GENETICALLY MODIFIED ORGANISMS, GM PRODUCTS & WTO JURISPRUDENCE

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Abstract

The research paper consist the analysis of possible conflicts between national import regulation and WTO jurisprudence in relation to import of GMOs and GM products, including import restrictions, risk assessment provisions and labeling requirements. Further Author will be looking at precautionary measures as how far they are justified as ban on importation of GMOs. The main objective of the research is to take up the interaction of genetically modified organisms their GM products, WTO Regulations. Author through this research paper has tried to find out the answer to the following relevant questions as:

- *What are the relevant WTO Agreements and how would they apply to GMO import regulations?*
  a) Could a ban on imports of GMOs be justified as a precautionary measure?
  b) Is the precautionary principle recognized within the World Trade Organization (WTO)?
- *How might the Cartagena Protocol on Biosafety impact on possible WTO disputes related to GMO import regulations?*

Scope

The scope of the research confines to the study of WTO regulations and EU policies in regard to import of GMOs and GM products. The focus for genetically modified organisms (GMOs) is on food and feed products, consisting of or containing GMOs, seeds and crops. Thus, GMOs related to agricultural food and feed production and consumption are considered.

Research Methodology

Doctrinal method of research has been used. Books, articles, case study, newspapers, law magazines, authentic internet resources are utilized for the final making of the project.

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INTRODUCTION

Genetically Modified Organisms especially for GM food and feed are hot topic for discussion due to controversial aspect relating to the health, environment and economic issues to find out the potential benefits and losses in present as well as future. Supporters of the GMOs claim reduced pesticide usage and substantial yield improvement on one side and on the other opponents raise questions in regard to contamination of non GMO crops and damage to health and environment. On the one hand, genetic engineering (GE) has virtually unlimited technical possibilities. Seeds, crops, plants and animals may obtain properties that are beneficial (e.g. less water use, less sensitivity for pests, fast growth, etc.). However, the risks of introducing such organisms into the ecosystem have often not been investigated thoroughly, especially long-term risks. Contamination of nearby fields is occurring regularly, and weeds may evolve taking over herbicide resistance properties. Moreover, economic aspects exist, such as research and development costs and costs for using patented GMO seeds. Social aspects of GMOs may be, for instance, control of the world food supply, possibilities for farmers to use last year's harvested seeds, and ethical considerations such as patenting of organisms.

The total area of land used to grow GMO crops has been growing since 1996, with a growth of 5% between 2012 and 2013[2]. The total area is 175.2 million hectares by the end of 2013. Twenty-seven countries are growing GMOs commercially, but the US, Canada, Argentina and Brazil dominates, with India and China close behind. Four crops represent almost all commercial cultivation: soy, maize, cotton and canola, with over 50 million hectares of land used for soy, that is, more than 50% of the total area of land with GMO crops.

From the very beginning United State has been the major producer of the GM crops with 70.1 million hectares, which produce 95% of the nation's sugar beets, 94% of the soybeans, 90% of the cotton and 88% of the feed corn.[3]In U.S. there is no segregation system followed for GM and Non-GM, which has lead to widespread cross contamination. The concept of "substantial equivalence" as applied by the **Food and Drug Administration (FDA)** does not recognize any inherent risk depending on the source of the product. Europe has very different view point as regard to GMOs, they

[2] International Service for Acquisition of Agri-biotech Applications
http://www.isaaa.org/resources/publications/briefs/46/pptslides/default.asp
[3] "Genetically modified crops had bumper year in 2011". USA Today, August 2, 2012
http://www.usatoday.com/topic/a5c9ad5f-fc8d-49ff-ba16-6279e1e40e63/2012-year-in-review/

consider products of biotechnology as inherently distinguished from the products traditionally developed by natural crops. EU has strictest framework in regard to adoption of GM food and seeds with its precautionary approach. As of 2012, just two GM crops have been approved for cultivation in Europe[4]:

1. The more widely grown of the two, MON810, is a type of maize that helps fight off pests, such as the European corn borer.

2. The second approved product is a potato for industrial use called Amflora, approved in 2010. Its waxy starch content is useful for making paper, for example.

The EU's cautious approach, before 2003 resulting in a de facto moratorium on GMOs, and the member state bans have led the United States, Canada and Argentina to start a trade dispute within the **World Trade Organization (WTO)**, challenging EU legislation. This is the so-called EC - Biotech case.

A WTO dispute panel came with a ruling in the EC - Biotech case in May 2006. This ruling may have a profound effect on EU policy with respect to GMOs, even though the panel did not deal with many of the more contentious issues, and did not completely rule in favour of the US. The case ties together the field of genetic engineering, world trade rules, and domestic policies on GMOs, more specifically EU policies in this area. Many issues discussed within the trade and environment field are at stake.

[4] EuropaBio
http://www.europabio.org/which-gm-crops-can-be-cultivated-eu

GENETICALLY MODIFIED ORGANISMS

1. Introduction

A genetically modified organism (GMO) can, according to the European Union (EU), be defined as (EU, 2001):

"... an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination".

The altering of genetic material is commonly called genetic engineering (GE). The first GMO was demonstrated in 1973 (NCBE, 2006), and the technology has caught on since the 1980s, with the first commercial product, the FlavrSavr ® tomato, getting market approval in 1994[5]. Developments have since then diverged widely, dependent on the world region. In the United States, GE varieties of some crops such as soya, maize, and oilseed rape are forming a substantial part of the market, while in other parts such as Europe the use of GE has been very limited. Especially between the US and Europe, these diverging developments are not only seen at the farm level, but also at the political and consumer level.

The technology used to alter the genetic make-up of an organism by introducing genetic material from other organisms, in order to change the properties of the former, is called genetic engineering (GE), or recombinant DNA technology. GE may be applied to microorganisms, seeds or animals. Biotechnology is a term describing the development of seeds and crops, not necessarily by altering the genetic material. Thus, GE may be considered a subset of biotechnology.

GE can be defined as[6]:

"the formation of new combinations of heritable material by the insertion of nucleic acid molecules, produced by whatever means outside the cell, into any virus, bacterial plasmid or other vector system so as to allow their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation".

GMOs in the context of food and feed generally have one or more of five characteristics: They may be herbicide resistant, disease or insect resistant, have improved quality (e.g. flavour, structure, etc.),

[5] Consumers' Research Magazine;Jul99, Vol. 82 Issue 7, p41

[6] Indian Council of Medical Research
http://icmr.nic.in/ihd/Ministry%20of%20Env%20&%20Forests%20notification.doc.

or contain added nutrients - so-called nutraceuticals. The three most common properties, herbicide resistance, insect resistance and disease resistance, are discussed below[7]:

- **Herbicide resistant GMOs**

Herbicide resistant GMOs are crops that tolerate a certain herbicide, so that this herbicide may be used by the farmer to kill weeds present in the field. Usually both the organism and the herbicide are developed and sold by the same company. The herbicides are commonly broad-spectrum, that is, they attack many different weeds. Thus, by applying one herbicide several weeds may be kept away from the crop, this in contrast to the situation where several herbicides must be applied on the same crop in order to keep away different weeds. Thus, the total amount of herbicide may be reduced.

- **Insect resistant GMOs**

GMOs that are insect resistant may produce their own insecticide, thus offering the possibility for the farmer to reduce the usage of insecticide. The most common kind of insecticide incorporates genetic material from the soil bacteria Bacillus thuringiensis (Bt), of which now thousands of varieties are known, where a variety may target a specific insect. Other, more experimental strategies than allowing the GMO to produce Bt toxins are to modify the plant to produce lectins, a protein toxic to many insects, or to produce a substance inhibiting an insect's capability of breaking down proteins.

- **Disease resistant GMOs**

A third, less common, trait for GMO crops is resistance to diseases, especially those caused by viruses. This gives rather special problems, since these GMOs have viral nucleic acid sequences in their genome, which may interfere with any invading virus's replication, since genetic exchange is common for viruses. Thus, these GMOs could facilitate the evolution of viruses, possibly leading to 'the emergence of novel disease-causing viruses'.

3.2 Sustainability aspect of GMOs

Compared to conventional crops, genetically engineered crops may have a different impact on sustainability, i.e. the environmental properties, social aspects or economic factors.

[7] Ellie Cijvat, The *EC – Biotech* case at the crossroads of genetic engineering, world trade and EU politics(2006), IIIEE Theses 2006

- **Environmental aspects**

Ever since the beginning of genetic engineering, there have been concerns about negative impacts on the environment of GE crops. These impacts may be divided into three categories: effects caused by the GMO itself, effects resulting from dispersal of genes from GMOs to other organisms in the environment, and effects due to altered practices in the use of an organism because of the new plant characteristics.

Environmental Benefits:

For herbicide resistant GMO crops, potential benefits are first of all a reduction in use of herbicides. This will reduce water pollution through run-off, and the use of resources is decreased. Moreover, less soil cultivation may be needed, especially when using post emergence broad-spectrum herbicides. This results in less erosion while organisms and moisture are conserved in the soil.

If special properties are built into the GMO crops, more environmental benefits may be gained; for instance, plants may need less water in order to reach similar growth or yield, or plants may get nitrogen-fixing abilities. This may bring significant environmental advantages, since in that case the use of artificial fertilizer may be reduced, bringing benefits such as energy savings and reduced run-off pollution.

Environmental Disadvantages

In respect to herbicide resistant GMO crops, some environmental disadvantages may be seen as well. One is the impact on plants around farmland; the herbicides used in GMO cultivation are often broad-spectrum, and will thus impact surrounding plants, which may have negative consequences for insects and farm birds that depend on these plants. One of the main issues of GMOs is their spread into the environment, that is, their invasiveness. This is an important issue in the controversies regarding GMOs in e.g. the EU, or the US. First of all, seeds or pollen may be spread into the environment, through insects, birds or mammals, the wind, or during transport or handling. Second, these seeds or pollen may settle in the environment.

Major invasions are hard to predict, and far from all invasions are successful, but some invasions may cause substantial damage and may be hard if not impossible to eradicate. Third, the effect of the invasion may be the persistence of pesticide resistant weeds, or the pollution of conventional or organic crops with GE plants.

- **Social aspect**

One of the main differences between GE and conventional food production is the patentability of GE crops. This creates a different relationship between the company owning the seed patent and the farmer, something that has severe social consequences with respect to for instance inequalities but also the capacity for self-sufficiency.

Social Benefits

According to the pro-GMO NGO ISAAA (International Service for the Acquisition of Agri-Biotech Applications), GMOs could contribute to fighting poverty, since yields may improve. This could raise the income of many subsistence farmers in developing countries, thus leading to substantial improvements in quality of life[8].

A second social benefit is improved health related to the potential of decreasing the use of herbicides and insecticides, with farm workers being less exposed to these compounds. Of course second-generation GMOs, containing nutraceuticals, may contribute to improved health. A well-known example is Golden Rice™, now owned by Syngenta that contains vitamin A. It is claimed that this rice could help solve vitamin-A deficiencies in developing countries.

Social Disadvantage

An important health drawback of GMOs is the risk for the occurrence of allergens. This may happen unexpectedly, as in the recent case of peas.[9] An important social disadvantage of GE is related to empowerment. Due to the structure of the biotech industry, where patents and corporate ownership of seeds and plants are common – farmers must often sign a gene licensing agreement[10] before using GMO seeds – and pesticides are sold by the same corporation, farmers become more dependent on that corporation. The difference in resources between a farmer and a corporation, e.g. in case of a court case related to a supposed violation of patent rights, probably only serves to increase the feeling of disempowerment of the farmer. Also the aforementioned 'Terminator Technology', where seeds cannot be saved for next year's cultivation, would not contribute to farmer empowerment.

[8] International Service for Acquisition of Agri-biotech Applications
http://www.isaaa.org/resources/publications/briefs/46/pptslides/default.asp
[9] Immunogenicity of GM peas, Rudolf Valenta and Armin Spök
http://www.bfn.de/fileadmin/MDB/documents/service/skript239.pdf
[10] Such an agreement clarifies the patent situation, e.g. forbids the farmer to save seeds, and in many cases prohibits the farmer to discuss the seeds or crops in public (Soil Association, 2002).

- **Economic aspect**

From an economic perspective some of the obvious aspects of GE are the large investment costs for research activities, economic aspects of patenting, costs of GMO seeds for the farmer, and possible profit margins due to increased yields or decreased investments in pesticides. For the consumer, the impact seems to be relatively small, since either GMO products are similar to conventional products or GMOs are just a part of an end product with a rather marginal impact on consumer price.

Economic benefits

For seed producers, economic benefits of GMOs lie in the higher price that can be charged for GMO seeds. Moreover, the patents that are granted on GE products or processes are an asset to the company, and may provide income.

For farmers, the potential yield improvements may provide a larger income to the farmer. Also, if the use of external inputs such as herbicides and pesticides is reduced, costs for cultivation will be reduced.

Economic disadvantages

Large investments need to be made for GE research. This is an economic drawback for seed producers. Moreover, patent applications are costly. For the farmers, costs for GE seeds are relatively high. Also, seeds may not be saved by the farmer for next year, so this investment must be made every year.

REGULATORY FRAMEWORK FOR GENETICALLY MODIFIED ORGANISMS

GMOs are regulated at the international, national and sometimes local level.

1. The Convention on Biological Diversity

The only international treaty considering genetically modified organisms is the Convention on Biological Diversity, under auspices of the United Nations (UN). Within the convention, the Cartagena Protocol on Bio safety has been signed regulating cross-border trade in living modified organisms.

In 1992 the Convention on Biological Diversity (CBD) was signed by 150 government leaders at the Earth Summit in Rio de Janeiro. To date, the convention has 193 parties, of which 168 have ratified it.[11] It entered into force on December 29th, 1993.

The objectives of the Convention on Biological Diversity are "the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources"[12]. These are translated into binding commitments in its normative provisions, contained in Articles 6 to 20.

The Convention recognizes that the causes of the loss of biodiversity are diffuse in nature, and mostly arise as a secondary consequence of activities in economic sectors such as agriculture, forestry, fisheries, water supply, transportation, urban development, or energy, particularly activities that focus on deriving short-term benefits rather than long-term sustainability. Dealing with economic and institutional factors is therefore key to achieving the objectives of the Convention. Management objectives for biodiversity must incorporate the needs and concerns of the many stakeholders involved, from local communities upward.

A major innovation of the Convention is its recognition that all types of knowledge systems are relevant to its objectives. For the first time in an international legal instrument, the Convention recognizes the importance of traditional knowledge - the wealth of knowledge, innovations and practices of indigenous and local communities that are relevant for the conservation and sustainable use of biological diversity. It calls for the wider application of such knowledge, with the approval and involvement of the holders, and establishes a framework to ensure that the holders share in any benefits that arise from the use of such traditional knowledge.

[11] Convention on Biological Diversity 1992

[12] Article 1, Convention on Biological Diversity 1992

The Convention therefore places less emphasis on a traditional regulatory approach. Its provisions are expressed as overall goals and policies, with specific action for implementation to be developed in accordance with the circumstances and capabilities of each Party, rather than as hard and precise obligations. The Convention does not set any concrete targets, there are no lists, no annexes relating to sites or protected species, thus the responsibility of determining how most of its provisions are to be implemented at the national level falls to the individual Parties themselves.

Institutional Structure of the convention

The Convention establishes the standard institutional elements of a modern environmental treaty: a governing body, the Conference of the Parties; a Secretariat; a scientific advisory body; a clearing-house mechanism and a financial mechanism. Collectively, these translate the general commitments of the Convention into binding norms or guidelines, and assist Parties with implementation.

The **Conference of the Parties (COP)**, as the governing body of the Convention process. The principal function of the COP is to regularly review implementation of the Convention and to steer its development, including establishing such subsidiary bodies as may be required. The COP meets on a regular basis and held five meetings in the period 1994 to 2000. At its fifth meeting (2000) the COP decided that it would henceforth meet every two years.

The **Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA)** is the principal subsidiary body of the COP. Its mandate is to provide assessments of the status of biological diversity, assessments of the types of measures taken in accordance with the provisions of the Convention, and advice on any questions that the COP may put to it. SBSTTA met five times in the period 1995 to 2000 and, in the future, will meet twice in each two-year period between meetings of the COP.

The principal functions of the **Secretariat** are to prepare for and service meetings of the COP and other subsidiary bodies of the Convention, and to coordinate with other relevant international bodies. The Secretariat is provided by UNEP and is located in Montreal, Canada.

The Convention provides for the establishment of a **clearing-house mechanism** to promote and facilitate technical and scientific cooperation.[13] A pilot phase of the clearing-house mechanism took place from 1996 to 1998 and, following evaluation of this, the COP has approved a clearing-house mechanism strategic plan and a programme of work until 2004.

The Convention establishes a **financial mechanism** for the provision of resources to developing countries for the purposes of the Convention. The financial mechanism is operated by the Global

[13] Artide 18,Convention on Biological Diversity,1992

Environment Facility (GEF) and functions under the authority and guidance of, and is accountable to, the COP.

1.1. Cartagena Protocol on Bio safety

Within the **Convention on Biological Diversity (CBD)**, on January 29th 2000 a protocol has been agreed upon that is crucial for trans boundary movements of GMOs: the **Cartagena Protocol on Biosafety, or Biosafety Protocol (BP)**. It refers to a precautionary approach and confirms the notion of precaution established in the **Rio Declaration on Environment and Development (UN, 1992)**. On September 11th, 2003, it entered into force, and as of this date it had been accessed by 166 countries out of which 103 have signed it. Notably, the United States, Argentina and Canada are not amongst the countries that have ratified or accessed the protocol; the US has not signed it, while Argentina and Canada have signed it.

The protocol lays down rules for international trade in living modified organisms, or LMOs. LMOs are basically GMOs that have not been processed, and that could live if introduced into the environment, such as seeds.

Under the protocol, a country which wants to export LMOs for "intentional introduction into the environment" (such as seeds for planting) must seek advance informed agreement from the importing country before the first shipment takes place. Exports of LMOs which are to be used for food, feed or processing do not have to go through advance informed agreement; rather, trading partners will inform each other of their policies through a "biosafety clearing-house". The protocol provides for decisions to be based on risk assessment. Under certain circumstances, importers can ask the exporter to carry out the risk assessment. In addition, the protocol contains provisions related to identification of LMOs in international trade.

If a dispute is brought to the WTO, the panel can only judge compliance with WTO Agreements. In doing so the Cartagena Protocol would presumably be taken into account as a relevant international treaty. The relationship of the protocol with the SPS Agreement and other international agreements is not clear.[14]

[14] Cartagena Protocol on Biosafety
http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c8s1p1_e.htm

1.2. The Nagoya Protocol on Access and Benefit-sharing

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity is an international agreement which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components. It was adopted by the Conference of the Parties to the Convention on Biological Diversity at its tenth meeting on 29 October 2010 in Nagoya, Japan. Up to the date only 61 countries have signed it. Convention on Biological Diversity 1992 covers the objective of Nagoya Protocol by stating one of the three fundamental objectives, as set out in its Article 1, as the: "fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding". A framework for the implementation of this third objective of the Convention with regard to access to genetic resources and benefit-sharing (ABS) is provided in Article 15 of the Convention.

The Convention on Biological Diversity recognizes the sovereign rights of States over their natural resources in areas within their jurisdiction. Parties to the Convention therefore have the authority to determine access to genetic resources in areas within their jurisdiction. Parties also have the obligation to take appropriate measures with the aim of sharing the benefits derived from their use. In addition, Article 8(j) contains provision to encourage the equitable sharing of the benefits arising from the utilization of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for conservation and sustainable use of biological diversity. These provisions are also linked to the provisions on access to, and transfer of technology (Article 16), exchange of information (Article 17), technical and scientific cooperation (Article 18), the handling of biotechnology and distribution of its benefits (Article 19, paragraphs 1 and 2), and financial resources and financial mechanism (Article 20 and Article 21).

2. World Trade Organization

The World Trade Organization (WTO) originates from the beginning of the 20th century. After the economic crisis of the 1930s and World War II, negotiations were held to increase worldwide trade in goods and reduce trade barriers. The opinion that tariffs and other barriers to trade had contributed to the 1930s crisis as well as to World War II is seen as a motivation for this. The negotiations initially resulted in the foundation of the International Trade Organization (ITO), which in 1948 was replaced by the General Agreement on Tariffs and Trade (GATT). Around that time even the so-called Bretton Woods institutions (the International Monetary Fund and the World Bank) were founded.

In the so-called Uruguay Round, lasting from 1986 to 1993, cross-border trade in services and intellectual property rights were included, and an umbrella organisation, the World Trade Organisation, was founded, which formally became operational in 1994. In all, the influence of the GATT and WTO has moved from tariffs on goods to many aspects of society, amongst others protection of health and the environment.

Trade problems arise when countries have different regulations regarding the testing and approval procedures necessary to place GMOs and their products on the market, or when they disagree about labelling and identification requirements. Some countries ban imports and sales of GMOs and their products altogether. In other countries, a large part of the production of some crops, such as maize or soybeans, is from genetically modified seeds, and is mixed with non-modified varieties during storage, transport and processing. These countries argue it would be unnecessary and very costly to keep GMOs separate, and consider that labelling requirements or import bans are unnecessary trade barriers.

So far, no trade dispute over GMOs has been examined by a WTO dispute settlement panel. Several WTO agreements could apply to the topic, including SPS, but also the TBT Agreement, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and the GATT.

2.1 Important WTO Agreements in Correlation with GMOs

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)). So far, no trade dispute over GMOs has been examined by a WTO dispute settlement panel. Several WTO agreements could apply to the topic, including SPS, TBT Agreement and the GATT, but also the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)

2.2 SPS and TBT

Out of nineteen agreements negotiated as part of the Uruguay Round of Trade Agreements, two explicitly address non-tariff barriers to trade. These are the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement). As tariff rates were lowered following Uruguay Round conducted within the framework of the GATT non-tariff barriers have become of increasing concern.

SPS Agreement, itself does not establish international standards for GMOs, but establishes rules that limit the ability of states to adopt trade-restrictive regulations without "scientific justification". Member States are required by Article 2.2. to "ensure that any sanitary or phytosanitary measure ... is based on scientific principles and is not maintained without sufficient scientific evidence". The same Article also states that measures, only to extent necessary to protect human, animal or plant life or health". This means that the measure may not be more trade restrictive than necessary, although member states may determine own level of protection. The only exception is given in paragraph 7 of the Article 5, where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures…" This paragraph may be considered as precautionary approach. This article describes insufficient information, what means little or no reliable information. In this way specifically is stated that scientific uncertainly is not included in this. Article 5.1 states that measures must be based on a risk assessment. Risk assessment is defined in Article 4 of Annex A, "The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the

territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs". This definition is unclear, not covers all possible risks including socio-economic risks and does not describe who will bear the costs for the risk assessment, importer or member state have to prove that the risk with a certain GMO are too large.

SPS deal with food safety, while TBT cover consumer safety, health, environmental protection and labeling that may impact trade. The Organization for Economic Co-operation and Development (OECD) reported in 2003 that the main focus of the TBT work on trade barriers since 1995 are food labeling. Given continued disagreement on labeling, this focus is likely to continue. According to Center for Science in the Public Interest (CSPI)[15] food labels as an essential source of information for consumers to enable them to have effective control and choice over what they eat, is illegal under SPS and TBT Agreements. Mandatory labeling requirement, even if it does not treat imports differently than domestic products, is not permitted if it is maintained "without sufficient scientific evidence"[16] or if it restricts international trade more than is necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment [of that objective] would create (Article 2 TBT agreement). In the same time "Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility"[17].

In applying the SPS and TBT Agreements, the WTO extensively relies on decisions by the Codex Alimentarius Commission[18] (Article 3 of the SPS Agreement and Article 2 of the TBT Agreement). The Codex standards have been seen by most legal experts as "semi-binding" on WTO members. A national standard that provides a greater level of protection than Codex is a "trade barrier" which "could be seen as illegitimate protectionist measures and become the subject of trade disputes and targets for WTO authorized and potentially costly trade retaliation, especially for smaller economies or more trade-dependent sectors". Influence of corporations on the committee's work is undeniable, in each meetings of the Codex Committee on Food Labeling industry representatives make up a

[15] The Impact of the TBT and SPS Agreements on Food Labeling and Safety Regulations. CSPI International: http://cspinet.org/reports/codex/wtospsbt.htm
[16] Artide 2 SPS Agreement
[17] Artide 5 SPS Agreement
[18] Artide 3 of the SPS Agreement and Artide 2 of the TBT Agreement

significant share in relation to the total number of participants (National Food Alliance, 1993; Sklair, 2002; Consumer International, 2006). Codex discussion of the GMO labeling began in October 1994 and so far there is no consensus. U.S. and Canada are constantly resisted labeling GMOs.

2.3 GATT Regulations

If there is a gap in the SPS Agreement, a complaining country could still fall back on the GATT provisions. SPS case law indicates that such an approach is possible, and commentators have also addressed the GMF issue in terms of GATT requirements. The GATT provisions strive for equal treatment of imported goods through application of non-discrimination principles.

There are two aspects to these: 1) non-discrimination by an importing country among importers and 2) non-discrimination between imported goods and domestic like-products. A violation of either of these rules may provide the exporting country with a legitimate complaint under GATT rules. The question would then arise whether the approval provisions discussed above are discriminating between "like" products or among importers. At least two commentators argue that in the case of GMF, there would be no discrimination, since a proper reading of GATT art. III (4) makes clear that GMF and traditional foods are not "like". The argument is that the genetic modification creates a completely new product, and is thus correctly distinguished from the traditional product.

There is also a health and safety exception to the GATT non-discrimination rules. Art XX provides a list of exceptions. In the case of the approval process for GMF, the importing country would most likely rely on GATT art. XX (b), the health and safety exception that was the forerunner of the SPS Agreement. The art. XX exception states:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures necessary to protect human, animal or plant life or health….

The requirements for imposing the art. XX (b) exception are thus that it be "necessary", not discriminate arbitrarily and not be a disguised restriction on international trade. In order for a measure to be considered "necessary" it must be the least trade restrictive alternative available. The question to be resolved would be whether the approval processes outlined above constitute unnecessary or discriminatory measures, or a disguised barrier to trade.

Many of the approval processes are modeled on the procedures required under the Protocol. It is open to question whether measures which comply with a multi-national environmental treaty can be

considered discriminatory, even against a country which is not a party to it. Regarded in this light, they would not be considered unilateral measures, which has been important to the GATT panels in the past. The approval processes are designed to be rules and science based, which should eliminate the argument that they are discriminatory. Certain commentators argue that such measures would be considered merely the operational requirements of a non-protectionist scheme for health regulation, and that there is no element of discrimination between domestic products and imports. All GMF are regulated the same. Opponents of the approval requirements will certainly argue that since there is little to no domestic production of GMF in the regulating countries, the measures are clearly a disguised barrier to trade. By regulating only GMF, the importing countries are giving an unfair advantage to domestic traditional production.

The GATT practice has traditionally been to construe Art XX narrowly in favor of trade and against nontariff barriers to trade. Crucial issues will be whether the approval processes are considered discriminatory and whether the GMF are considered "like" traditional counterparts. It is thus possible that the approval measures could fail a challenge under GATT art. XX, but on balance, the approval processes should withstand the challenge.

2.4 TRIPS

TRIPS came into force six months after Convention on Biological Diversity (CBD). The convention recognized for the first time in international law that the conservation of biological diversity is "a common concern of humankind" and describes equal sharing of resources and access to technology, precautionary approach and valuation of traditional knowledge. Because of the substantial differences two agreements regulating trade with GMOs: TRIPS and CBD are in conflict. 192 countries and the EU are parties to the Convention. The US has signed but not ratified the treaty, and is unlikely to now that they have passed into law the Monsanto Protection Act of 2013. The TRIPS-CBD relationship has yet to be resolved. Developing countries seek to amend TRIPS so that it will support the objectives of the CBD. Seventeen countries, so-called mega diverse countries, which represent between 60 and 70 percent of the biodiversity of the planet wants to stops commercialization of their biological and traditional knowledge resources[19]. By contrast, the U.S. prefers contract law to more global regulation. The TRIPs Agreement requires countries to provide

[19] Artide on European Regulation on GMOs and the WTO by Joanne Scott, Hein online http://heinonline.org/HOL/Page?handle=hein.journals/coljeul9&div=16&g_sent=1&collection=journals#219

a minimum level of protection for certain intellectual property rights. However, only new inventions have to be patentable, not discoveries. Even where a patent is granted, the government can still regulate or ban a product from sale. With respect to GMOs, countries may exclude from patentability plants and animals as well as essentially biological processes for the production of plants and animals. However, they must provide protection for microorganisms and non-biological and microbiological processes. The TRIPs Agreement also allows temporary exclusion from patentability when necessary to protect human, animal or plant life or health or to avoid prejudice to the environment. The TRIPs Agreement would normally not be invoked in a conflict regarding market access for GMOs, but it might be invoked in a dispute on intellectual property protection related to GMOs.

2.5 The "Three Sister" Organizations

The three standard-setting organizations explicitly referenced in the SPS Agreement had been in existence long before the Uruguay Round begun. However, prior to the adoption of the SPS Agreement, their norms were not directly linked with any international trade agreement. This changed with the inception of the SPS Agreement, which, through Article 3, recognizes the standards, guidelines and recommendations of these international bodies. The SPS Committee also monitors the use of these international standards.

The work of the three sister organizations depends on the participation of their members. All Members of the SPS Agreement are therefore encouraged to become members of these organizations and to actively participate in the work agendas of the three sister organizations[20]

- **Codex Alimentarius Commission**

In the early 1960s, the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO) recognized the importance of developing international food standards for the purposes of protecting public health and minimizing disruption of international food trade. The Joint FAO/WHO Food Standards Program was established, and the Codex Alimentarius Commission was designated to administer the program.

The leaders who established the Food Standards Programme and the Codex Alimentarius Commission were concerned with protecting the health of consumers and ensuring fair practices in the food trade. They felt that both of these objectives could be best met if all countries harmonized their food regulations and adopted internationally agreed standards. Through harmonization, they

[20] World Trade Organisation
http://www.wto.org/english/tratop_e/sps_e/sps_agreement_dbt_e/c7s1p1_e.htm

envisaged fewer barriers to trade and a freer movement of food products among countries, which would be to the benefit of farmers and their families and would also help to reduce hunger and poverty. The founders concluded that the Food Standards Programme would be a solution to some of the difficulties that were impeding free trade.

The advantages of having universally uniform food standards for the protection of consumers were recognized by international negotiators during the Uruguay Round. It is not surprising, therefore, that the SPS Agreement and TBT Agreement both encourage the international harmonization of food standards. Importantly, the SPS Agreement cites Codex standards, guidelines and recommendations as the preferred international measures for facilitating international trade in food. The Codex Alimentarius is a science-based activity. Independent experts and specialists in a wide range of disciplines have contributed to its work to ensure that its standards withstand the most rigorous scientific scrutiny. The work of the Codex Alimentarius Commission, together with that of FAO and WHO in their supportive roles, has provided a focal point for food-related scientific research and investigation, and the Commission itself has become an important international medium for the exchange of scientific information about the safety of food.

Over the years, the Codex has developed over 200 standards covering processed, semi-processed or raw foods intended for sale for the consumer or for intermediate processing; over 40 hygienic and technological codes of practice; evaluated over 1000 food additives and 54 veterinary drugs; set more than 3000 maximum levels for pesticide residues; and specified over 30 guidelines for contaminants.[21]

- **Office International des Epizooties**

The Office International des Epizooties (OIE) is the world organisation for animal health recognized by the SPS Agreement. Founded in 1924, the OIE has three main missions:

•To inform members of the occurrence and course of animal diseases throughout the world and of means of controlling these diseases;

•To co-ordinate international research devoted to the surveillance and control of animal diseases; and

•To promote the harmonisation of health regulations for trade in animals and animal products among members.

[21] World Trade Organisation
http://www.wto.org/english/tratop_e/sps_e/sps_agreement_dbt_e/c7s1p1_e.htm

These missions are achieved through different activities including the establishment of standards, guidelines and recommendations pertaining to animal health. Examples of the OIE work in this area include the following:

•International Animal Health Code (for mammals, birds and bees)

•Manual of Standards for Diagnostic Tests and Vaccines

•International Aquatic Animal Health Code (for fish, molluscs and crustaceans), and Manual for Aquatic Animal Diseases

•Lists of countries recognized as being free from the most serious diseases (foot and mouth disease)

The OIE keeps lists of the most important diseases. List A diseases are transmissible diseases that have the potential for very serious and rapid spread, irrespective of national borders, which are of serious socio-economic or public health consequence and which are of major importance in the international trade of animals and animal products. List B diseases are defined as transmissible diseases which are considered to be of socio-economic and/or public health importance within countries and which are significant in the international trade of animals and animal products.

The above-mentioned Codes as well as their associated Manuals are designed as reference documents to be used by the veterinary administrations or the competent authorities of the member countries, to assist them in establishing the health regulations that their countries should apply to the import and export of live animals and animal products, so that the spreading of pathogens responsible for List A or List B diseases to other animals or to human beings is avoided.

In addition to recommendations specific to List A and List B diseases, the OIE has also developed general principles relating to risk analysis methodology, which is comprised of four components, namely import risk assessment, assessment of veterinary services, zoning/regionalisation, and surveillance and monitoring.

- **Secretariat of the International Plant Protection Convention**

The International Plant Protection Convention (IPPC) is a multilateral treaty for international cooperation in plant protection The Convention makes provision for the application of measures by governments to protect their plant resources from harmful pests (phytosanitary measures) which may be introduced through international trade. The IPPC is deposited with the Director-General of the FAO and is administered through the IPPC Secretariat located in FAO's Plant Protection Service. The IPPC was first adopted in 1951 and has been amended twice, most recently in 1997.

The revision of the IPPC approved in 1997 represents an updating of the Convention to reflect contemporary phytosanitary concepts and the role of the IPPC in relation to the Uruguay Round

Agreements of the WTO, particularly the SPS Agreement. The SPS Agreement identifies the IPPC as the organization providing international standards for phytosanitary measures. The IPPC complements the SPS Agreement by providing the international standards that help to ensure that phytosanitary measures have a scientific basis for their placement and strength and are not used as unjustified barriers to international trade.

IPPC work includes standards on pest risk analysis, requirements for the establishment of pest-free areas, and others which give specific guidance on topics related to the SPS Agreement.

The three sister organizations have begun work on GMOs, and any standards, recommendations and guidelines they develop will be international standards in the sense of the SPS Agreement.

Codex has established an ad hoc task force on foods derived from biotechnology. The task force is developing general principles for risk analysis for GM foods, and specific guidance on risk assessment. It is also examining the analytical methods available for detection of GMOs in foods. To support the work of the task force, there has been a joint FAO/WHO expert consultation on safety aspects of genetically modified foods of plant origin in May/June 2000, and further expert consultations are planned on the safety of genetically modified foods from animals and micro-organisms, plus a working group on testing methods.

Some of the standards developed by the OIE deal with diseases that have human health and biosafety significance. These standards are approved by the OIE member countries and published in the OIE International Animal Health Code. The OIE also publishes the Manual of Standards for Diagnostic Tests and Vaccines. A few of the tests and vaccines use genetically modified organisms. The OIE has had a working group on biotechnology since 1996.

The IPPC has formed an open-ended working group on phytosanitary aspects of GMOs, biosafety and invasive species. It will develop standards for risk analysis as applied to environmental hazards.

2.6 The "Precautionary Principle"

In short, the "precautionary principle" is a notion which supports taking protective action before there is complete scientific proof of a risk; that is, action should not be delayed simply because full scientific information is lacking. The "precautionary principle" or precautionary approach has been incorporated into several international environmental agreements, and some claim that it is now recognized as a general principle of international environmental law.

In the fields of food safety, plant and animal health protection, the need for taking precautionary actions in the face of scientific uncertainty has long been widely accepted. There may be instances

when a sudden outbreak of an animal disease, for example, is suspected of being linked to imports, and trade restrictions must be immediately imposed while further information about the source of the outbreak and its extent are gathered. The discipline of risk assessment, one of the basic obligations of the SPS Agreement, was developed to guide action in the face of incomplete knowledge about risks to health. It focuses on probabilities of hazards occurring, and the probable consequences, because complete knowledge is very rare. Furthermore, it is virtually impossible to scientifically prove the "safety" of a food or product, rather scientists seek evidence of any harm.

With respect to food safety, the Codex Committee on General Principles is developing general principles for risk analysis, and in this context discussing under what conditions precautionary actions may be warranted, and what criteria should be respected in taking such actions.

In the beef hormones dispute[22], the Panel and Appellate Body noted that the "precautionary principle" was reflected in the SPS Agreement, but that it did not override the specific obligations in the Agreement. The Appellate Body considered that the notion of precaution was, in particular, incorporated in paragraph 6 of the Preamble, Article 3.3, and Article 5.7 of the SPS Agreement.

Paragraph 6 of the Preamble embraces precaution by encouraging harmonization of national SPS measures with international standards without requiring Members to change their sovereignty-determined appropriate levels of health protection. Article 3.3 of the SPS Agreement entails a precautionary approach because it explicitly permits Members to adopt SPS measures which are more stringent than measures based on the relevant international standards.

Article 5.7 allows Members to take provisional measures when sufficient scientific evidence does not exist to permit a final decision on the safety of a product or process. The provisional measure must take into consideration available pertinent information. The Member adopting the measure must seek to obtain the additional information necessary for a more objective assessment of risk, and must review the SPS measure within a reasonable period of time.

The European Union did not invoke Article 5.7 in the beef hormones dispute[23], stressing that its import ban was not a provisional measure. However, in the variety testing dispute[24], Japan did claim that its measure was a provisional measure, in accordance with Article 5.7. The panel found no evidence that Japan had actively sought to obtain additional information in order to review its

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22 Beef Harmone Dispute 1990
http://www.wto.org/english/tratop_e/sps_e/sps_agreement_dbt_e/c5s3p1_e.htm

23 Tim Josling, Donna Roberts and Ayesha Hassan'The Beef-Hormone Dispute and its Implications for Trade Policy' http://www.pf.uni-lj.si/media/beef.hormones.pdf

24 Variety testing dispute 1997, http://www.wto.org/english/tratop_e/sps_e/sps_agreement_dbt_e/c5s5p1_e.htm

measure within a reasonable period of time. The Appellate Body noted that the "reasonable period of time" had to be established on a case-by-case basis, and that in this case, although Japan's measure had been in place for over twenty years, the obligation to review the measure came into existence only with the entry into force of the SPS Agreement in 1995. The Appellate Body agreed with the panel finding that Japan's measure was in violation of Article 5.7

Similarly in EC- Biotech Case[25] the Measure at issue were: (i) Alleged general EC moratorium on approvals of biotech products; (ii) EC measures allegedly affecting the approval of specific biotech products; and (iii) EC member State safeguard measures prohibiting the import/marketing of specific biotech products within the territories of these member States and the Product at issue was Agricultural biotech products from the United States, Canada and Argentina. EU again followed the Precautionary Principle and banned the agricultural biotech products from the US.

Key Findings of the case were:

Existence of moratorium: The Panel found that a general de facto moratorium on approvals of biotech products was in effect on the date of panel establishment, i.e., August 2003. It was general in that it applied to all applications for approval pending in August 2003 under the relevant EC legislation and de facto because it had not been formally adopted. Approvals were prevented through actions/omissions by a group of five EC member States and/or the European Commission.

• SPS Arts. 5.1 (risk assessment) and 2.2 (sufficient scientific evidence): The Panel found that the EC decision to apply a general moratorium was a decision concerning the application/operation of approval procedures, i.e., a procedural decision to delay final substantive approval decisions. It was not applied for achieving the EC level of sanitary or phytosanitary protection and, hence, was not an "SPS measure" subject to Arts. 5.1 or 2.2.

• SPS Annex C(1): (a) and Art. 8 (control, inspection and approval procedures): The Panel found that the general moratorium led to undue delay in the completion of the EC approval procedure conducted in respect of at least one biotech product at issue and thereby to the European Communities acting inconsistently with Annex C(1)(a) and, by implication, Art. 8.

[25] EC-Biotech Case 2003
http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm

Product-specific measures

• SPS Annex C(1): (a) and Art. 8 (control, inspection and approval procedures): The Panel found that in 24 ofthe 27 product-specific approval procedures it examined, the procedure had not been completed without undue delay.

In respect of these procedures, the European Communities had, therefore, acted inconsistently with Annex C (1) (a) and, by implication, Art. 8.

EC Member State safeguard measures

• SPS Arts. 5.1, 2.2 and 5.7 (provisional measure): According to the Panel, the record did not indicate that there was insufficient evidence to conduct a risk assessment within the meaning of Art. 5.1 and Annex A(4) for the biotech products subject to safeguard measures. As a result, Arts. 5.1and 2.2 were applicable. In this regard, the Panel found that none of the safeguard measures at issue were based on a risk assessment as required under Art. 5.1 and definedin Annex A(4). By maintaining measures contrary to Art. 5.1, the European Communities had, by implication, also acted inconsistently with Art. 2.2.

CONCLUSION & RECOMMENDATION

The current genetic engineering industry is based on intellectual property and patenting of GMO traits and it is promoting a highly technological agriculture based on monoculture. This has significant disadvantages. Inherent disadvantages of monoculture are a reduction in biodiversity and in food security. Moreover, it may lead to wealth concentration amongst farmers instead of wealth distribution. An important drawback is the dominance of companies owning the patents, selling the seeds, and the specific pesticides to go with a certain GMO crop. This situation may lead to dependence and disempowerment of farmers, since GMO seeds are expensive compared to conventional seeds, and a farmer is not allowed to save GMO seeds for next year's cultivation.

Due these issues and for public concerns about GMO, the European Union (EU) has implemented GMO legislation based on a cautious approach. Important elements of the legislation are, for instance, an approval procedure for bringing GMOs on the market or releasing them into the environment (i.e. commercial cultivation or field trials), on a case-by case basis, and with a compulsory risk assessment. In addition, labeling and traceability of products containing or consisting of GMOs is obligatory. Moreover, member states are allowed to install safeguard measures on a national level, thereby blocking GMOs that are approved at the EU level if sufficient concerns exist.

It is crucial to understand important terms used within the World Trade Organization (WTO) that are relevant for the GMO debate. Among them are 'like products', risk assessment, scientific evidence, uncertainty and insufficiency. Under like products it is sometimes argued that GMO- and non-GMO products are inherently similar, that is, they are similar as long as the end products have similar properties. This argument follows the reasoning that process and production methods may not be used as reasons to discriminate one product over another product. However, consumers, especially in the EU, generally consider GMO- and non-GMO products to be different.

Risk assessment is regulated in the most relevant agreement within the WTO with respect to GMOs, the agreement on Sanitary and Phytosanitary measures (SPS). This agreement concerns protective measures against pests, and it states that such measures must be based on a valid risk assessment and not cause undue delay, something that may be challenging for GMOs since the technology develops fast and new information may come up. The SPS agreement allows for temporary measures with a precautionary notion, as long as there is insufficient scientific evidence. This is a crucial aspect in the EC - Biotech case.

There are potential conflicts between trade agreements and the Convention on Biological Diversity (CBD), and more especially it's Cartagena Protocol on Biosafety, or Biosafety Protocol, both multilateral environmental agreements. Trade agreements and these environmental agreements are based on different premises. WTO agreements generally proclaim a reduction of trade barriers, also for GMOs, while the CBD proclaims the use of a precautionary approach. With regards to patenting, there are conflicting agreements as well.

The WTO's agreement on Trade-Related Intellectual Property Rights (TRIPs) is based more upon protection of intellectual property, while the Biosafety Protocol values traditional knowledge and sharing of benefits.

Recommendations

There is need to:

- Strengthen EU GMO legislation, taking a precautionary approach especially as long as long-term environmental or health effects are not known. Important issues are coexistence and liability;
- Demand a sustainability impact assessment of producers and importers of GMOs, where environmental, social and economic aspects are taken into account, both upstream (the producers or farmers) and downstream (the consumers);
- Have a capacity-building program for developing countries regulators and competent authorities, so that they can receive support if they desire to have a strict and arguably complicated and high-tech regulatory system;
- Support research on long-term environmental and health impacts of GMOs;
- Support research on how to minimize risks to the environment associated to GMOs, such as contamination, herbicide resistance, etc.;
- Respect and act upon the values behind the Convention on Biological Diversity, such as valuing biodiversity, traditional knowledge, sustainable development and public participation;
- Try to balance public interest and private intellectual property rights, and consider a form of public property rights, to be used for public benefit;
- Support research on pest management in organic farming;

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