting of GM maize. The discovery led the Mexican Congress, environmental groups and farm organizations to call on the government to ban the importation of GM corn (BTB 20 December 2001). While the new draft legislation includes safeguards on the experimental planting of GMOs and seeks to protect native maize varieties, environmentalist groups warned that the safeguards were not adequate (BTB 1 May 2003).

1.6 Africa

Many countries in Africa have developed, or are in the process of developing, biosafety policies and laws to comply with the requirements of the Cartagena Protocol on Biosafety (Kameri-Mbote 2002). Kenya, for instance, adopted *Regulations and Guidelines for Biosafety in Biotechnology for Kenya* in 1998, which charge the National Biosafety Committee, set up in 1996, with the approval of GMO imports. Egypt's regulations, adopted in 1995, required an advance permit for importation of genetically engineered materials. The permit should be obtained from the Supreme Committee for Food Safety established under the Ministry of Health, and then submitted to the National Biosafety Committee. In early 2002, Nigeria launched the Nigeria Biosafety Committee (NBC) and the National Coordinating Committee (NCC), charged with the development of Nigeria's national biosafety framework. Zambia has developed draft guidelines to regulate the use of GM food and animal feed, which were submitted to Zambia's Parliament in January 2003 (Irin 2003).

Efforts are also underway at the regional level to establish biotechnology-related policies. In October 2002, the Southern African Development Community (SADC) set up an Advisory Committee on GMOs to develop guidelines that would assist member states to guard against potential risks in food safety, contamination of genetic resources, ethical issues, trade-related issues and consumer concerns. Shortly afterwards, in November 2002, member states of the Common Market for Eastern and Southern Africa (COMESA) agreed to create a regional GMO policy, thereby responding to recent concerns throughout the area regarding GMOs, in particular GM food aid. Most recently, the New Partnership for African Development (NEPAD) has announced its intention in July 2003 to set up an advisory panel on biotechnology and biosafety in an effort to develop an African strategy on biotechnology and to harmonize biosafety regulations across the continent.

Most countries, however, still need to put into force legislation concerning existing policies. To date, only South Africa and Zimbabwe have put in place a biosafety law, while in the rest of Africa framework legislation on biosafety is lacking and most countries depend on existing science and technology laws and policies. Only South Africa has so far approved the commercial growing of GM crops. Research and testing on similar products is being conducted in other African countries, including Kenya, where the first field trials of virus resistant sweet potatoes were completed in 2001, and Burkina Faso where field trials for Bt cotton have gone underway in July 2003. However, the approval of GM crops for commercialization and import of GM commodities continues to be extremely slow (Paarlberg 2002).

The refusal of food aid containing GM maize by a number of Southern African countries, including Zambia, Zimbabwe, Malawi and Mozambique, attracted widespread public attention. The governments turned away the food aid reportedly due to concerns that accepting the donation of whole-grain maize might have a significant impact on the country's exports to the EU (BTB 27 June 2002). However, most countries subsequently agreed to allow food aid into the country that contained GM maize provided that it was milled immediately upon arrival (BTB 11 July 2002). The controversy has been publicized both by the proponents and opponents of GMOs in support for their positions, with the U.S. depicting African countries as misguided victims of the EU's regulations - a charge that the EU strongly rejects (ICTSD 2003).

South Africa

The South African Executive Council for Genetically Modified Organisms was set up in 1997 under the *Genetically Modified Organisms Act 1997* as the responsible agency for authorizing imports and release of GMOs.[21] The Council can require that any applicant has a permit for development, production, use, application or environmental release of GMOs, to submit a risk assessment and, where required, an assessment of possible environmental impacts. Permits will be issued by the registrar who is charged with administering the Act. The Act, which is administered by the Department of Agriculture, is currently being updated to include some aspects of transboundary movement of LMOs.[22]

Regarding GM foods, the South African government released the (Draft) *Regulations Governing the Labelling of Foodstuffs Obtained Through Certain Techniques of Genetic Modification* on 4 May 2001, which set out labelling requirements for GM foods.[23] In particular, the Regulations would require, *inter alia*, those GM foods to be labelled, that are significantly different regarding the composition, nutritional value and mode of storage, preparation or cooking; and contain allergens from any of

[21] *Genetically Modified Organisms Act* (1997), http://196.36.153.56/doh/docs/index.html on 31 Aug 03.
[22] Personal communication, Wilna Jansen Van Rijssen, 5 August 2002.
[23] *Regulations Governing the Labelling of Foodstuffs obtained through Certain Techniques of Genetic Modification* (4 May 2001). http://www.africabio.com/policies/GMlabellingE.htm on 6 Jan 03.

the products listed in the Regulation. Labels indicating that the food product is 'GMO-free' (or use similar wording) would not be permitted, and products could only be labelled as "not genetically modified" if they are produced in accordance with an identity preservation system, which is currently being developed.[24] The Regulations have been published for comments and the revised draft has been submitted for legal advice. [25]

In December 2001, the Executive Council approved the first biotech food crop (soybeans), the fourth GM crop to be commercialized in South Africa since 1998 (Monsanto 2001). Other approved crops include pest-resistant maize used for animal feed, as well as herbicide-tolerant and pest-resistant varieties of cotton.

Zimbabwe

The statutory instruments dealing with biosafety in Zimbabwe is the *Research (Biosafety) Regulations 2000*, which focuses on biosafety considerations in the context of research and field testing of GM crops (Kameri-Mbote 2002; Mohamed-Katerere & Saruchera 2001). Under the Act, the Research Council of Zimbabwe has established the Biosafety Board, which is charged with advising the Research Council on all aspects concerning the development, production, use, application and release of GMOs, including approving safety aspects of imports of GMOs and advising customs authorities on imports. Furthermore, in consultation with the Research Council, the Board may issue biosafety guidelines or standards of practice and procedure, e.g. for the import and export of GMOs. Such Guidelines have been adopted for containment facilities in the laboratory environment, biological containment, physical containment and intentional releases.

Non-binding standards for GM food labelling are currently being developed by the Standards Association of Zimbabwe. No GMO crop has so far been approved for commercial release in Zimbabwe (Paarlberg 2002).

OAU Model Law on Biosafety

The Organization of African Unity (OAU, now African Union), in collaboration with the Ethiopian Environmental Protection Agency, has developed a draft African *Model Law on Safety in Biotechnology* to serve as a basis for formulating national biosafety laws. The development of the draft Model Law as well as efforts to elaborate an African-wide biosafety system which would coordinate the implementation of the Model Law across countries was officially endorsed by the OAU Assembly of the Heads of State in July 2001. The draft Model Law covers the import, contained use, release or placing on the market of any GMO or GMO product, and includes detailed provisions for institutional arrangements, decision-making procedures, risk management and labelling.

As defined in the draft Model Law, GMOs refer to all genetically modified entities capable of replication or transferring genetic material - similar to "living modified organisms" as defined in the Cartagena Protocol on Biosafety. 'Products of GMOs' are defined as any material derived by processing any GMO or product of a GMO. It is unclear whether this definition also covers products derived from, but no longer containing, GMOs. Overall, the draft Model Law takes a precautionary note, including a reference to the "precautionary principle" in the preamble. Furthermore, it stipulates that approval should only be given if there is firm and sufficient evidence that the GMO or GMO products pose no risks to the environment, biodiversity and health; if the

[24] as defined in the draft Regulation: "a system by which the identify of a non-GMO and the products derived from it, is preserved by segregating the handling and processing thereof throughout the food chain from those of a GMO and products derived from it"

[25] Personal communication, Wilna Jansen Van Rijssen, 5 August 2002.

GMO or GMO products benefit the country without causing any significant risk, contributes to sustainable development, and has no adverse socio-economic impact.

To date, no country has implemented the draft Model Law.[26]

[26] Personal communication, Hartmut Meyer, 2 August 2002.

2 Compatibility Between Domestic GMO Import Regulations And WTO Rules

Biotechnology-related concerns are increasingly cropping up in trade discussions, both at the World Trade Organization (WTO) and in other forums. In May 2003, the U.S. initiated WTO consultations with the EU regarding the EU's *de facto* moratorium on the approval of new GMOs.[27] The U.S. is also challenging a number of marketing and import bans in certain EU member states, including Austria, France, Greece and Italy where the importation and marketing of GM products is prohibited although they have been approved for sale in the EU. Requests for consultations were also received from Canada and Argentina, while Australia, Argentina, Brazil, Canada, Chile, Colombia, India, Mexico, New Zealand and Peru joined as third parties. Following failure of the talks, the U.S., Argentina (as a third party to the U.S.) and Canada on 29 August submitted requests for the establishment of a WTO panel to the Dispute Settlement Body to rule on their complaints. The dispute settlement process usually takes 12-18 months (including an appeal to the WTO Appellate Body). While the European Commission has repeatedly stressed that the *de facto* moratorium on the approval of new GMOs would be lifted once the labelling and traceability regulations are in place (expected to enter into force in late-2003), it remains unclear whether the U.S. and others would drop their WTO challenge even if approvals resumed.

WTO Members have also raised concerns over domestic import regulations for GMOs in the Committees for Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT). At the Committee meetings, the EU traceability and labelling regulations and the continued *de facto* moratorium have drawn strong criticism from a number of GMO exporting countries, including the U.S., Canada and Argentina. China has also come under pressure for its GMO import regulations at the SPS and TBT Committees. Besides, the U.S. is reported to have raised the possibility of a WTO challenge with regard to GMO regulations in Sri Lanka, Bolivia and Croatia (FOEI 2001).

How the U.S.-EU dispute will play out is hard to predict at this early stage in the proceedings. Similarly, the outcomes of a possible challenge to a country's traceability and labelling scheme for GMOs are difficult to forecast given that so far no mandatory labelling scheme has been formally challenged at the WTO, let alone one related to GMOs. The following discussion aims to outline some of the arguments that might be raised for or against some of the described import regulations and measures, and how these arguments might fare if scrutinized by a WTO panel. The analysis is neither meant to be exhaustive nor legally thorough, but rather aims to raise some points for consideration. Also, much of the discussion will necessarily focus on the EU regulatory system as those rules have attracted most attention, but the conclusions are equally valid for many other import regulations.

Bearing these caveats in mind, the remainder of the section will briefly outline the relevant WTO agreements, assess the trade-restrictiveness of mandatory traceability and labelling requirements, evaluate whether GMO regulations covering substantially equivalent GM products might be trade-discriminatory, look at the role of precaution as a justification for an import ban on GMOs, and briefly discuss the Cartagena Protocol on Biosafety and how its provisions might impact on a possible dispute at the WTO.

2.1 Relevant WTO Agreements

[27] *European Communities – Measures Affecting The Approval And Marketing Of Biotech Products - Request for Consultations by the United States*, WT/DS291/1, 13 June 2003, searchable at http://docsonline.wto.org/

What are the relevant WTO Agreements and how would they apply to GMO import regulations?

Of particular relevance to GMO import regulations are the Agreements on the Application of Sanitary and Phytosanitary Measures (SPS) and on Technical Barriers to Trade (TBT), as well as the General Agreement on Tariffs and Trade (GATT).

SPS Agreement

The SPS Agreement has two objectives, namely to (i) recognize the sovereign right of Members to provide the level of protection of human, animal or plant life or health they deem appropriate, and (ii) ensure that sanitary (human and animal health) and phytosanitary (plant health) measures do not represent unnecessary, arbitrary, scientifically unjustifiable or disguised restrictions on international trade (Preamble, Article 5.5). The Agreement provides two ways of ensuring that SPS measures have the required scientific basis. First, Members are encouraged to "base" their measure on international standards, guidelines and recommendations where they exist (Article 3.1). Three international standard-setting bodies are explicitly recognized under the Agreement: the Codex Alimentarius Commission (CAC; food safety), the Office International de Epizooties (OIE; animal health) and the Secretariat of the International Plant Protection Convention (IPPC; plant health). Standards set by these three bodies are presumed to be consistent with the SPS Agreement (Article 3.2). Where no standards exist or a Member chooses to adopt a stricter standard, an SPS measure must be based on a risk assessment (Articles 3.3, 5.1 - 5.3).

In cases "where relevant scientific evidence is insufficient", Members are allowed to provisionally adopt SPS measures, provided they seek to obtain additional information necessary for a more objective risk assessment "within a reasonable period of time" (Article 5.7, see also chapter 2.4). Any SPS measures, including those under Article 5.7, should not be more trade-restrictive than required to achieve the appropriate level of sanitary or phytosanitary protection (Article 5.6).

With regard to GMOs, the SPS Agreement would apply if the measure was aimed at the protection against food safety risks or damage caused by pests. International standards related to the safety of foods derived from biotechnology are currently being developed at the CAC (see below), while the Interim Commission on Phytosanitary Measures (ICPM) - the IPPC's interim governing body - has recently set up an Expert Working Group to formulate a draft standard providing guidance on the conduct of pest risk analyses for living modified organisms (ICPM 2002).

TBT Agreement

The Technical Barriers to Trade (TBT)Agreement applies to product requirements that are mandatory (technical regulations) as well as voluntary (standards) and to conformity assessment procedures. Similar to the SPS Agreement, TBT measures should not be more trade-restrictive than necessary to achieve a legitimate objective, though the TBT does not require the same rigorous standard of scientific basis demanded in the SPS obligations. As defined in the Agreement, "[s]uch legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment" (Artcile 2.2). Whether the provision of consumer information through measures such as labelling would fall under this definition, as advocated by the EU, continues to be hotly debated in the TBT Committee. SPS measures are explicitly excluded from the coverage of the TBT Agreement.

A number of other provisions are noteworthy in the context of GMO import regulations. Thus, while the Agreement encourages the use of international standards, it does not explicitly refer to the three standard setting bodies. Furthermore, the TBT Agreement does not allow for

discrimination between "like" products, with the concept of "like" left undefined (Article 2.1). At the same time, technical regulations can include "terminology, symbols, packaging, marking or labelling requirements that apply to a product, process or production method". The relevance of these provisions for GMOs is further discussed in chapter 2.3.

GATT

The GATT, which deals with trade in goods, contains several provisions, for example those referring to non-discrimination and quantitative restrictions, that are relevant to the trade in GMOs. Furthermore, Article XX sets out a number of exceptions, allowing Members to take measures which would otherwise violate GATT rules to, *inter alia*, protect public morals, human, animal or plant life or health and to conserve exhaustible natural resources (Article XX(a), (b) and (g)).

Relationship between the agreements

In cases of a dispute, the compatibility of a domestic regulatory measure is likely to be examined first under the SPS Agreement, followed by the TBT Agreement and then the GATT (Marceau & Trachtmann 2002). As mentioned above, the TBT Agreement is explicitly not applicable to SPS measures covered by the SPS Agreement. Thus, the purpose of a measure becomes the determining factor when deciding on the application of the two Agreements (see Box 1). However, a government might implement a measure that contains some elements, which are covered by the TBT Agreement while others fall within the scope of the SPS Agreement. For instance, regulations on pesticides might incorporate quality requirements and safe handling instructions, which would be covered by the TBT Agreement, while maximum residue levels of pesticides in foods would fall under the SPS Agreement (Wolff 2001).

Regarding the relationship between the SPS Agreement and the GATT, the Preamble of the SPS Agreement states that it is intended to "elaborate rules for the application of the provision of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)". In addition, SPS measures that conform with the SPS Agreement are presumed to be consistent with the GATT, although this presumption is understood as being rebuttable (Article 2.4). This suggests that if a measure is found to be inconsistent with the SPS Agreement, it is likely that a panel or the Appellate Body would not carry out an analysis under the GATT (Marceau & Trachtmann 2002).

The relationship between the TBT Agreement and the GATT is less clear as no presumption of consistency exists. However, the Appellate Body in the *EC-Asbestos* case stated that the TBT Agreement was a specialized legal regime for a limited class of measures that imposed obligations different from and additional to the obligations imposed on WTO members under the GATT.[28]

Health-related and environmental concerns

Health concerns related to GM food products include the use of antibiotic resistance marker genes,[29] increases in the allergenicity and toxicity of food, unintended side effects resulting from the process of genetic modification itself and changes in nutritional value (FAO/WHO 1996). Various experts agree that the risks of consuming GM food to human health are relatively small (AMA 2000; Donaldson & May 1999; FAO/WHO 1996; US FDA 1995; US DoS 2000a). Thus, WTO Members might find it difficult to justify a measure by citing health concerns based on the scientific data currently available. However, most experts also agree that genetic modification is still a young science and future developments will need to be watched closely, and that additional research

[28] *European Communities - Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R, 2001.
[29] Op. cit. no 5

should be carried out (Donaldson & May 1999). This could serve as an argument to implement provisional measures based on a precautionary approach (see chapter 2.4)

Which Agreement would apply would depend on the precise nature of the disputed measure. While food safety regulations are generally covered by the SPS Agreement, other health concerns may be addressed by the TBT Agreement (see Box 1). Any regulation concerned with toxic substances that might be present in GM food or feed would be covered by the definition of an SPS measure contained in Annex A of the SPS Agreement (Wolff 2001). Whether testing and labelling requirements related to allergies would be covered by the SPS Agreement is less clear, but regardless of whether the SPS or TBT Agreement applies, such requirements are likely to be in conformity with the relevant provisions (Wolff 2001). Measures related to changes in nutritional value of GM foods that are not related to food safety would be dealt with by the TBT Agreement, while measures addressing the possible risks of using antibiotic resistance marker genes might be covered by both Agreements depending on the precise objective.

Environment-related measures that are aimed at addressing pest risks would fall under the SPS Agreement. In particular, Members could argue that the use of GM crops might lead to pesticide resistance in target pests, thus making them more difficult to manage. Also, crops engineered to be herbicide resistant could become weeds, or, alternatively, their genes could be transferred to wild relatives, thereby producing other herbicide-tolerant weeds (Nuffield Council 1999; Royal Society 1998). Non-pest related environmental concerns would be covered by the TBT Agreement, such as adverse effects of pest-resistant GM crops on non-target species.

The likelihood of negative environmental impacts of GMOs remains hotly debated and an assessment of the findings to date would go far beyond the scope of this paper. A review of existing scientific literature conducted in 2000 showed that key experiments on both the environmental risks and benefits are still lacking, and that possible risks and benefits can vary spatially and temporally on a case-by-case basis (Wolfenbarger & Phifer 2000). Due to the complexity of the ecological systems and the resulting difficulties for experiments to evaluate the risks and benefits, either party in a potential dispute might find it challenging to conclusively show the presence or absence of environmental risk.

Box 1: Applicability of the SPS and TBT Agreements to GMO-related measures

Whether the SPS or the TBT Agreement applies to a particular measure, depends on the purpose of a regulation.

SPS: Sanitary and phytosanitary measures aimed at the protection against food safety risks or damage caused by pests (including voluntary standards and mandatory technical regulations).

Some GMO-related regulations could include:

- Regulation concerned with toxic substances
- Risks from using antibiotic resistance marker genes (related to food safety or pest risk)
- Environment-related measures that are aimed at addressing pest risks (e.g. measures to avoid herbicide-resistant crops to become weeds or transfer their resistance to wild relatives)

TBT: Technical regulations and standards necessary to meet legitimate objectives and not covered by the SPS Agreement.

Some GMO-related regulations could include:

- Measures related to changes in nutritional value of GM foods (not related to food safety)
- Risks from using antibiotic resistance marker genes (not related to food safety or pest risk)

- Non-pest related environmental concerns (e.g. measures to avoid adverse effects of pest-resistant GM crops on non-target species)

2.2 Trade-restrictiveness of labelling and traceability regulations

Are mandatory traceability and labelling requirements unnecessarily trade-restrictive?

Both the SPS and TBT Agreements require measures to be no more trade-restrictive than necessary in order to fulfil the objectives of the Agreements. The burden of proof to show that a less restrictive measure is available rests with the party that brings a dispute to the WTO.

Regarding the European traceability and labelling regulations, the U.S., Canada, Australia, Argentina and other countries have argued that they are unnecessarily trade-restrictive, and that less trade-restrictive measures could be put in place to achieve the desired objectives. This applies in particular to products derived from, but no longer containing, GMOs and GM feed both of which have so far been excluded from the labelling requirements. Often cited in this context are the costs of segregating modified from non-modified products, of monitoring a particular crop throughout the food chain (e.g. by using identity preservation systems), and of testing for the presence of GM materials to comply with the labelling threshold of 0.9 per cent and the threshold of 0.5 per cent for the accidental presence of GMOs as set up by the regulations. The U.S. estimates that compliance with the regulations could cost U.S. companies up to USD four billion a year in export earnings (Paarlberg 2002). Alternative measures could include labelling requirements to address particular health concerns such as allergenicity or toxicity; management strategies to deal with potential environmental risks, such as minimum isolation distances between crops or requirements for refuge sizes; or voluntary labelling schemes for GM-free foods to provide consumer information.

The European Commission argues that the traceability requirements are necessary to allow for withdrawal of products should an unforeseen risk to human health and the environment be established; targeted monitoring of potential effects on human health or the environment, where appropriate; and control and verification of labelling claims (European Commission 2001b). The new European regulations build on existing EU requirements for the traceability of food, feed, food-producing animals and any other substances intended for food use – as laid down in Regulation (EC) 178/2002 which entered into force on 21 February 2002. While acknowledging that the costs of compliance are difficult to estimate, the Commission expects that the transmission and retention of the required information could largely be incorporated into existing systems for transactions and would therefore not imply significant extra costs for operators. Also, differences and overlap in national laws and regulations concerning the traceability of GMOs may hinder the free movement of products, thereby creating conditions of unequal and unfair competition, the Commission argues. Thus, the harmonized framework for traceability will provide legal certainty and a coherent approach that would contribute to effective functioning of the international market.

While the implementation of any traceability system can be expected to create additional costs, the actual increase in costs is difficult to estimate as it depends on various factors and circumstances (e.g. DG Agriculture 2000; ERS 2001). Estimates range from U.S.$5 to $25 per ton depending on the different grains and the identity preservation system (DG Agriculture 2000). Factors contributing to differences in costs include the threshold for the accidental presence of GMOs (e.g. 0.5 per cent in the EU and 1 per cent in Australia) or for which labelling is required (e.g. if GMO content exceeds 0.9 per cent in the EU and 1 per cent in Brazil), i.e. the more stringent the purity

requirements, the greater the additional costs. Additional costs will also increase as the volume traded under the identity preservation system decreases. Furthermore, the magnitude of additional costs is not fixed and is likely to change as the industry adapts to the traceability requirements and as the volume of material involved increases (Buckwell *et al* 1998).

The divisions regarding the need for traceability are also reflected in discussions at the Codex Alimentarius Commission and were until recently a major stumbling block at the Codex Intergovernmental Task Force on Foods Derived From Biotechnology. In the end, countries agreed at the third meeting of the Task Force (4-8 March 2002) to include the "tracing of products" and food labelling as risk management tools in the *Principles For The Risk Analysis Of Foods Derived From Modern Biotechnology* of GM foods. The principles were subsequently adopted by the Codex Alimentarius Commission in July 2003 (CAC 2003a). Some believe that this agreement might mark a major breakthrough in international negotiations on the use of traceability systems and at least partially vindicates the EU's insistence on introducing such requirements for GM foods (BTB 21 March 2002). This assessment of the Codex standard's relevance assumes that 'tracing of products' and 'traceability' are the same. However, the U.S. continues to insist that the two terms are not equivalent, arguing that 'product tracing' is limited to 'one step forward and one step back' whereas 'traceability' of products refers to the whole production chain of a product. To date, there is no agreed Codex definition for traceability and/or product tracing and the Codex Committee on General Principles has set up a Working Group to develop a definition (BTB 17 April 2003). Efforts are also underway to develop labelling standards for GM foods at the Codex Committee on Food Labelling (BTB 16 May 2002).

2.3 Substantially equivalent GM products

> Are import regulations covering 'substantially equivalent' GM products trade-discriminatory?

The TBT Agreement stipulates that Members are not allowed to give less favourable treatment to any products "than that accorded to *like* products of national origin and to *like* products originating in any other country" (Article 2.1, emphasis added).[30] Some argue that import regulations that impose special risk assessment, traceability and/or labelling requirements for 'substantially equivalent' GM products might contravene this provision as they discriminate against 'like' products (see Box 2).

As mentioned above, the new EU regulations (adopted in July 2003) require all foods and feeds to be subject to the full authorization procedure as well as traceability and labelling requirements, including those that are substantially equivalent. If the EU were to justify these regulations as a legitimate objective (e.g. consumer information) under the TBT Agreement, they would be required to show that the measures do not run counter to the non-discrimination provision for 'like' products. According to established practices under the GATT, likeness is determined on a case-by-case basis according to four criteria, i.e. the products' physical properties, end-uses, tariff classification and consumers' tastes and habits (Musselli & Zarrilli 2002). Given the strong physical similarity between traditional foods and substantially equivalent GM foods, the latter are likely to be viewed as 'like' under the first three criteria. The EU would thus need to show that consumers' perceptions and behaviour affect the degree of substitutability and competitiveness in the market-place (Musselli & Zarrilli 2002). In addition, for the measures to be in violation of the TBT

[30] Note that the SPS Agreement does not contain provisions dealing with 'like' products. Rather, the focus of analysis centres on the situation under the SPS prohibition itself, i.e. under Article 2.3 Members are not allowed to discriminate between Members "where identical or similar conditions prevail" (Marceau & Trachtmann 2002)

Agreement, it would also need to be shown that 'like' imported products are given less favourable treatment than 'like' domestic products.

If the measure is aimed at ensuring food safety, it might be justifiable under the SPS Agreement which does not include a 'like' product provision. The EU might find it challenging to show that such products might pose health risks (in particular with regard to feed) given the widespread application of the substantial equivalence concept, including in the recently adopted Codex standard (see below), or that the measure was necessary to prevent the spread of pests. Another option would be to justify the regulations under the exceptions of GATT Article XX, i.e. to show that the measure was necessary to protect public morals, human, animal or plant life or health, or to conserve exhaustible natural resources. However, proving that the measure is covered by the exceptions might be equally difficult.

The *Guideline for the Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Plants* adopted at Codex Alimentarius Commission in July 2003 also include the concept of 'substantial equivalence' as the "starting point" for safety assessment rather than a safety assessment in itself (CAC 2003a). However, the standard also includes a footnote stating that "in the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts". How the latter provision - included despite U.S. efforts to define conventional counterparts as including GMOs - might be interpreted in potential future WTO disputes remains to be seen.

Box 2: Substantial equivalence

The concept of 'substantial equivalence' was first introduced by the Organisation for Economic and Cooperative Development (OECD) in 1993 as a guiding principle for safety assessment of GM foods (OECD 1993). The concept is based on the assumption that modern biotechnology "does not inherently lead to foods that are less safe than those developed by conventional techniques" and consequently safety evaluation of GM foods "does not necessitate a fundamental change in established principles, nor does it require a different standard of safety" (OECD 1993, p.10). Thus, safety assessment should begin by comparing the GMO to its conventional counterpart. If found to be substantially equivalent, the same safety considerations apply as for conventional foods. If a food or food component was found to differ substantially from its counterpart, the safety evaluation should focus on the identified differences. The principle has subsequently been acknowledged as an important component in the safety assessment of GM foods, including by the 1996 FAO/WHO Joint Expert Consultation (FAO/WHO 1996). However, the concept has recently come under criticism as "inherently anti-scientific because it was created primarily to provide an excuse for not requiring biochemical and toxicological tests" (Millstone, Brunner & Mayer 1999). One particular concern has been that the application of substantial equivalence might not reveal any unexpected effects of genetic modification (Royal Society 2002). When the concept was subsequently reviewed, many experts agreed on the general usefulness of the principle as a starting point for risk assessment, but also stressed the need for a more structured approach to assessing substantial equivalence (Royal Society 2002; FAO/WHO 2000; OECD 2000).

In the U.S., safety evaluation of GMOs is also based on the concept of substantial equivalence, albeit not explicitly. Based on three principles formulated by the National Academy of Science in 1987 and later reviewed by the U.S. National Research Council, it is assumed that the process of genetic modification does not pose a unique hazard; that the same risks arise from GMOs as from organisms modified by traditional means; and that the risk assessment should be based on the properties of the organism and the environment, not the process by which it was produced (SBC 2001).

2.4 The role of precaution

Could a ban on imports of GMOs be justified as a precautionary measure?

As mentioned above, the concept of precaution is embodied in Article 5.7 of the SPS Agreement.[31] In contrast, the TBT Agreement does not require any form of specific evidence nor does it include a provision to deal with cases where scientific evidence is insufficient. Nevertheless, such evidence might be required when a Member is called on to demonstrate that the TBT measure in question is no more restrictive than necessary (Marceau & Trachtmann 2002).

The differing approaches to precaution in the EU and U.S. partly lie at the root of the ongoing disagreement between the U.S. and EU over the European *de facto* moratorium on the approval of new GMOs (see Box 3; Lehmann 2002). For the EU *de facto* moratorium - or an import ban on GMOs in general as temporarily instituted by Sri Lanka and Bolivia, though later revoked - to be justifiable under Article 5.7, it would need to constitute a provisional measure and the EU would have to demonstrate that it was actively seeking "to obtain the additional information necessary to make a more objective assessment of risk" and review the SPS measure "within a reasonable period of time" (Article 5.7). The moratorium had originally been invoked until revision of Directive *90/220/EEC* had been finalised and the revised Directive had entered into force (17 October 2002). However, some EU member states subsequently stated that they would not agree to a lifting of the ban until the traceability and labelling requirements entered into force, while others went even further, saying that they would await the finalization of liability regulations (BTB 20 December 2001). The EU's ability to justify the *de facto* moratorium by invoking the precautionary provisions of the SPS Agreement might depend on whether the EU will indeed resume approvals on the regulations that enter into force later this year.

In its defence, the EU might also invoke the 'precautionary principle' as a customary rule of international law, rather than refer to Article 5.7, if the measure is not intended to be provisional, as it did in the *EC-Hormones* case[32]. While the Appellate Body ruling in this dispute did not reach a conclusion whether the precautionary principle had become a general principle of law, it acknowledged that the principle "indeed finds reflection in Article 5.7 of the SPS Agreement". However, the Appellate Body also agreed with the previous finding of the panel "that the precautionary principle would not override the explicit wording of Articles 5.1 and 5.2" (covering the need for risk assessment of SPS measures to be based on scientific evidence).[33] Thus, even if the precautionary principle was recognized as a principle of international law, this would not add to or diminish the rights and obligations of WTO Members (Marceau & Trachtmann 2002). Nevertheless, recognition of its status as a general principle would be of relevance for the outcomes of a WTO dispute as such principles would be taken into account in the interpretation of relevant WTO provisions. Also, WTO Members would be required to comply with both their WTO obligations and any law of the generally accepted principles of international law.

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[31] "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time." (Article 5.7)

[32] *EC Measures Concerning Meat and Meat Products (Hormones)*, AB-1997-3, WT/DS26/AB/R, 1998.

[33] Appellate Body Report, *EC-Hormones*, WT/DS26/AB/R, WT/DS48/AB/R. Searchable at http://docsonline.wto.org/

It remains unclear how the TBT Agreement would deal with precautionary measures, as their application has not yet been tested in a dispute. However, similar to the findings of the Appellate Body in the *EC-Hormones* case, it seems likely that invoking the precautionary principle in general would not allow WTO Members to violate the TBT Agreement (Wolff 2001).

While the precautionary principle as such has not been included in international standards, the Codex principles for Codex *Principles For The Risk Analysis Of Foods Derived From Modern Biotechnology* adopted in July 2003 include elements of precaution, requiring authorities to take into account uncertainties identified in safety assessment and allowing them to implement appropriate risk management measures. Precaution as an "inherent element of risk analysis" (including risk assessment, management and communication) is included in the *Working Principles for Risk Analysis in the Framework of the Codex Alimentarius*, adopted in July 2003 (CAC 2003b). It is important to note, however, that these Principles only apply in the framework of the CAC, not to governments, i.e. it will be included in the Procedural Manual as general guidance to the Codex Alimentarius Commission and its subsidiary bodies. The Committee will elaborate a second separate set of Principles that would apply to governments. Given the controversy that has surrounded the inclusion of references to precaution in past Codex meetings, it is by no means certain that the second set of Principles will include explicit references to precaution (BTB 17 April 2003).

Box 3: Different approaches to precaution

The precautionary principle first emerged in German national law as the *Vorsorgeprinzip* ("precaution" or "foresight" principle) in the early 1970s. At the international level, it was first introduced in the Ministerial Declaration of the Second Conference on the Protection of the North Sea (1987). Other multilateral treaties and international declarations subsequently adopted the principle, including the Montreal Protocol (1987), the Rio Declaration (1992), the Convention on Biological Diversity (1992), the UN Framework Convention on Climate Change (1992) and the Treaty of the European Union (1992). The most explicit reference to the precautionary principle can be found in the Cartagena Protocol on Biosafety (2000), which aims to achieve its objectives "in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration" (Art. 1) and allows for precautionary decision-making with regard to importing living modified organisms. These provisions were widely seen as the first operationalization of the precautionary principle in the body of an international environmental agreement. Disagreements, however, persist, whether the principle should be seen as a general principle of international law.

In the EU, the precautionary principle has been the basis for Community policy on the environment since its inclusion in the 1993 Treaty of the European Union (Maastricht Treaty). In the Treaty itself, the precautionary principle is left undefined and is only prescribed to protect the environment. According to a Communication from the European Commission on the principle, however, its scope is in practice much wider, covering potentially dangerous effects on the environment, human, animal and plant health (European Commission 2001c). The Communication furthermore asserts that the principle has now become a "full-fledged and general principle of international law". The principle was also endorsed in a Resolution of the European Council in December 2000, which considers "that WTO rules do basically allow account to be taken of the precautionary principle" (European Council 2000). The principle is also included in Directive *2001/18/EC* on the environmental release of GMOs. Most recently, the principle has been elaborated for the first time in EU food legislation in Article 7 of Regulation *(EC) 178/2002*, which includes similar language as found in the SPS Agreement, i.e. that precautionary measures should not be more trade-restrictive than necessary and should be reviewed "within a reasonable

period of time".[34]

In the U.S., the precautionary principle is not expressly mentioned in national laws or policies even though some laws have a precautionary nature, including *the Clean Air Act*, the *National Environmental Policy Act*, the *Federal Food, Drug and Cosmetics Act* and the *Clean Water Act*. While the U.S. "believes firmly in a context-specific precautionary approach to protect human health and the environment" (U.S. DoS 2000b), it has generally opposed references to the precautionary principle at the international level and does not agree with the EU that it has become a general principle of environmental law. Instead, the U.S. emphasizes that regulations must be based on a science-based decision-making process. Also, the U.S. believes that the application of the principle "does not allow for an assessment of all the risks, including indirect risks of alternative technologies, nor does it contemplate the benefits of an activities, to achieve an overall comparison" (Katz 2001). Based on this logic, risk assessments should also take into account risks of applying the principle, including for trade (Lehmann 2002).

2.5 Cartagena Protocol on Biosafety

How might the Cartagena Protocol on Biosafety impact on possible WTO disputes related to GMO import regulations?

The Cartagena Protocol on Biosafety - adopted in January 2000 under the Convention on Biological Diversity (CBD) and set to enter into force on 11 September 2003 - regulates "the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health" (Art. 4).

The Protocol primarily deals with two categories of living modified organisms (LMOs):

- LMOs for "intentional introduction into the environment of the Party of import" (e.g. seeds intended for planting). These LMOs are subject to an Advance Informed Agreement (AIA) procedure, which requires the importing country to give its consent prior to the first intentional transboundary movement of the LMO (Articles 8-10).
- LMOs "intended for direct use as food or feed, or for processing" (e.g. soybeans for use in food). The AIA procedure does not apply to this category of LMOs. Instead, exporting countries are required to send information on any new LMO to the Biosafety Clearing House (BCH) where it can be accessed by potential importers who then decide on the import under their domestic policy (Article 11). Shipments of these LMOs have to be identified as "may contain" LMOs and as not intended for intentional introduction into the environment (Article 18). Detailed requirements, including specification of the LMO's identity and a unique identification, will be finalized by the Conference of the Parties (COP) to the Protocol no later than two years after its entry into force.

It is important to note that the Protocol refers to "living modified" rather than "genetically modified" organisms. This distinction becomes important when discussing the applicability of the Protocol to domestic import regulations for GMOs. LMOs can be seen as a sub-set of GMOs which includes any living organism - i.e. "any biological entity capable of transferring or replicating

[34] Regulation *(EC) No 178/2002* Of The European Parliament And Of The Council of 28 January2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf on 6 Jan 03.

genetic material, including sterile organism, viruses and viroids" - that "possesses a novel combination of genetic material obtained through the use of modern biotechnology" (Article 3). Thus, while LMOs for use in food, feed and processing are included, GM products derived from but no longer containing GMOs are not covered.

Once the Protocol has entered into force in September 2003, Parties to the Protocol whose import measures are challenged at the WTO might justify these regulations by referring to the Protocol's provisions, including notification and labelling requirements and import bans covered by the Protocol. However, when the Protocol was adopted, several issues remained unresolved and were left to the COP to finalise once the Protocol has entered into force. For instance, the Protocol only covers LMOs "that may have adverse effects" on conservation and sustainable use of biodiversity and on human health (Article 4). The COP will identify any LMOs not subject to this condition and therefore not subject to AIA (Article 7(4)). The basis on which adverse effects will be decided was left undefined. Also, as mentioned above, the COP has yet to work out the detailed requirements for identifying shipments of LMOs for direct use as food, feed, or for processing. Similarly, the Protocol largely fails to establish standards and instead calls for the COP to assess the need for and modalities of developing standards for the identification, handling, packaging and transport practices (Article 18(3)). Given that the TBT and SPS Agreements encourage Members to base their measures on international standards, the decision of the COP could be of importance in future disputes. However, any standards developed by the COP will have little impact on risk management standards for LMOs during use, handling and transport which were left to be dealt with at the domestic level (Article 16).[35]

The Protocol could also be of relevance in future disputes with regard to the use of precaution. In particular, the Protocol contains what many see as the first operationalization of the precautionary principle in the body of an international environmental agreement. The precautionary approach "contained in Principle 15 of the Rio Declaration on Environment and Development" (Article 1) can be employed for both categories of LMOs (Articles 10(6) and 11(8)). Once the Protocol has entered into force, Parties defending their import regulations at the WTO might refer to these provisions, which would then need to be taken into account when interpreting WTO rules (see chapter 2.4)

The provisions of the Protocol will only apply to those countries that have ratified or acceded. To date, Parties to the Protocol include the EC and several of its member states, as well various developing countries, including India, Mexico and South Africa. The question arises how a possible dispute at the WTO would play out if a non-Party to the Protocol challenged GMO import regulations implemented by a Party (which could conceivably be the case as the U.S. has not ratified the CBD and consequently is not a signatory to the Biosafety Protocol). The Biosafety Protocol's relationship to the WTO was left rather ambiguous. The Preamble states that the Protocol does not change the rights and obligations of a Party under any existing international agreements. At the same time, the preamble states that this clause is not intended to subordinate the Protocol to other international agreements. This wording suggests that both the Protocol and WTO rules should be read as mutually supportive and not conflicting (Cosbey & Burgiel 2000). Should a conflict arise, the resulting dispute would most likely be settled at the WTO with its far more established dispute settlement body.

Negotiations are currently underway at the WTO to address the relationship between multilateral environmental agreements (MEAs) and WTO rules as part of the single undertaking launched at the

[35] Risk assessment procedures and information requirements should include strategies for risk management and dealings with LMOs, but these strategies are only required *where appropriate* (Annex I, l) and *where necessary* (Annex II, 8(c)), and the scope of potential strategies is not specified.

Fourth WTO Ministerial Conference in Doha, Qatar, in November 2001, and set to be finalized by 1 January 2005. The Biosafety Protocol has been identified as one of six MEAs with specific trade obligations that WTO Members generally agree should be discussed in the negotiations.[36] While the negotiations might go some way towards clarifying the relationship between the Biosafety Protocol and WTO rules, they will not provide guidance on how to deal with disputes between Parties and non-Parties, as the "negotiations shall not prejudice the WTO rights of any Member that is not a party to the MEA in question".[37]

[36] The other MEAs include the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES), the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, the Montreal Protocol on Substances that deplete the Ozone Layer, the Rotterdam Convention on Prior Informed Consent Procedures for certain hazardous chemicals and pesticides (not yet in force) and the Stockholm Convention on Persistent Organic Pollutants (not yet in force).

[37] Para. 31(i) of WTO Ministerial Declaration adopted at the Fourth WTO Ministerial Conference on 14 November 2001. http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm on 6 Jan 03.

Final Remarks

Domestic import regulations for GMOs are proliferating around the world, ranging from simple (draft) pre-market notification requirements and voluntary labelling guidelines in the U.S. to strict risk assessment, labelling and traceability requirements in the EU. At the same time as import regulations are being tightened, approval processes appear to be slowing down, largely due to concerns regarding export losses in key markets such as the EU, Japan and Korea; the new EU's import regulations; and the ongoing trade dispute between the U.S. and EU over the EU's *de facto* moratorium on the approval of new GMOs. How the U.S.-EU dispute at the WTO will play out is difficult to predict at this stage, as many questions remain open that have not yet been tested in the WTO dispute settlement system. The same is true for a possible dispute over the EU's newly adopted traceability and labelling regulations. While the regulations might be justifiable on environmental or health grounds, scientific uncertainty continues to surround the likelihood of environmental impacts of GMOs (and to a lesser extent possible health-related effects). If, as the EU argues, the regulations should rather be treated under the TBT Agreement as measures to ensure consumer choice, it still remains to be shown that this would qualify as a "legitimate objective" under the Agreement.

The case becomes even more difficult for GM food and feed derived from but no longer containing GMOs, which are substantially equivalent to their conventional counterparts. Given the widespread use of the concept of 'substantial equivalence' as a starting point for risk assessment, the EU might find it difficult to justify their labelling and traceability requirements for these products on environmental or health grounds. If intended as measures to provide consumer choice under the TBT Agreement, the requirements would be unlikely to comply with the 'like' product provision as the final products are usually indistinguishable from traditional foods, unless the EU was able to show that consumers' perceptions and behaviour affect the degree of substitutability and competitiveness in the market-place. Also uncertain is the degree of the 'trade-restrictiveness' of the regulations given that additional costs of implementing them are difficult to estimate and are likely to change over time.

To justify the *de facto* moratorium as a precautionary measure under the SPS Agreement, the EU, *inter alia*, would have to show that the moratorium constituted a provisional measure. The moratorium was originally set to stay in place until adoption of traceability and labelling regulations. Thus, the EU's ability to invoke the precautionary provisions of the SPS Agreement might depend on whether the EU will indeed resume approvals once the regulations enter into force later this year. If based on the 'precautionary principle', the outcomes of a dispute might depend on whether the principle is acknowledged as an established principle of international law, which would need to be taken into account by a WTO panel in its decision. The Cartagena Protocol on Biosafety, once it enters into force in September 2003, might play a role in this context as many see it as the first operationalization of the precautionary principle in international law. Other provisions of the Protocol might also influence the outcomes of a possible dispute, even in cases that involve non-Parties to the Protocol like the U.S.. However, as some of the key provisions in the Protocol still remain to be resolved (including documentation requirements for some GMOs and standards for the identification, handling, packaging and transport practices), the relevance of the Protocol as a justification for a country's import regulations remains open.

These uncertainties are further complicated by the fact that biotechnology in general and GM foods in particular continue to be highly controversial and emotive issues that have brought together those concerned about the environment, human health and economic dominance of multinational corporations. Thus, even if the WTO panel ruled in favour of the U.S. regarding the EU's *de facto*

moratorium, the U.S. might still lose out in the long run due to the consumer backlash in the EU that such a ruling would likely evoke. The outcome of the U.S.-EU dispute will also be of great significance to developing countries that are currently in the process of setting up their own biotechnology regulations by potentially restricting or supporting their flexibility to institute import measures for GMOs that respond to the individual countries' biosafety and development priorities.

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TABLE 1: Summary Of Domestic GMO Import Regulations

Country	Regulation	Focus	Agency	Labelling*	Products / Coverage
Argentina	Resolution nº 656 (30 July 1992), Resolution nº 131 (1998), Resolution nº 289 (9 May 1997) (and existing regulations for the agriculture and fishing sector)	RA⊗ (based on 'substantial equivalence')	Secretary of Agriculture, Livestock, Fisheries and Foods (based on the opinion of the National Advisory Commission on Agricultural Biotechnology (CONABIA))	N/A	GMOs for research and environmental release
Argentina	Resolution No. 412 (10 May 2002) Resolution N° 511 (10 August 1998) Resolution N° 289 (9 May 1997)	RA (based on 'substantial equivalence')	National Service of Health and Agrofood Quality (SENASA)	no mandatory labelling requirements	GMOs that are not substantially equivalent to their conventional counterparts
Australia	*Gene Technology Act 2000* and associated Acts (*Gene Technology (Consequential Amendments) Act 2000* and *Gene Technology (Licence Charges) Act 2000)*	RA	Gene Technology Regulator (plus three advisory committees)	N/A	GMOs
Australia	Standard A18 *Foods Produced using Gene Technology* (1999) in the Australian *Food Standards Code* (Standard 1.5.2 in the joint Australia New Zealand *Food Standards Code*)	labelling	*Australia New Zealand Food Authority* (ANZFA) and the *Australia New Zealand Food Standards Council* (ANZFSC)	Threshold: 1% Exempt from labelling: foods derived from GMOs, most processing aids and food additives, flavours present in a concentration less than or equal to 0.1%, and food prepared at point of sale	GM food and food with GM ingredient(s), which contains novel DNA and/or novel protein; or has altered characteristics
Brazil	*Brazilian Biosafety Law (Lei No 8974)*	RA	Técnica Nacional de Biossegurança (CTNBio)	N/A	GMOs
Brazil	Decree No 3.871 (not implemented)	labelling		requires labelling if GM content > 4%	GM products approved by CTNBio

* The threshold refers to the percentage of GM materials accidentally introduced into foods. If the amount is below the threshold, GM foods are not required to be labelled

⊗ RA = risk assessment

Country	Regulation	Focus	Agency	Labelling*	Products / Coverage
Brazil	Decree No 4.680 (April 2003)	labelling		requires labelling if GM content > 1%	GM plant products and derivatives; animals fed with GM grains and products prepared with these animals; 2003 soybean harvest exempt
China	Administrative measures on Hygiene of GMO Foodstuffs (11 December 2001)	RA, labelling	GMO Food Expert Commission under the Ministry of Health	required for any food products, including raw and processed foods	foods and food additives made form the animals, plants and microorganisms whose genome composition is modified through biotechnology
China	Issued 5 January 2002: ▪ *Implementation Regulations on Safety Assessment of Agricultural GMOs* ▪ *Implementation Regulations on Safety of Import of Agricultural GMOs* ▪ *Implementation Regulations on Labelling of Agricultural GMOs* Note: These regulations were temporarily waived until 30 Sept. 03 (under *Circular of the Ministry of Agriculture No 190*) (based on *Regulations on Safety Control of Agricultural GMOs*, 23 May 2001)	RA, labelling	Agricultural GMO Committee responsible for safety evaluations of Ag GMO imports, Agricultural GMO Safety Administration Office responsible for safety administration of Ag GMO imports, approval by the Ministry of Agriculture	required for certain agricultural GMOs, including those derived from but no longer containing GMOs, as set out in the labelling regulations	agricultural GMOs (i.e. animals, plants, microorganisms and their products whose genetic structures have been modified by genetic engineering technology for the use of agricultural production or processing)
EU	"Council Directive on the deliberate release into the environment of genetically modified organisms" (*2001/18/EC*; revision of *90/220/EEC)*- adopted in March 2001, entry into force: 17 October 2002	RA, labelling & traceability	member state where the product is first placed onto the market		Any GMO or product consisting of or containing GMOS, including products derived from GMOS but not containing GMOs
EU	Regulation (EC) 258/97 on Novel foods and novel food ingredients, Regulation (EC) 50/2000 on additives and flavourings, Regulation (EC) 49/2000 on	RA, labelling	European Food Authority (previously the member state where the product is first placed onto the market)	▪ Threshold: 1 % ▪ no labelling required for foods derived from GMOs	Any GMO or product consisting of or containing GMOs, including products derived from GMOS but not

Country	Regulation	Focus	Agency	Labelling*	Products / Coverage
	adventitious contamination of GM material in conventional food				containing GMOs
EU	Proposals by the European Commission: ▪ Regulation on traceability and labelling of GMOs and products produced from GMOs (*COM 2001 - 1821 final*, 25 July 2001) ▪ Regulation on GM food and feed (*COM 2001 - 425* final, 25 July 2001) Note: While the regulations have been adopted, the final versions have not yet been published.	labelling, RA	European Food Authority (previously the member state where the product is first placed onto the market)	▪ Threshold for accidental presence: 0.5 %, ▪ Labelling threshold: 0.9% ▪ Full approval procedure and labelling also required for foods and feed derived from GMOs	Any GMO or product consisting of or containing GMOs, including products derived from GMOs but not containing GMOs
India	*Rules for the Manufacture, use, import, export and storage of hazardous micro-organisms, genetically engineered organisms or cells* (1989)	RA	Department of Biotechnology and various competent authorities	N/A	Genetically engineered organisms, micro-organisms and cells; substances and products and food stuffs etc of which these form part
Japan	*Guidelines for Application of rDNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries* in April 1989 (reissued partly revised in April 1992, April 1995, and August 1995)	RA	Ministry for Agriculture, Forestry and Fishery	N/A	all recombinant DNA (rDNA) organisms (crop plants, micro-organisms, and small laboratory animals) to which new properties have been introduced using rDNA technology
Japan	*Labelling Standard for Genetically Modified Foods* (Notification No. 517, 31 March 2001)	labelling	Ministry for Agriculture, Forestry and Fishery	Exempt from labelling: foods derived from but no longer containing GMOs; processed food where GM ingredient is not a main ingredient	GM agricultural products and foods processed therefore (listed in the Standard)
Japan	*Specifications and Standards for Foods, Food Additives and Other Related Products* (Ministry of Health and Welfare Announcement No.370 - Dec. 1959) (amended to require mandatory safety	RA	Ministry of Health and Welfare	N/A	foods and food additives produced by rDNA techniques

Country	Regulation	Focus	Agency	Labelling*	Products / Coverage
	assessment as of 1 April 2001)				
Mexico	*Draft Official Mexican Standard NOM-056-FITO-1995*	RA	General Directorate of Plant Health (DGSV) under the Secretariat of Agriculture, Livestock, and Rural Development (SAGARPA)	N/A	organism manipulated by genetic engineering for agricultural use
Mexico	*Health Act*	labelling	Secretariat of Health	Labelling requirements adopted by the Mexican Senate in 2000, awaiting approval by the Chamber of Duties	GM food, ingredients, addtitives and raw material
Philippines	*Rules and Regulations on the Importation and Release into the Environment of Plants and Plant Products Derived from the use of Modern Biotechnology* (Administrative Order No. 08, 3 April 2002) - entry into force on 1 July 2003	RA (based on 'substantial equivalence')	Bureau of Plant Industry (under the Department of Agriculture), RA conducted by a Scientific Technical Review Panel set up by PBI	N/A	plant or plant product altered or produced through the use of modern biotechnology
South Africa	Genetically Modified Organisms Act, 1997	RA	Executive Council for Genetically Modified Organism (established under the 1997 Act)		
South Africa	(Draft) Regulations Governing the Labelling of Foodstuffs obtained through Certain Techniques of Genetic Modification (Government Notice NO. R. 366, 4 May 2001)	labelling	Ministry of Health	Threshold: 1%	certain GMOs as described in the Regulation
US	Existing regulations Guidance documents: ▪ Statement of Policy: Foods Derived from New Plant Varieties (1992) ▪ Premarket Notice Concerning Bioengineered Foods (Draft, 2001) ▪ Draft Guidance for Industry Voluntary Labelling Indicating	RA, labelling	▪ USDA - Department of Agriculture's Animal and Plant Health Inspection Service (development and field testing on most GMOs) ▪ EPA - Environmental Protection Agency (development and release of	Voluntary	Bioengineered Foods

Country	Regulation	Focus	Agency	Labelling*	Products / Coverage
	Whether Foods Have or Have Not Been Developed Using Bioengineering (2001)		GM plants with pest control properties) ▪ FDA - Food and Drug Administration (safety of food and feeds)		
Zimbabwe	*Research (Biosafety) Regulations 2000*	RA	Biosafety Board (set up under the Research Council of Zimbabwe)	N/A	GM crops for research and field testing