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# Trade related environmental measures in the field of safety in biotechnology



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## United Nations Environment Programme

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## Foreword

The relationship between international trade, environmental protection and sustainable development represents one of the most important, complex and encouraging policy dialogues since the 1992 Rio Summit. There, governments, industry, NGOs and public citizens agreed that in order for sustainable development to move from a general policy goal to specific operational commitments, core economic and environmental policies need to be integrated. The intersection of international trade and environmental policies represents a compelling opportunity to ensure that economic growth and development options stemming from increased trade liberalisation, continue to act as a positive force towards environmental protection, and sustainable development.

The establishment of the World Trade Organisation (WTO) in early 1995 represents an historic coalition of national interests, moving towards a shared goal of an open, fair and non-discriminatory trading system. Similar evidence of international co-operation also continues in the environmental area. In late 1994, for example, the world community met to review, revise and strengthen the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), and the Convention on Biodiversity. In early 1995, governments met to review national plans related to climate change and global warming.

As the commitments of the Uruguay Round and the growing and constantly changing body of international environmental laws are implemented on the national level, the potential for conflict between these two bodies of international law may increase. Our goal is to make certain potential conflicts are identified well in advance, that effective preventative measures are defined, and workable solutions found. The record of the trade-environment debate clearly shows that the more both communities share perspectives and build confidence, the greater the potential that conflicts will diminish, and positive synergies between trade and environmental policies will take shape.

*Elizabeth Dowdeswell*
*Executive Director*

# Contents

# Introduction

With recent developments in biotechnology and to ensure that populations at large benefit from new technology, adequate and transparent safety requirements are being incorporated in various international instruments. The purpose of this paper is to illustrate how safety requirements in the field of biotechnology can sometimes take the form of trade measures when they create a restriction on trade to protect the environment and/or human health from the potential adverse effects of biotechnology products.

Trade related environmental measures have been applied in various multilateral environmental agreements (MEAs) to help achieve the environmental objectives of these agreements. The term "trade related environmental measures" (TREMs) refers to any measure aimed at protecting the environment, but which takes the form of a trade instrument. In other words, TREM is a restriction on international trade with the purpose of promoting an environmental objective. Annex I of this paper presents an overview of trade measures used for environmental purposes and the ways in which these measures have been classified.

Safety requirements taking the form of TREMs may interact with the GATT/WTO system which is based on the concept of trade liberalization. This paper intends to show how the two systems may interact and the extent to which the acceptability of biosafety requirements is guaranteed under GATT/WTO1[2]. Through this process, this paper aims at drawing attention to the issues related to the two disciplines in both the environmental and trade communities.

The first section of the paper introduces the issue of biotechnology and the need for safety in this field. An indicative list of safety requirements, such as transfer provisions, notification requirements, ban on transfer and eco-labelling is provided in the second section. As noted above, safety requirements may take the form of TREMs and might interact with the GATT/WTO system. In the final section, the paper provides, an overview of GATT/WTO core principles and relevant WTO Panel Reports through which this possible interaction is analyzed.

[2] This paper does not intend to interpret GATT/WTO rules, but rather to list core principles and analyse the possible interaction between those principles and requirements in the field of safety in biotechnology.

# 1

# Safety in Biotechnology

Several definitions of *biotechnology* have been provided in different fora , notably organisations or bodies such as Agenda 21, OECD, Convention on Biological Diversity. Article 2 of the Convention on Biological Diversity states that: "*Biotechnology* means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use".

Some bio-techniques have been used for many centuries to produce, for example, beer, wine, cheese, bread and other foods (Table 1). Biosafety issues considered in international instruments are related to modern biotechnology. There seems to be a general agreement[3] that modern biotechnology includes methods of genetic modification by recombinant DNA, as well as techniques which modify genes and genetic material in ways which do not occur naturally by mating or natural recombination.

**Table 1. Traditional processed foods using biotechnology**

| |
|---|
| Alcoholic beverages: beer; wine |
| Cheese |
| Bread |
| Vinegar |
| Yoghurt |
| Fruit and vegetable products |
| • Pickles |
| • Soya sauce |
| • Sauerkraut |
| By-products of fermentation |
| • Enzymes |
| • Flavours |
| • Additives |
| Dietary supplements |
| • Amino acids |

It is generally accepted that biotechnology can make a "significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, improved supplies of potable water, more efficient industrial development processes for transforming raw material, support for sustainable methods of deforestation, and detoxification of hazardous wastes" (Agenda 21).

[3] See, UNEP/CBD/COP/2/7. 1995. "Report of the Open-Ended Ad hoc Group of Experts on Biosafety".

However, the full benefits of this new technology will only be felt by the community at large when adequate safety measures are applied. That is what biosafety is concerned with. In this context, decisions are taken following a risk analysis process, which involves hazard identification, and where hazards have been identified, risk assessment (the scientific estimation of the likelihood and magnitude of threat), and risk management (the process concerned with how to deal with the risk).

Since 1970, experiments in the field of modern biology have led to the discovery of new techniques and considerable experience has now accumulated as to their application, particularly in the use of new genetic techniques in laboratories and in small-scale field trials both for agricultural and commercial purposes (Table 2).[4]

**Table 2. Examples of genetically modified crops**

| Product/food | Action/application |
|---|---|
| Apples | Insect resistance |
| Bananas | Integrated pest management of virus and fungi |
| Broccoli | Slow ripening for longer freshness |
| Celery/carrots | Crispness retention |
| Chicory | Increased availability of fructans |
| Coffee | Better flavour, higher yields and lower caffeine |
| Cole crops | Resistance to insect predators |
| Corn | Insect resistance |
| Cucurbita | Viral, fungal and bacterial resistance |
| "Euromelon" | Ripens on demand |
| Grapes | New seedless varieties |
| Lettuce | Smaller size and insect resistance |
| Potato | Resistance to several diseases |
| Rapeseed | Production of hard fats in the plant |
| Raspberries | Slower ripening through ethylene control |
| Soybean | Herbicide resistance |
| Strawberries | Frost resistance |
| Sunflower | Lower saturated fatty acid content |
| Tomatoes | Improve colour and flavour, retarded softening, resistance to viral diseases |
| Wheat | Herbicide resistance |

[4] These and other products are still largely at the research and development stage with few having yet reached the market.

In the past few years, a number of new products developed by means of new biotechnologies have passed through the necessary regulatory process and have been approved for commercial use.

**Table 3. Crop's varieties released on the US market**

| No. of varieties | Crops | Approved for release on the intl. market |
|---|---|---|
| 5 | Tomato | Approved by the EC |
| 4 | Cotton | |
| 1 | Soybean (Monsanto) | |
| 1 | Rapeseed | |
| 1 | Canola | |
| 2 | Squash | |
| 1 | Potato | |
| 5 | Corn | |

Most of these have been pharmaceuticals, new animal vaccines and animal growth hormones produced by recombinant DNA technology and a few plants with novel characteristics. Major commercial biotechnology products that will be introduced to markets within the next decade will include plant varieties bearing genes that will have increased resistance to insect or viruses (Table 3).[5]

Before products resulting from modern technology are released commercially, safety requirements have to be met and certain measures adopted.[6] The commercial release of products resulting from modern biotechnology involves not only domestic, but also international trade as these products will be subject to imports and exports. Therefore, safety procedures will have to be applied in order to meet safety requirements at an international level. The use of trade measures in biotechnology is closely related to, and a consequence of, safety concerns in biotechnology applications.

[5] Data contained in Table 3 are as of early 1996. The number of varieties is expected to increase.

[6] Regarding, for example, food safety requirements, process standards (see Annex I) are often used to protect food safety by regulating the process by which food is produced rather than regulating the condition of the final product.

# 2

# Identification of types of TREMS related to safety in biotechnology

As noted above, TREMs refers to measures that aim at protecting the environment, but which take the form of a trade instrument. TREMs can be variously classified as trade restrictions, standards, taxes and sanctions.[7] Amongst these categories, trade restrictions

[7] See Annex I.

and standards can apply to biosafety. An indicative list of safety requirements which might take the form of TREMs, without being exhaustive, could include:

- transfer provisions, in particular:
  a) packaging, labelling and handling requirements in case of transfer;
  b) notification requirements (together with or prior to an intended transfer, and in combination with advance informed agreement);
- eco-labelling;
- ban on transfer.

2.1. *Transfer provisions*

2.1.1 Packaging, labelling and handling requirements in case of transfer

The trade of organisms with novel traits implies their transport and transit. Environmental protection and human health and safety considerations must be safeguarded during this stage by means of packaging, labelling and handling requirements in line with the level of risk involved.

Existing recommendations and agreements regulate the international transport of dangerous goods. The United Nations Recommendations on the Transport of Dangerous Goods, based primarily on existing international and national regulations, consider under the section on infectious substances[8] risk groups of micro-organisms and genetically modified organisms that "are known or reasonably expected to cause infectious disease in animals or humans". According to the Recommendations, packaging requirements and communication of information should be respected and provided to "ensure that packages are

[8] UN Recommendations on the Transport of Dangerous Goods.1995, pp. 210-218.

prepared in such a manner that they arrive at their destination in good condition and present no hazard to persons or animals during transport".

Under the recommendations on consignment procedures[9], marking of packages and labels identifying risks are considered as "measures to be taken to ensure that the potential risks of the dangerous goods offered are adequately communicated to all who may come in contact with the goods in the course of the transport" and in storage. The inclusion of relevant information in transport documents is also considered in these recommendations.

The "European Agreement concerning the international carriage of dangerous goods by road" (ADR) contains the same definition of infectious substances as listed in the UN Recommendations, in which micro-organisms and genetically modified organisms are considered.[10] Packaging and labelling requirements are also included as part of the agreement.

The International Plant Protection Convention (IPPC) also contains provisions on transfer and transit. Article IV (iii) of the IPPC requires the disinfection of consignments of plants, and plant products moving in international trade, and their containers (including packaging material), storage places or transportation facilities of all kinds.

Existing national legislations also regulate the transport of some goods. For example, the USDA Federal Register rule on the deliberate release of genetic engineered organisms and products,[11] contains a section on "marking and identity" which states that "...any regulated article to be imported other than by mail, shall,

[9] UN Recommendations on the Transport of Dangerous Goods.1995, pp. 367-383.

[10] European Agreement concerning the international carriage of dangerous goods by road (ADR) and protocol of signature (adopted in Geneva on 30 September 1957). January 1995. Vol.1, pp.275-277.

[11] USDA Federal Register. June 16 1987. Vol. 52, No. 115.

at the time of importation into the United States, plainly and correctly bear on the outer container" information regarding the nature, origin and quantity of the contents as well as place of destination. A section on "container requirements for the movement of regulated articles" lists a series of packaging requirements necessary for the safe movement of such articles.

Packaging, labelling and handling are considered as components of the physical characteristics of a product, and are subsequently classified under product standards.[12]

2.1.2 Notification requirements

Notification requirements refer to import and export restrictions of a product. The supply of information by the exporting country related to a product's safety will determine whether any restrictions will be imposed. This will also include information on safety regulations in handling organisms that is required by the exporting country, as well as any available information on the potential adverse impact of the organisms concerned.[13]

[12] See Annex I.

[13] Notification requirements are considered, *inter alia*, in the Convention on Biological Diversity, the UNEP Technical Guidelines for Safety in Biotechnology, the FAO International Code of Conduct on the Distribution and Use of Pesticides (1990 amended version), the FAO Preliminary Draft International Code of Conduct on Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources, the FAO International Plant Protection Convention (IPPC) and the UNIDO Voluntary Code of Conduct for the Release of Organisms into the Environment. Notification requirements are also considered in international instruments not related to safety in biotechnology such as the London Guidelines, Basel Convention and CITES.

A country exporting organisms with novel traits has to comply with the safety regulations of the importing country.[14] As a number of countries have not yet fully implemented such regulations , it will be necessary to develop an information process that will not only include the simple exchange of information but also, in some cases, *prior informed consent*[15] or *advanced informed agreements*[16] procedures.

The principle of *prior informed consent* (PIC) has been defined in the London Guidelines as the "principle that international shipment of a chemical that is banned or severely restricted in order to protect human health or the environment should not proceed without the agreement, where such agreement exists, or contrary to the decision, of the designated national authority in the importing country".[17]

With regard to the case of transfer of specific categories of organisms with novel traits, some form of consent of the recieving country will be necessary to move the product across boundaries: this will be referred to as an advanced informed agreement (AIA). In this context, the UNEP International Technical Guidelines consider the possibility of having notification requirement prior to the transfer when the transferred organisms are subject to the release into the environment for research reasons or when placed on the market. The notification requirements according to the UNEP International Technical Guideline, can be provided together with a transfer when the organisms are intended to be user in containment and not placed on the market or rèceased into the environment.

[14] The UNEP Technical Guidelines for Safety in Biotechnology provide a possible mechanism for such notification requirements.

[15] See the London Guidelines and Convention on Biological Diversity (Article 15. 5).

[16] See Convention on Biological Diversity, Article 19 (3); and the UNEP Technical Guidelines for Safety in Biotechnology.

[17] UNEP London Guidelines, *infra*, para. 1 (g).

### 2.2. *Eco-labelling*

Eco-labelling refers to the labelling of products developed in a less environmentally damaging manner than competing products, as well as to the labelling on product characteristics. In this context, biotechnology products, if environmentally friendly, could be labelled in order to increase consumer awareness. Eco-labelling schemes refer to standards (Annex I).

The Codex Alimentarius Committee on Food Labelling met from 14 to 17 May 1996 in Ottawa, Canada, and considered the possibility of establishing guidelines on the labelling of biotechnology products. The Committee will meet again in April 1997 to examine the proposal on guidelines.

Existing eco-labelling schemes include: the "Blue Angel" in Germany; the European Union Eco-label Award Scheme[18]; the "Nordic Swan"; the "Environmental Choice" in Canada; the "Sello Ozono" in Chile; the Green Label in Singapore; and the "Dolphin Friendly Tuna" in the USA. These eco-labelling schemes are based on life-cycle analysis.

### 2.3. *Ban on transfer*

A ban on the introduction of a biotechnology product can be exercised by the importing country when the product is considered to be harmful to the environment and/or human health. Bans on transfer are a trade restriction. The fact that no bans on biotechnology products have, to date, been exercised by any country is probably explained by the burgeoning nature of this market.

The IPPC contains requirements on the prohibition of the importation of particular plants or plant products, or of particular

[18] Established by the Council Regulation (EEC) No. 880/92 of 23 March 1992 (Ref. No. L 99/1 of 11.4.92)

consignments of plants or plants products (Article VI, paragraph 1 (b). Article VI, paragraph 2 (b) also states that in the event that an import restriction has been imposed, they should immediately notify the FAO, as well as any regional plant protection organization, or any other concerned party, the contracting party is affiliated to.

# 3

# Interaction between TREMS for Safety in Biotechnology and GATT/WTO Rules

## 3.1 *GATT/WTO core principles*

The application of TREMs may lead to inconsistencies with GATT/WTO principles and specific agreements such as the Agreement on Technical Barriers to Trade (TBT) and the Agreement on Sanitary and Phytosanitary Measures (SPS). To better understand the interaction between TREMS and GATT/WTO,

it is worthwhile to introduce the three core principles[19] on which the GATT/WTO is based on:

i) the Most Favoured Nation (MFN) obligation, (Article I);
ii) the National Treatment obligation, (Article III); and
iii) the prohibition on quantitative measures, (Article XI).

Article I requires a GATT/WTO member to extend immediately and unconditionally any advantages or privileges it provides to a product, to like products imported from, or destined for, all other contracting parties. An important provision of the MFN is that any advantage granted by any GATT contracting Party to any other country *must* be granted to all other contracting Parties. Thus, advantages granted by a contracting Party to a non-Party must also be granted to all Parties. Such a principle is aimed at averting any cases of favoritism amongst GATT/WTO trading partners.

Article III covers the national treatment obligation requiring GATT/WTO contracting parties to treat foreign products no less favorably than like domestic products. While the MFN requires that all foreign goods should be given equal treatment, national treatment ensures that there is no discrimination or differentiation in the treatment of imported versus domestic products.

The third GATT/WTO core principle is enshrined in Article XI which calls for the general elimination of quantitative restrictions (e.g., quotas or embargoes). This Article generally bans the use of prohibitions or restrictions, both on exports and on imports.

Considerable discussion has taken place with respect to the term *like or similar products,* introduced in Article I and contained in a number of other GATT articles. Many Panel reports have addressed the complex concept of *like product* used as a means to classify and describe similar products. The 1970 Working Party

[19] See Annex II.

Report on "Border Tax Adjustment", recommended that each problem arising from the interpretation of the term *like product* should be examined on a case-by-case basis, following suggested criteria such as: the product's end-use in a given market; consumers' tastes and habits, which vary from country to country; the product's properties; and its nature and quality.[20] Regulatory distinctions, the Working Party Report stated, need to relate to the physical characteristics of the product.

In subsequent Panel decisions [21] it was noted that contracting parties had still not elaborated a general definition of the term *like product* and that past decisions on this question had been made on a case-by-case basis after examining relevant criteria such as the ones mentioned above. This was reiterated in the 1992 Panel Report on "United States - Measures Affecting Alcoholic and Malt Beverages"which examined the excise tax exemption accorded by the state of Mississippi to wine made from scuppernong grapes.

The Panel noted that, in determining whether two products subject to different treatment are like products, it is necessary to consider whether such product differentiation is made *so as to afford protection to a domestic product*. This second test of the likeness of products was picked up in the "Auto taxes Panel Report" which reasoned that "issues of likeness [under Article III] should be analyzed primarily in terms of whether less favourable treatment was based on a regulatory distinction taken so as to afford protection to domestic production". However, in the same Report, the Panel noted that the regulatory distinction

[20] See L/3464, adopted on 2 December 1970, 18S/97, 102, para. 18.

[21] It is important to note that under GATT/WTO Panels, decisions do not constitute *stare decisis*, this means that future Panels are free to conduct their own line of analysis. Even though GATT Panels have generally applied and followed the jurisprudence of previous panels in reaching their decisions, some Panels (e.g. Tuna/Dolphin II) have refused to follow the same jurisprudence as previous Panels (e.g. Tuna/Dolphin I)

should be related to the product, thereby narrowing the breadth of this alternative *like product* analysis.

3.2. *GATT/WTO Article XX*

Measures violating one of the abovementioned obligations can be justified by the exceptions under Article XX. The preamble of Article XX states that measures taken under this article may not operate in a manner that "would constitute a means of arbitrary or unjustifiable discrimination between countries where the same condition prevail, or a disguised restriction on international trade". The preamble was primarily inserted into this article as a response to the concern that such exceptions could be misused for indirect protection, and as a prevention of "abuse of the exceptions of Article XX". [22]

With regard to the interpretation of the preamble of Article XX, the 1982 Panel Report on "United States - Prohibition of Imports of Tuna and Tuna Products from Canada" noted that prohibition of imports of tuna and tuna products had not been taken exclusively against Canada, but similar actions had been taken against imports from Costa Rica, Ecuador, Mexico and Peru for similar reasons. Therefore "the Panel felt that the discrimination of Canada in this case might not necessarily have been arbitrary or unjustifiable...". The same Panel felt that the United States action should not be considered to be a *disguised restriction on international trade* because it was taken as a trade measure and publicly announced as such. Canada reacted, in discussions on this report at the 1982 Council meeting, by underlining that it was not sufficient "for a trade measure to be publicly announced as such for it to be considered not to be a disguised restriction on international trade" within Article XX.

A subsequent Panel[23] noted that "the Preamble of Article XX

[22] See WTO. 1995. Analytical Index, Guide to GATT Law and Principle". Vol.1, pg. 563-564.

[23] The 1983 Panel Report on "United States - Imports of Certain Automotive Spring Assemblies".

made it clear that it was the application of the measure and not the measure itself that needed to be examined" to understand whether the measure constituted a disguised restriction. Therefore, a measure might, at first sight, appear discriminatory and not run afoul of the Article XX preamble because it has been fairly applied or viceversa.

The preamble of Article XX has also been one of the issues considered by the Appellate Body to the 1996 WTO Panel Decisions on the U.S. Clean Air Act Regulations[24]. The Appellate Body reiterated that the purpose of Article XX is the prevention of "abuse of the exception of Article XX", as noted above. In this context, it was also recognized that the exceptions of Article XX should not be abused or misused, and "the measures falling under these exceptions must be applied reasonably, with due regard both to the legal duties of the party claiming the exception and the legal rights of the other parties concerned".[25]

Among the ten paragraphs in Article XX, paragraphs (b) and (g) represent the 'environmental exceptions'. Under Article XX (b), a GATT/WTO contracting party may take trade measures that are *necessary* to protect human, animal, plant life, or health. Furthermore, Article XX (g) states that a party may take trade measures that are related to "the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption".

The meaning of the word *necessary* is not specified in the GATT/WTO text. While the GATT preparatory history suggests

[24] The Clean Air Act Amendment of 1990, directed the U.S. Environmental Protection Agency to promulgate new regulations to reduce vehicle emissions from gasoline. In December 1993, the EPA finalized a rule linked to baseline emissions level in existence during 1990. The dispute at WTO, subsequent to a complaint by Venezuela and Brazil, concerns the determination of the baseline.

[25] WT/DS2/AB/R, pg.22.

that the term *necessary* was presumed to be science-based,[25] its interpretation has been, in a certain sense, clarified by some panel decisions. For example, the 1992 Panel Report on "Thailand - Restriction on Importation of and Internal Taxes on Cigarettes" examined measures taken by Thailand to prohibit cigarette imports . The panel concluded that a measure "could be considered to be *necessary* in terms of Article XX (b) only if there were no alternative measures consistent with the General Agreement, or less inconsistent with it, which Thailand could reasonably be expected to apply to achieve its health policy objectives". In order for a measure to qualify, the Panel Report mentions that the enacting party should reasonably be expected to apply a measure that is the least inconsistent with GATT principles and panel rulings.

It is interesting to note, in this context, the Tuna\Dolphin I and II Panels definition of the term "necessary". Both Panels have raised additional jurisdictional barriers to a party successfully relying upon Article XX (b) and (g). The first decision held that the environmental exceptions can be advanced only on behalf of measures operating within the jurisdiction of the party taking the measures and when the party taking a measure had exhausted other options which are less inconsistent with GATT principles and panel rulings. The Tuna\Dolphin II Panel revisited the question of whether measures taken to protect the environment outside a country's territorial jurisdiction were acceptable. The Panel determined that a measure that aims to change the policies of other countries, acting within their own jurisdiction, and that would achieve its intended effect only if it were followed by such changes, would "seriously impair the objective of the GATT"

[25] See "Second Session of the Preparatory Committee of the United Nations Conference on trade and Employment, UN Docs E/PC/T/A/PV/30 (1984); Third Committee : Commercial Policy, Summary Record of the Thirty-fifth Meeting, UN Conference on trade and Employment, UN Doc. E/Conf.2/C.3/SR.35 (1984).

shouldd neither be considered "necessary" as required by Article XX (b) exception, nor "primarily aimed at" legitimate conservation goals as required by Article XX (g).

Under Article XX (g), as mentioned above, a party may take trade measures that are related to " the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption". The 1988 Panel Report on "Canada - Measures Affecting Exports of Unprocessed Herring and Salmon"[27] concluded that while a trade measure did not have to be necessary or essential to the conservation of an exhaustible natural resource, it had to be "primarily aimed at" the conservation of an exhaustible natural resource to be considered as 'relating to' conservation within the meaning of Article XX (g). This view was also used by the Appellate Body to the 1996 WTO Panel Decisions on the U.S. Clean Air Act Regulations, because in the appeal, no party had called into question the lower panel's reliance on the term "primarily aimed at". However, the Appellate Body did note that the phrase "primarely aimed at" is not itself treaty language and was not designed as a simple litmus test for inclusion or exclusion from Article XX.

Further, the Appellate Body noted that Article XX (g) needs to be read in context, and in such a manner as to give effect to the purposes and objects of the General Agreement along the lines of a fundamental rule of treaty interpretation contained in

[27] The Panel examined the issue whether export prohibitions of certain unprocessed salmon and unprocessed herring, conceded to be contrary to Article XI:1 of the General Agreement, were or were not justified by, *inter alia*, Article XX (g).

[28] In seeking to clarify the provisions of the General Agreement, the Appellate Body has applied the "general rule of interpretation". This reflects a measure of recognition that the General Agreement is not to be read in isolation from public international law.

the Vienna Convention on the Law of the Treaties [28] (Article 31, *General Rule of interpretation)* [29].

The Herring and Salmon Panel similarly considered that the terms 'in conjunction with' in Article XX (g) had to be interpreted in a way that ensures that the scope of possible actions under that provision would correspond to the purpose for which it was included in the General Agreement. A trade measure could therefore, in the view of the Panel, only be considered to be made effective "in conjunction with" production restrictions if it was primarily aimed at rendering these restrictions effective".

In this context, the Appellate Body to the 1996 WTO Panel Decision on the U.S. Clean Air Act Regulations did not believe that the clause "if made effective in conjunction with restrictions on domestic production or consumption" was intended to establish an empirical "effects test" for the availability of the Article XX (g) exception. The Appellate Body saw that difficulties existed in determining causation and that the conservation of exhaustible natural resources implied that a substantial period of time may elapse before the effects of a given measure can be observed. This represents a shift in the interpretation of Article XX (g) which had required that Parties demonstrate the actual effectiveness of measures in order to qualify them for paragraph (g) protection.

### 3.3 *Biosafety regulations and the GATT/WTO system*

To date, biosafety regulations have not been challenged under GATT\WTO. The acceptability, in principle, of biosafety regulations grounded on scientific evidence should be guaranteed under Article XX, including conformity with the headnote to Article XX and provisions in Article XX (b) which allows measures

[29] Art. 31 "General rule of interpretation" states that: *A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.*

taken for the protection of "human, animal, or plant life, or health". The acceptability of biosafety regulations should also be guaranteed under the "Agreement on the Application of Sanitary and Phytosanitary Measures" (SPS)[30]. However, Article 2 paragraph 2 of the SPS Agreement states that these protection measures have to be based on scientific principles and not maintained without sufficient scientific evidence, except as provided in paragraph 7 of Article 5. This paragraph on "Assessment of Risk and Determination of the Appropriate Level of Sanitary and Phytosanitary Protection", states that "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 measures accordingly within a reasonable period of time."

Therefore, the SPS Agreement "clearly permits the precautionary taking of measures when a government considers that sufficient scientific evidence does not exist to permit a final decision on the safety of a product or process. This also permits immediate measures to be taken in emergency situations"[31]. This is all about the precautionary principle which is a basic principle for environmental law and policy. The core of the principle is reflected in Principle 15 of the Rio Declaration, which provides that: "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for

[30] Annex III to this paper provides the definitions of sanitary and phytosanitary measures as stated in the WTO SPS Agreement.

[31] See WTO, 1996. Understanding the World Trade Organization Agreement on Sanitary and Phytosanitary Measures, Pg.10.

postponing cost-effective measures to prevent environmental degradation".

Nevertheless, it is important to bear in mind that the SPS Agreement allows countries to determine their own level of acceptable risk (addressing: "national concerns regarding what are necessary health precautions"). As countries may not assess and handle risks in the same way, the interpretation, in Article 5.7, of the terms "insufficient" scientific evidence and "reasonable" period of time may not allow for sufficient legal certainty.

Both the SPS and the TBT Agreements encourage governments to harmonize or base their national measures on international standards, guidelines or recommendations, such as, for example, those of the FAO/WHO Codex Alimentarius Commission (for food safety), the International Office of Epizootics (for animal health) and the FAO International Plant Protection Convention (for plant health). Under the SPS Agreement, harmonization is considered as the "establishment, recognition and application of common sanitary and phytosanitary measures by different Members". Those measures should be based, according to Article 3 paragraph 1, on "international standards, guidelines, or recommendations". Biosafety requirements, as contained in a protocol or guidelines, should provide such standards, guidelines or recommendations and can therefore be considered as non-protectionist if challenged in the WTO.

It is sometimes difficult for some countries to implement international standards at the national level, but the SPS Agreement explicitly allows governments to choose not to use the international standards. However, if the national requirement results in a greater restriction of trade, a country may be asked to provide scientific justification, demonstrating that the relevant international standard would not result in the level of health protection considered appropriate for the country [32]. In addition,

[32] Ibid. Pg 4, See also Article 3 (3) of the SPS Agreement.

Article 5.5 of the TBT Agreement states that to harmonize conformity assessment procedures, Members shall actively participate "in the preparation by appropriate international standardizing bodies of guides and recommendations for conformity assessment procedures".

The SPS Agreement "allows countries to give food safety, animal or plant health priority over trade, provided there is a demonstrable scientific basis for their food safety and health requirement". Nevertheless, Article 5.4 requires that WTO Members "take into account the objective of minimizing negative trade effects" when determining the appropriate level of protection. Furthemore, Article 5.6 states that the SPS measures established to achieve the appropriate level of protection should not be "more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection" if these measures are technically and economically feasible. The footnote to Article 5.6 specifies that "a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade".

In the case of a trade dispute, the WTO's dispute settlement procedures allows governments, who may be unable to reach a mutually acceptable bilateral solution, to choose to follow either any of the means of dispute settlement or to request that an impartial Panel of trade experts be established and make recommendations. The Panel dealing with a dispute on SPS measures can seek scientific advice.

During the first fourteen months[33] of the SPS Agreement, six complaints were formally lodged at the Dispute Settlement Body (DSB). The complaints have involved issues such as inspection

[33] The SPS Agreement entered into force with the establishment of the WTO on 1 January 1995.

procedures, animal diseases, disinfection treatments for beverages and the use of veterinary drugs in animal rearing. None of these complaints involve multilateral measures.

3.4. *Packaging, marking and labelling requirements*

Packaging, marking and labelling requirements which may be part of an international instrument on safety in biotechnology, as mentioned in sub-section 2.1.1. above, could be construed as technical barriers to trade under the TBT Agreement. Under the TBT Agreement, countries are allowed to establish standards, technical regulations or procedures for conformity assessment. Such standards must be non-discriminatory for imports; should not create unnecessary trade barriers ; and should "not be more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfilment would create"[34]. Among such legitimate objectives are also the "protection of human health or safety, animal or plant life or health, or the environment. The TBT Agreement encourages Parties to harmonize standards and to adopt international standards, based on transparent provisions.

In assessing such risks, relevant elements of consideration are, *inter alia,* available scientific and technical information, related processing technology or intended end-uses of products" (TBT Agreement, Article 2.2.) are also included as legitimate objectives. Some packaging and labelling requirements, if directly related to the safety of food, are also subject to the SPS Agreement.

3.5. *Notification requirements*

Notification requirements, described in sub-section 2.1.2. above, can be incompatible with both GATT/WTO Articles III and XI, respectively on the national treatment and on quantitative restrictions. Such incompatibility would be justified under GATT/

[34] See WTO Agreement on Technical Barriers to Trade, Article 2.

WTO Article XX (b) or (g). The dangers posed by the unrestricted introduction of biotechnology products would place notification requirements within the scope of the "environmental exceptions" of Article XX. If these requirements are not only directly aimed at preventing environmental damage, but are also taken pursuant to an international instrument, they should pass, in the event of a Panel dispute within the WTO, the "necessary" test of paragraph (b) and the "primarily aimed at" test of paragraph (g).

### 3.6. *Eco-labelling*

Eco-labelling constitutes a way to provide accurate information to consumers about the ecological impact of production, thus enabling concerned consumers to exercise their existing preferences in an informed way. Eco-labelling schemes could be a tool to guide consumer preference towards environmentally friendly products. A shift in consumer choice could be a consequence of such schemes with potential effects on international trade and market access.

The eco-labelling issue is still under discussion within the WTO Committee on Trade and Environment. The debate focuses on whether eco-labels should be based exclusively on product characteristics or include non-product related criteria (which may involve production processes of non-product related criteria). This is one of the most complex issues in discussion relating to trade and eco-labelling schemes, most of which place emphasis on the coverage under the TBT and full life-cycle analyses. Consensus on this issue has not been reached in the WTO Committee on Trade and Environment. Approaches on this item may be articulated in the December 1996 Ministerial report.

### 3.7. *Ban on transfer*

As noted above in paragraph 2.3., a country may ban the import of a biotechnology product when it is considered harmful

to the environment and/or human health. A ban on biotechnology products probably does not constitute a violation of the WTO rules, provided that the ban applies to domestic production, as well as to all trading partners. Bans can also be justified under both under Article XX (b), where there are not any other least GATT/WTO inconsistent measures, and under the SPS Agreement which does not affect a sovereign decision to ban the production, sale and import of products based on the scientific evidence that they pose unacceptable risks to human, animal or plant health. Under the SPS Agreement countries can decide on their acceptable level of risks. Of course, it is conceivable that alternative measures, not more trade restrictive than required, might exist (e.g. treatment, quarantine or increased inspection), and could be used to achieve the same level of protection to the same degree of certainty. When these alternative measures are put into place, according to the SPS Agreement, they may limit a country's discretion to impose a ban, as it would not, in this case, pass the *least GATT inconsistent test.*[35]

[35] WTO. 1996. Understanding the World Trade Organization Agreement on Sanitary and Phytosanitary Measures, p.10.

# 4

# Conclusion

The trade implications of some safety requirements in the field of biotechnology has not yet been explored. Further analysis of this issue could help enhance awareness, improve experience and assist countries, especially developing countries, in strengthening their capacities for access to, acquisition and transfer of, biotechnology and biotechnology products.

To date, biosafety regulations, as multilateral measures, have not been challenged under GATT/WTO. The acceptability, in principle, of scientifically-based regulations should be guaranteed under Article XX, under the SPS and the TBT Agreements. No formal disputes have arisen between an MEA and the WTO. Therefore, the WTO has no position regarding the WTO-consistency of MEA-related trade measures. In this context, item one of the WTO CTE Agenda, "trade measures taken pursuant to MEAs", is quite relevant. Solutions and approaches on this item could be broached in the Ministerial Report presented at the WTO Ministerial Conference held in Singapore in December 1996.

Making environment and trade mutually supportive is one of the stepping stones towards sustainable development. Exchange of information, further analysis and transparency in trade related environmental issues are important components of this process.

# Annex I

**Trade related environmental measures (TREMs)**

The term "trade related environmental measures" (TREMs) refers to any measure whose justification is primarily the protection of the environment, but which takes the form of a trade instrument. TREM is a restriction on international trade with the purpose of promoting an environmental objective [36].

[36] Steve Charnovitz. 1993. "A taxonomy of Environmental Measures". Georgetown International Environmental Law Review.

TREMs can be classified as: trade restrictions, standards, taxes or sanctions. While standards and taxes represent laws regulating internal commerce and also applying to imports, trade restrictions and sanctions regulate only international commerce.

- Trade restrictions can be identified as types of quantitative export and import restrictions. An example of an export restriction is a ban on the export of hazardous wastes. An import restriction can be a ban on the import of a harmful product.
- Sanctions may be used to punish another country for environmental reasons. There is usually no relationship between the product restricted as a result of a sanction and an environmental goal. For example, country A may decide to restrict the import of wine from country B (which is possibly an important wine exporter to A) because B is slaughtering too many seals.
- There are numerous standards applied on both a national and international level. They can be applied to determine acceptable quality of air, fresh water management, etc. International standards can be administered either within a Multilateral Environmental Agreement (MEA) or a Codex. For example, standards on milk products are considered under the Codex Alimentarius.[37]
- Energy taxes, e.g., a higher tax rate on leaded fuels are examples of taxes with an environmental purpose.

It is also important to distinguish between TREMs based on product standards which focus on issues such as consumption, and those based on process standards which deal with production issues. Product standards relate to tangible factors such as size,

[37] A joint FAO/WHO Expert Consultation on the Food Safety Aspects of Biotechnology was held in Rome from 30 September to 4 October 1996.

design (both related to physical characteristics of a product), and safety in use. These characteristics should be verifiable by inspection. For example, a law setting a minimum size for marketable bananas would be a product standard.

On the other hand, a process standard reflects the way in which the product is manufactured, harvested and extracted. Contrary to what applies to product standards, which relate to testable and/or observable characteristics of the product, process standards relate to production aspects and are, in some cases, impossible to verify through inspection. These standards are referred to as non-product related PPMs (Process and Production Methods). In some cases, it may be possible to verify a process standard through inspection of the product in trade, even if differences are not detectable, by using documents certifying that a specific process was used.

Another important reference to be made is to the issue of trade measures taken "pursuant to" environmental agreements, these would include any measure taken unilaterally by a sovereign state to apply the agreement, but which are not explicitly stated in the MEAs. For example, several Members began to use labelling schemes following the implementation of the Montreal Protocol, in spite of the fact that labelling schemes are not identified any where in the protocol itself.

Concern has been expressed on an aspect of TREMs relating to trade restrictions which are not subject to mutual agreements: for example, measures affecting non-Parties to an MEA. Some Agreements, e.g. the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), the Basel Convention and the Montreal Protocol, prohibit trade in particular products between Parties and non-Parties. There might be exceptions to this when, for example, trade is permitted with non-Parties that conform with the substantive obligations of the MEA. This process has led to the strengthening of monitoring and compliance mechanisms within the agreements.

Both trade measures taken in line with environmental agreements and measures affecting non-Parties to an MEA are two of the Agenda items currently under discussion within the WTO Committee on Trade and Environment.

Out of a total of approximately 180 multilateral environmental agreements (MEAs), 18 (see Annex IV) have been identified as containing trade measures. While noting that there has not been any new post-1991 MEA explicitly containing trade measures, it is important to recognize that several key MEAs have reiterated, strengthened or adopted new TREMs since the UNCED in 1992. Although several other more recent MEAs do not contain explicit trade measures, they may in the near future employ TREMs as well.

Trade measures have, so far, addressed the three following types of environmental objectives[38] :

- Agreements to protect wildlife, which usually make use of import or export restrictions between Parties (e.g. 1973 CITES, Articles. III, IV and V), or between non-Parties (e.g. 1973 CITES, Article X) and which are often based on a permit process, as well as on a transit through Parties' territory (e.g. 1940 Western Hemisphere Convention, Article IX).
- Agreements to protect the environment of the importing state from harmful organisms and products, which have generally been concerned with plant pests, hazardous waste or pesticides. These agreements rely primarily on import restrictions[39] although export restrictions have been also used. Restrictions on exports and imports either imply a

[38] Philippe Sands. 1995. Principles of international environmental law. Vol. I. Manchester University Press.

[39] 1951 International Plant Protection Convention, Art. I; 1954 African Phyto-Sanitary Convention, Preamble; 1956 Plant Protection Agreement for the South East Asia Pacific Region, Preamble; 1976 North American Plant Protection Agreement.

complete ban[40], or make imports conditional on the granting of a permit[41] or the prior informed consent of the relevant authorities of the importing state[42], or a combination of techniques. And

- Agreements to protect the global commons (e.g. the Montreal Protocol).

[40] 1989 Lome' Convention, Art. 39; 1991 Bamako Convention, Art. 4; 1956 Plant Protection Agreement for the South East Asia and Pacific Region, Art. IV and Appendix B.

[41] UNEP. 1989. Basle Convention, Art. 4(1); FAO. 1951 International Plant Protection Convention, Art. VI(1).

[42] UNEP. 1989. London Guidelines and 1985 FAO Pesticides Guidelines.

# Annex II

**GATT/WTO core principles**

Article I

*Most Favoured Nation*

"With respect to customs duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports, and with respect to the method of levying such duties and charges, and with respect to all rules and formalities in connection with

importation and exportation, and with respect to all matters referred to in paragraph 2 and 4 of Article III, any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties."

Article III

*National Treatment*

"The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use..."

Article XI

*Quantitative Restrictions*

"No prohibition or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licenses or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party."

Article XX

*General Exceptions*

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 disguised restriction on international trade,

nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

("environmental exceptions")

(b) necessary to protect human, animal or plant life or health;
(g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption;"

# Annex III

*Sanitary and Phytosanitary measures*[43] - Any measures applied:

(a) to protect animal or plant life or health within the territory of the Member from the risks arising from the entry establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

[1] The results of the Uruguay Round of multilateral trade negotiations. The legal text. 1994. Agreement on the Application of Sanitary and Phytosanitary Measures. Annex A. p. 78.

(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or Phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packing and labelling requirements directly related to food safety.

# Annex IV

**Multilateral Environmental Agreements with trade provisions**

1. Convention Relative to the Preservation of Fauna and Flora in their Natural State, 1933.
2. Convention on Nature Protection and Wildlife Preservation in the Western Hemisphere, 1940.
3. International Convention for the Protection of Birds, 1950.
4. International Plant Protection Agreement, 1951.

5. Plant Protection Agreement for the South East Asia and Pacific Region, 1956.
6. Convention on the Conservation of North Pacific Fur Seals, 1957.
7. Agreement Concerning the Cooperation in the Quarantine of Plants and their Protection against Pests and Diseases, 1959.
8. Phyto-sanitary Convention for Africa, 1967.
9. African Convention on the Conservation of Nature and Natural Resource, 1968.
10. European Convention for the Protection of Animals during International Transport, 1968.
11. Benelux Convention on the Hunting and Protection of Birds, 1970.
12. Convention on International Trade in Endangered Species of Wild Fauna and Flora, 1973.
13. Agreement on the Conservation of Polar Bears, 1973.
14. Convention for the Conservation and Management of the Vicuna, 1980.
15. ASEAN Agreement on the Conservation of Nature and Natural Resources, 1985.
16. Montreal Protocol on Substances that Deplete the Ozone Layer, 1987.
17. Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, 1989.
18. London Guidelines for the Exchange of Information on Chemicals in International Trade, Amended 1989.

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