tkn executive summary August 2003

trade knowledge network

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

Some Key Issues

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Published by the International Institute for Sustainable Development

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Executive Summary

While the estimated global area of transgenic or genetically modified (GM) crops continues to increase, the vast majority of acreage (99 per cent) remains confined to just four countries, namely the US, Argentina, Canada and China. 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. Even countries that have in the past moved rapidly on the adoption of GM 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 US 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 GM 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 US 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 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.

Review of Selected Domestic Import Regulations for GMOs

European Union
The EU has set up the most stringent import regime for GMOs worldwide. 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, direct or indirect, immediate or delayed, also taking into account the cumulative and long-term effects on human health and the environment. This procedure has recently been strengthened under the revised Directive *2001/18/EC* on the environmental release of GMOs, which entered into force on 17 October 2002. In particular, the 2001 Directive introduces 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.

While mandatory labelling requirements for food and food ingredients, which contain or consist of GMOs, have been in place for some time, they have recently been tightened under new traceability and labelling regulations adopted in July 2003. The regulations require all GM food and feed to be labelled, irrespective of whether the GM material can still be detected. In contrast, under the previous rules, GM foods derived from, but no longer containing GMOs, which are substantially equivalent, and GM feed had not been subject to labelling requirements. As a result of an ongoing *de facto* moratorium, no commercial releases of GMOs have been approved since 1998 following calls by a number of European

countries for the suspension of new authorizations pending the adoption of the revised rules on labelling and traceability of GMOs and GMO-derived products.

USA

In contrast to the EU, the U.S. has not developed separate regulations for biotechnology, but rather regulates GMOs through existing legislation. While no mandatory risk assessment requirements for GMOs exist, the proposed *Premarket Notice Concerning Bioengineered Foods* will require companies to submit information on safety considerations before marketing GM foods. Regarding labelling, the U.S. Food and Drug Administration have issued voluntary draft guidelines for the labelling of GM foods. In addition, efforts are currently underway in the states of Oregon and California to introduce mandatory labelling requirements for GM foods and transgenic fish respectively, while draft legislation requiring the labelling of GM foods was introduced in the House of Representatives in May 2002.

Australia / New Zealand

Australia has one of the most developed regulatory systems for GMOs. All 'dealings' with GMOs are regulated by the *Gene Technology Act (2000)*, which, inter alia, set up the office of the *Gene Technology Regulator* charged with monitoring and enforcing the legislation. Safety assessment and labelling of GM foods are governed by Standard A 18, developed jointly with New Zealand, which sets out some of the strictest labelling requirements in the world. 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 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. However, in contrast to the proposed EU regulations on labelling and traceability, GM foods derived from but no longer containing GMOs are exempt from labelling. While Australia has approved four GM crops for commercial release and is conducting various field trials, New Zealand has placed a moratorium on the environmental release of GMOs until 31 October 2003.

Asia

In Asia, the only major GM crops approved for commercial release are Bt 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 GM soybeans or rice. 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. For its part, Japan requires all recombinant DNA (rDNA) organisms to which new properties have been introduced using rDNA technology to undergo a safety evaluation, which should be submitted to the Ministry for Agriculture, Forestry and Fishery for approval. In addition, certain GMO agricultural products need to be labelled. Korea's Ministry of Agriculture & Forestry requires mandatory labelling for certain GM "raw materials", including GM soybean, corn and bean sprouts as of 1 March 2001 and GM potatoes as of 1 March 2002. In April 2002, the Philippines adopted regulations for GMOs, which will require importers of GM plants for environmental release, and GMOs for food, feed and processing to acquire a permit as of 1 July 2003.

Several other countries in the region have also made efforts to control imports of GMOs. In 2001, Thailand banned all GM field experiments and has restricted GM imports, most 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. 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. India had not approved the commercial planting of any GM crops until March 2002 when the Indian Genetic Engineering Approval Committee finally approved the commercial production of three varieties of GM cotton amid widespread protests by anti-GM activists.

Latin America

In Latin America, Argentina is the world's second largest producer of GMOs after the U.S., and is by the far the biggest player regarding the commercialization of GM crops. Argentina's regulations set out a number of requirements, which must be met in order to permit the release of GMOs into the environment; these are taken into account by National Advisory Commission on Agricultural Biotechnology (CONABIA) when evaluating each application. 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.

In contrast, several other important agricultural states in the region, notably 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. The Brazilian Biosafety 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. Only one GM crop - Monsanto's Roundup Ready soybeans - has been approved for commercial release by Técnica Nacional de Biossegurança (CTNBio). However, an injunction on the commercial planting of the soybeans in Brazil has been in place since 1999 and government approval of the commercial release of GMOs has been put on hold.

Concerns have also repeatedly been raised in Mexico regarding the importation GM corn. These concerns were further fuelled by recent findings that Mexican native varieties of corn grown in remote regions of Mexico have been contaminated by transgenic DNA despite a ban imposed in 1998 on the planting of GM corn. This discovery led the Mexican Congress, environmental groups and farm organizations to call on the government to ban the importation of GM corn. For its part, Bolivia imposed a ban on the imports of GMOs in January 2001, which was revoked in October 2001, allegedly due to pressure by the Argentinean soy corporate sector.

Africa

Only South Africa and Zimbabwe have put in place a biosafety law. Many other 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. Kenya, for instance, adopted Regulations and Guidelines for Biosafety in Biotechnology 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. Both Nigeria and Kenya are also in the process of developing their national biosafety regulations. Most African countries, however, still need to put into force legislation concerning existing policies.

Efforts are also underway at the regional level to establish biotechnology-related policies, including the Southern African Development Community (SADC), the Common Market for Eastern and Southern Africa (COMESA) and the New Partnership for African Development (NEPAD). Furthermore, the Organisation of African Unity has developed a draft African Model Law on Safety in Biotechnology

to serve as a basis for formulating national biosafety laws. However, no country has implemented the draft Model Law to date.

Only South Africa has so far approved the commercial growing of GM crops. While research and testing on similar products is being conducted in other African countries, the approval of GM crops for commercialization and import of GM commodities continues to be extremely slow.

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., together with Argentina, Canada and several other countries, initiated WTO dispute settlement proceedings against the EU's *de facto* moratorium on the approval of new GMOs and a number of marketing and import bans in certain EU member states. WTO Members have also raised concerns over domestic import regulations for GMOs, including in the EU and China, in the Committees for Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT). 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.

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.

What are the relevant WTO Agreements and how would they apply to GMO import regulations?
The Agreements on the Application of Sanitary and Phytosanitary Measures (SPS) and on Technical Barriers to Trade (TBT) are applicable to GMO import regulations. The SPS Agreement applies if the measure were aimed at the protection from food safety risks or from damage caused by pests. Any such measures should either be based on international standards or on a risk assessment. The TBT Agreement applies to product requirements that are mandatory (technical regulations) as well as voluntary (standards) and to conformity assessment procedures not covered by the SPS Agreement. Also of relevance is the General Agreement on Tariffs and Trade (GATT), which deals with trade in goods and 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 or 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)).

Are mandatory traceability and labelling requirements unnecessarily trade-restrictive?
Both the SPS and TBT Agreements require measures that are not more trade-restrictive than necessary in order to fulfil the objectives of the Agreements. Regarding the European Commission's proposed traceability and labelling regulations, the U.S. and other countries have argued in the past that the rules would be unnecessarily trade-restrictive, and that less trade-restrictive measures could be put in place to achieve the desired objectives. Often cited in this context are the costs of segregating modified from non-modified products, monitoring a particular crop throughout the food chain (e.g. by using identity preservation systems), and testing for the presence of GM materials to comply with the threshold of one per cent for the accidental presence of GMOs as proposed by the Commission. 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. Also, 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. Also, standards for foods derived from biotechnology adopted by the Codex Alimentarius Commission in July 2003 include the "tracing of products" and food labelling as risk management tools. Some see these standards as a major breakthrough in international negotiations on the use of traceability systems that at least partially vindicate the EU's insistence on introducing such requirements for GM food

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). 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. Under the proposed EU regulations, all food and feed derived from, but no longer containing, GMOs that are substantially equivalent to their conventional counterparts would also be subject to traceability and labelling requirements. 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 General Agreement on Tariffs and Trade (GATT), likeness is determined on a case-by-case basis according to four criteria; the products' physical properties, end-uses, tariff classification and consumers' tastes and habits. 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.

While the SPS Agreement does not include a 'like' product provision the EU might still 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 Codex standards, or that the measure was necessary to prevent the spread of pests. Similar considerations apply if the EU were to justify its regulations under the exceptions of GATT Article XX.

Could a ban on imports of GMOs be justified as a precautionary measure?
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. The concept of precaution is embodied in Article 5.7 of the SPS Agreement. For the EU *de facto* moratorium 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". The moratorium was originally set to stay in place until adoption of traceability and labelling regulations. Thus, 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 once the traceability and labelling regulations enter into force later this year. 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. It remains unclear, whether the principle constitutes an established principle under international law. Recognition of its status as a general principle would be relevant for the outcomes of a WTO dispute as such principles would be taken into account in the interpretation of relevant WTO provisions.

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 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". The Protocol applies to two categories of living modified organisms (LMOs), namely LMOs for "intentional introduction into the environment of the Party of import" (e.g. seeds intended for planting) and LMOs "intended for direct use as food or feed, or for processing" (e.g. soybeans for use in food), and sets out the different notification and approval procedures for the two categories. Once the Protocol has entered into force 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 restrictions covered by the Protocol. 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. However, when the Protocol was adopted, several issues remained unresolved and were left to the Conference of the Parties to be finalized once the Protocol has entered into force, including requirements for identifying shipments of LMOs for direct use as food, feed, or for processing and standards for the identification, handling, packaging and transport practices.