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A Re-Assessment of Article XX, Paragraphs (b) and (g), of GATT 1994 in the Light of Growing Consumer and Environmental Concern about Biotechnology

Philip Bentley Q.C.*

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Abstract

This Essay will seek to explain EU regulatory practice in relation to new technologies, principally GMOs, and to show that the EU should be able to find an approach that meets public concerns while remaining consistent with Article XX, paragraphs (b) and (g). This Essay will also identify those areas where Article XX, in its present form, it likely to be a source of justified public concern.

A RE-ASSESSMENT OF ARTICLE XX, PARAGRAPHS (b) AND (g) OF GATT 1994 IN THE LIGHT OF GROWING CONSUMER AND ENVIRONMENTAL CONCERN ABOUT BIOTECHNOLOGY

*Philip Bentley Q.C.**

INTRODUCTION

Article XX(b) of GATT 1994[1] recognizes that WTO Member Countries ("Member Countries") may adopt measures *necessary* to protect human, animal, or plant life or health while Article XX(g) recognizes that Member Countries may impose measures relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption. Paragraph (g) is important because, in the light of the Appellate Body's Report in the *Shrimp/Turtle* dispute,[2] sea turtles can constitute an exhaustible natural resource.[3] This approach is potentially extendible to other animal species, insects, and even plants. Both paragraph (b) and paragraph (g) are subject to the proviso set out in the chapeau to Article XX, namely that the measures must not constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade. The scope of these exceptions is narrow, and this narrowness has been experienced recently by the EU in the *EU Measures Concern-*

* Stanbrook & Hooper, Brussels, Belgium.

1. General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 1, 33 I.L.M. 1144 (1994) [hereinafter WTO Agreement], Annex 1A, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 27, 33 I.L.M. 1125 (1994).

2. *United States—Import Prohibitions of Certain Shrimps and Shrimp Products*, Report of the Panel, WT/DS58/R/Corr.1 (May 15, 1998). For a criticism of the Appellate Body's extensive interpretation of Article XX(g), see Wisam Abboud, *The WTO's Committee on Trade and Environment: Reconciling GATT 1994 with Unilateral Trade-Related Environmental Measures*, EUR. ENVTL. L. REV. 147 (2000).

3. Although the Appellate Body found that the U.S. measures were applied in a manner that created arbitrary and unjustifiable discrimination among Member Countries.

ing Meat and Meat Products (Hormones)[4] (*"Beef Hormones Case"*). The EU could be heading for a similar experience in relation to genetically modified organisms ("GMOs"). Issues such as hormones in beef, GMOs in food and BSE in cows fuel the debate between consumer and environmental organizations on the one hand and the proponents of free trade on the other. This debate arises out of a growing conflict between scientific objectivity and consumer mistrust of both scientists and politicians.[5]

Added to this is the question of the "ethical" choice of lifestyle. Movements in favour of macrobiotic or "green" farming have been premised on the argument that if food can be produced without spraying the environment with pesticides, herbicides, fungicides, or synthetic fertilizer, and without injecting animals with hormones, then in a rich civilized society we should refrain from such practices. These idealistic arguments do not always focus on the economic cost involved. For example, at the beginning of the century an average household might spend up to 80% of its budget on food, whereas today the proportion is only 15%. The relative reduction in the cost of food has been paid for by adopting production practices that are now called into question by sections of the population.

As a result of macrobiotic, "organically grown" and "green" movements, there exist food chains, and sections of supermarkets that deal exclusively in food produced under supervision by private certification bodies. Thus the consumer has the free choice of purchasing "standard" food or of possibly paying a higher price in order to obtain food that is certified as having

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4. *See EU Measures Concerning Meat and Meat Products (Hormones)—Complaint by the United States*, Report of the Panel, WT/DS26/R/USA (Aug. 18, 1997); *EU Measures Concerning Meat and Meat Products (Hormones)—Complaint by Canada*, Report of the Panel, WT/DS48/R/CAN (Aug. 18, 1997). All references in this Essay will be to *EC Measures Concerning Meat and Meat Products (Hormones)-AB-1997-4*, Report of the Appellate Body, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 5, 1998) [hereinafter *Beef Hormones Case*].

5. The recent report of Lord Phillips of Worth Matravers, to the British Minister of Agriculture, on the measures taken to protect the public from Creutzfeld-Jakob disease, a human version of bovine spongiform encephalitis ("BSE") transmitted to humans through consumption of meat from infected animals, found that the UK Ministry of Agriculture and Fisheries did not lean in favour of agricultural producers to the detriment of the consumer, and that the Government did not lie to the public about BSE. Nevertheless there were certain shortcomings and delays in turning policy into practice, and these have left an unfavourable image in the eyes of the British public. *See* UK MINISTRY OF AGRICULTURE, FISHERIES AND FOOD, THE BSE INQUIRY: THE REPORT (Oct. 2000), *available at* http://62.189.42.105/report.

been produced in accordance with particular "green" standards. This is a matter of free choice in a liberal society. It is also a matter of economics as food producers have realized the marketing potential in being able to offer a "green" or "organically grown" line of produce. Such freedom of choice is the driving force of the global economy in the 21st century. Member Countries have the freedom to sell their produce in all other WTO members' markets provided they comply with the requirements of the importing country justified by Article XX of GATT 1994, and especially those that are necessary to protect human, animal, or plant life or health. In certain circumstances, regulations requiring labeling of contents can be justified under this heading. A reasonable non-discriminatory labeling requirement preserves both freedom of trade and freedom of consumer choice.

The matter becomes more difficult when dealing with products that can be considered safe provided that they are used correctly, as in the case of the administration of hormones to beef cattle. It is even more difficult when there is no possibility of misuse and there is no scientific evidence that the consumption of the product may involve a risk to health, as is the case for *certain* GMOs. Looking into the future, the issue with some biotechnologies will not be so much a question of human health, but of respect for the ethical and moral positions taken by sections of the population.

Clearly, this is an area ripe for conflict in the WTO-free trade arena. "Green" and "organic" farming are becoming issues of international trade politics. It is a question of reconciling avowed support for free trade, and all the economic benefits that flow therefrom, with the domestic necessity of reassuring the public that all precautions are being taken so as not to subject them or the environment to any risk. In so doing, consumers will be given the choice if they do not want to consume or use certain types of products for ethical reasons.

This Essay will seek to explain EU regulatory practice in relation to new technologies, principally GMOs, and to show that the EU should be able to find an approach that meets public concerns while remaining consistent with Article XX, paragraphs (b) and (g). This Essay will also identify those areas where Article XX, in its present form, it likely to be a source of justified public concern.

I. *RECENT AMENDMENTS OF THE EC TREATY TO MEET CONSUMER AND ENVIRONMENTAL CONCERNS*

The EU Member States have played to consumer concerns by incorporating high-sounding principles into the founding treaty of the EU, the Treaty of Rome setting up the European Economic Community.[6] In 1993 the EC Treaty was amended by the Treaty of Maastricht to embody the objectives of "a high level of human health,"[7] "a high level of consumer protection,"[8] and "a high level of protection [of the environment]."[9] These principles were modified, effective May 1, 1999, by the Treaty of Amsterdam. The principles of "a high level of human health," a "high level of consumer protection" and a "high level of protection [of the environment]" are maintained, but the new wording shows an evolution in policy. Whereas under the amendments made by the Maastricht Treaty the emphasis was on the Community encouraging co-operation among the Member States; the new approach under the amendments made by the Amsterdam Treaty is to make human health, consumer protection, and the protection of the environment the primary objectives of Community action.[10] Of the three dispositions, Article 174(2) EC is significant because it states:

> Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall

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6. Treaty Establishing the European Community, Feb. 7, 1992, O.J. C 224/1 (1992), [1992] 1 C.M.L.R. 573 [hereinafter EC Treaty], *incorporating changes made by* Treaty on European Union, Feb. 7, 1992, O.J. C. 224/1 (1992), [1992] 1 C.M.L.R. 719 [hereinafter TEU]. The Treaty on European Union ("TEU") amended the Treaty establishing the European Economic Community, Mar. 25, 1957, 298 U.N.T.S. 11 [hereinafter EEC Treaty], *as amended by* Single European Act, O.J. L. 169/1 (1987), [1987] 2 C.M.L.R.741 [hereinafter SEA]. The Treaty establishing the European Community ("EC Treaty") was amended by the Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts, Oct. 2, 1997, O.J. C 340/1(1997) [hereinafter Treaty of Amsterdam]. These amendments were incorporated into the EC Treaty, and the articles of the EC Treaty were renumbered in the Consolidated version of the Treaty establishing the European Community, O.J. C 340/3 (1997), 37 I.L.M. 79 [hereinafter Consolidated EC Treaty], *incorporating changes made by* Treaty of Amsterdam, *supra*.

7. *Id.* art. 152.

8. *Id.* art. 153.

9. *Id.* art. 174(2).

10. For a detailed examination of the constitutional development of EU consumer protection law, see Jules Stuyck, *European Consumer Law After the Treaty of Amsterdam: Consumer Policy In or Beyond the Internal Market?* 37 COMMON MKT. L. REV. 367 (2000).

> be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.[11]

Although the precautionary principle has not been incorporated expressly into the EC Treaty's provisions on public health and consumer protection, it has been invoked in these areas both by private litigants and by EU Member States.

The "precautionary principle" referred to in Article 174(2) is not defined in the EC Treaty. It is taken from principle 15 of the Declaration of Rio, which states that "[i]n order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[12]

The precautionary principle represents a significant development in that it states that measures should be taken to control activities that could potentially threaten the environment even if there is lack of scientific certainty as to the true extent of any environmental damage flowing from such activities.[13] The words "lack of full scientific certainty" merit careful consideration. According to the natural sense of the words they do not mean "in the absence of any scientific evidence at all" but that the scientific evidence indicating that there is no risk to the environment

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11. "EC" appearing after an Essay reference is the standard shorthand for reference to an article of the EC Treaty in its form as last amended by the Treaty of Amsterdam.

12. United Nations Environment Programme, *Rio Declaration On Environment And Development* (June 14, 1992), *available at* www.unep.org/Documents/Default.asp?DocumentID=78&ArticleID=1163. The precautionary principle has also been incorporated into *The United Nations Cartagena Protocol on Biosafety to the Convention on Biological Diversity, available at* http://untreaty.un.org [hereinafter Convention on Biological Diversity]. Article 11(8) states: "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism (intended for direct use as a food or feed, or for processing), in order to avoid or minimise such potential adverse effects." Convention on Biological Diversity, *supra,* at art. 11(8).

13. *See* MAURICE SUNKIN ET AL., SOURCEBOOK ON ENVIRONMENTAL LAW 40, 50 (1998) (commenting on Principle 7 of the Declaration of the U.N. Conference on the Human Environment, Stockholm (1972) and on Principle 16 of the Rio Declaration).

is incomplete or uncertain. Thus the precautionary principle cannot be interpreted as requiring action just because there is a popular belief that a particular activity will damage the environment irreversibly. As soon as there is reason to suspect that a particular activity will harm the environment, it is necessary to move the debate into the objective scientific field by carrying out the necessary investigations so that any public debate on the issue can be properly informed. If the scientific evidence shows that there may be a risk, but the risk is not certain, precautionary action should be taken.

II. *THE NARROW SCOPE OF THE EXCEPTIONS IN ARTICLE XX, PARAGRAPHS (B) AND (G), OF GATT 1994*

The scope for Member Countries to adopt public health or environmental protection measures that restrict free trade is limited by the prohibition on arbitrary or unjustifiable discrimination and disguised restrictions on trade contained in the chapeau to Article XX. In the case of measures to protect exhaustible natural resources the measures must be made effective in conjunction with restrictions on *domestic* production or consumption. Unlike paragraph (b), there is no requirement in paragraph (g) of Article XX that the restrictive measures be "necessary" to achieve the objective of protecting exhaustible natural resources, presumably because any measure that limits depletion of a natural resource is justified *per se*.

In the case of measures to protect public health, on the other hand, these must be strictly necessary for the objective pursued. The "necessary" test does not authorize a Member Country to adopt a measure that is inconsistent with other GATT 1994 provisions if "an alternative measure that it could reasonably be expected to employ and which is not inconsistent with other GATT provisions is also available to it."[14] This result is similar to the proportionality test under EU law in deciding whether trade restricting measures that are justified by "mandatory requirements" fall within the prohibition of Article 28 EC (formerly Article 30) or are justified by the public policy exception of Article

14. *Thailand—Restrictions on Importation of and Internal Taxes on Cigarettes*, DS10/R (Nov. 7, 1990). *See generally* Carlos M. Correa, *Implementing National Public Health Policies in the Framework of WTO Agreements*, 34 J. WORLD TRADE 89, 96 (2000).

30 EC (formerly Article 36).[15] Just as in the EU, the way forward towards legal certainty is for the EU institutions to adopt directives harmonizing Member States' legislation, so too, in the WTO, the way forward to certainty in the application of Article XX is through specific agreements. This has been done in the plant, animal, and human health area through the Uruguay Round Agreement on the Application of Sanitary and Phytosanitary Measures[16] ("SPS Agreement").

The SPS Agreement begins by reaffirming that:

> [N]o Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade."[17] The purpose of the SPS Agreement is to "harmonise sanitary and phytosanitary measures between Members on the basis of international standards . . . without requiring Members to change their appropriate level of protection of human, animal or plant life or health."[18]

Article 5.1 of the SPS Agreement requires that "[m]embers shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations."[19]

This provision is designed to ensure that Member Countries do not use sanitary or phytosanitary measures as a disguised barrier to trade. Thus it is not enough for a Member Country to say, "We think we have to impose these restrictions in order to protect human, animal or plant life or health." The Member Country in question has to make a proper objective assessment of the risks to human, animal or plant life or health by taking

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15. *See* Jochem Wiers, *Regional and Global Approaches to Trade and Environment: The EC and the WTO*, 25 ISSUES EUR. INTEGRATION 93, 98-100.

16. The express link with Article XX(b) is made in the last recital of the Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, WTO Agreement, Annex 1, *at www.wto.org/english/docs_e/legal_e/final_e.htm* ("SPS Agreement").

17. SPS Agreement pmbl. at para. 1.

18. SPS Agreement pmbl. at para. 2.

19. SPS Agreement art. 5.1.

into account risk assessment techniques developed by relevant international organizations. This was the issue before the WTO Panel requested by the United States and Canada in relation to EU prohibitions on marketing or importing meat and meat products from animals to which certain hormones had been administered.

III. *THE EU BAN ON BEEF HORMONES CASE*

The Panel found that the EU ban on certain beef hormones was not based on a risk assessment and so the EU had acted inconsistently with the requirements of Article 5.1 of the SPS Agreement. The Appellate Body upheld this basic finding, although on more subtle grounds.[20] It is these grounds that assist us in assessing whether Article XX(b) provides adequate protection for Member Countries' concerns about the health and environmental risks arising from new technologies.

The discussion before the Appellate Body turned on the words "based on an assessment . . . of the risks." There are two important elements here: the notion of a risk assessment and the meaning of the expression "based on."

Risk assessment is defined in paragraph 4 of Annex A to the SPS Agreement as "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."[21] The Panel interpreted Article 5.1 as requiring the EU to assess the degree of risk, i.e., to quantify the risk involved in use of the prohibited hormones.

The Appellate Body disagreed with this approach. It held that there is no basis in the SPS Agreement for requiring a quantitative assessment. All that a panel can do is determine whether a given measure is "based on" a risk assessment, that is to say, that the measure is sufficiently supported or reasonably warranted by the risk assessment. As for the factors to be taken into account in the risk assessment, the Appellate Body upheld the Panel's finding that this referred to a process characterized by systematic, disciplined and objective enquiry and analysis.

The Appellate Body disagreed with the Panel, however, to

20. Two other findings of the Panel relating to Articles 5.5 and 3.1 of the SPS Agreement, were reversed by the Appellate Body.

21. SPS Agreement app. A.

the extent that the Panel purported to exclude from the scope of a risk assessment all matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences. As the Appellate Body rightly observed, some of the matters listed in Article 5.2, such as "relevant processes and production methods" and "relevant inspection, sampling and testing methods," are not necessarily or wholly susceptible of investigation according to laboratory methods.[22] Clearly the Appellate Body intended by this to give the notion of risk assessment a wide interpretation as it went on to say that the risk to be assessed extends to "risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die."[23]

We would argue that the expression "actual potential" has to be read against the requirement that the measure be sufficiently supported or reasonably warranted by the risk assessment. In many cases one cannot say that there is "zero risk" and so, in a sense, there is always "actual potential" for realization of the risk. The leading UK tort case of *Donoghue v. Stevenson*[24] shows that there was, and presumably still is, a risk of snails turning up in ginger beer bottles, but it is not for this reason that bottles of ginger beer are today prohibited from the market. The chances of error can be minimized through stricter cleansing requirements, good production practices, and selling ginger beer in transparent bottles, but at the end of the day, there is still a non-zero risk of a snail turning up in a ginger beer bottle. The law deals with this residual acceptable risk through rules on product liability of manufacturers, not by prohibiting the product.

In relation to the question as to whether the EU measures were "based on" a risk assessment, the Panel concluded that the EU had not provided any evidence that the studies it referred to or the scientific conclusions reached had actually been taken

22. "In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment." SPS Agreement art. 5.2.

23. *Beef Hormones Case* para. 187.

24. 1932 App. Cas. 562 (appeal taken from Scot.).

into account. Consequently such studies and conclusions could not be considered as constituting part of the risk assessment.

The Appellate Body disagreed with this procedural approach of the Panel. The Appellate Body felt that the legal test was not whether the studies and conclusions had been taken into account, because it is possible to take account of a study by choosing to reject it. The Appellate Body said that the test had to be whether there was an objective relationship between the measure in question and the risk assessment that led to its adoption.[25] On the facts of the case the Appellate Body came to the conclusion that there was no rational relationship between the EU prohibition on certain hormones in beef and a risk assessment, and so upheld the Panel's finding on this point, although on different grounds.

The substantive requirement of Article 5.1 of the SPS Agreement is that there has to be a rational relationship between the measure adopted and the risk assessment. The Appellate Body recognized that the existence of diverging opinions in the scientific community does not necessarily prevent a rational relationship between the measure in question and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety. Thus the question of whether there is such a rational relationship has to be determined on a case-by-case basis "after account is taken of all considerations bearing upon the issue of potential adverse health effects."

The Panel came to the conclusion that all the studies identified by the EU met the minimum requirements of a "risk assessment" but that the conclusions of all these studies were that the hormones in question were safe (other than the hormone MGA for which no evidence was submitted). The Appellate Body agreed that the studies did "not rationally support the EU import prohibition"[26] and that there was no risk assessment with regard to the hormone MGA.[27]

The EU also argued that while all the scientific evidence related to the risk of human ingestion hormone residue in treated meat, there was also a *distinguishable* risk arising from the failure

25. *See Beef Hormones Case* para. 189.
26. *Beef Hormones Case* para. 197.
27. *See Beef Hormones Case* para. 201.

to observe good veterinary practice, in combination with multiple problems relating to detection and control of such abusive failure in the administration of hormones to cattle. The Panel observed that the risk here was *no different* than the risk of abusive use of veterinary drugs, which are allowed in the EU. Moreover, the EU had not produced evidence to show that control of misuse of the hormones in question would be more difficult under a regime that allowed their use under specific conditions rather than a total ban. Thus, the Panel concluded that the banning of the hormones did not necessarily offer better protection of human health than other means of regulating their use.[28]

The Appellate Body agreed with the EU that it was allowed to take into account the risk of failure to comply with good veterinary practice in the administration of the hormones in question, as well as risks arising from difficulties of control, inspection, and enforcement of the requirements of good veterinary practice.

The Appellate Body then examined whether the EU had in fact submitted to the Panel a risk assessment demonstrating and evaluating the existence and level of risk arising from abusive use of hormones and the difficulties of control within the US and Canada as exporting countries, and at the frontiers of the EU as an importing country. On this particular point the Appellate Body agreed with the Panel that the EU had restricted itself to pointing out the possibility of failure to comply with good practice in the administration of hormones without providing an assessment of the potential adverse effects related to non-compliance with such practice.[29]

For all these reasons the Appellate Body concluded that the EU measures were not based on a risk assessment within the meaning of Articles 5.1 and 5.2 of the SPS Agreement, and were therefore inconsistent with the requirements of Article 5.1. The Appellate Body's report was accepted by the Dispute Settlement Body, and so the EU was bound to bring its hormone measures into conformity with the SPS Agreement. For internal political reasons the EU chose to maintain its hormone ban, and so Canada and the US asked for consultations. Since these consulta-

28. *See Beef Hormones Case* para. 203 (referring to U.S. Panel Report, para. 8.146 and Canada Panel Report, para. 8.149).

29. *See Beef Hormones Case* para. 207.

tions did not result in any mutually agreeable solution, Canada and the United States adopted countermeasures, and the EU had recourse to arbitration in order to determine the appropriate level of countermeasures.

Thus, rather than open its market to hormone-treated beef, the EU chose to pay the price in terms of suspension of tariff concessions by Canada and the United States. The EU consumer can continue to consume beef with the assurance that it has not been treated with hormones, that is assuming that he can rely on the frontier veterinary controls in relation to imported beef and on the internal veterinary controls in relation to beef produced within the EU.

IV. *MAD COW DISEASE AND THE IMPORTANCE OF EFFECTIVE INTERNAL HEALTH CONTROLS*

Sadly, when the EU consumer now contemplates beef in the supermarket, he is thinking more about BSE than hormones. The outbreak of mad cow disease illustrates how the public health issue is not one of preventing unbridled free trade but of ensuring adequate controls within one's own domestic territory. Here the cause for consumer concern arose within EU territory, not outside. Once it was realized, belatedly, that there was a risk from consuming beef produced within the United Kingdom, the European Community adopted the necessary measures to ensure not only that UK beef could not circulate freely within the other Member States, but also that it could not be exported to third countries.[30]

This ban was challenged in both the UK and the EU courts and all the actions came before the European Court of Justice, either as a direct challenge by the United Kingdom Government, or as an indirect challenge, on a reference of a point of EU law from the UK courts to the European Court of Justice.[31] The European Court of Justice had no difficulty in recognizing that the ban on UK beef imposed by the EU had been adopted validly under EU veterinary legislation. The ban was lifted when subsequently the UK established the necessary controls to be

30. Commission Decision No. 96239/EEC, O.J. L 78, at 4 (1996).

31. *See United Kingdom v. Commission*, Case C-180/96, [1998] E.C.R. I-2265; *The Queen v. Minister of Agriculture, Fisheries and Food, Commissioner of Customs and Excise, ex parte National Farmers Union and others*, Case C-157/96, [1998] E.C.R. I-2211.

able to assure consumers that all potentially infected beef had been excluded from the food chain, although some Member States, notably France, threatened not to accept the lifting of this ban.

With tragic irony other EU Member States have discovered that BSE infection is among their own beef herds. This brought home to the European Commission the need to take stricter control measures at an EU level and these have been duly adopted by the EU Council upon a proposal from the Commission.[32] The BSE case has shown that the problems of contamination can arise at home, which in turn, emphasizes the need for effective controls in the domestic territory. Such controls need to be exercised not just at the source (i.e., in the feeding of cattle) but also in the supply to the consumer (e.g., at the slaughtering stage).

In the case of imported beef from third countries both of these stages can occur in a third country, and so it becomes very difficult for the importing country to ensure that imported beef is free of BSE unless it relies on controls exercised in the country of export. If such controls are ineffective, and there is a real risk of infection, the importing country is entitled, under the SPS Agreement, to take measures to protect human health. The EU would no doubt admit that, in extreme cases, such measures of protection can extend to an import ban, because the EU itself imposed an export ban on the UK at a time that it was not possible to be sure that UK beef was free from contamination.

V. *BSE, GMOS—WHAT NEXT?*

It is not surprising that after the discovery of the extent of BSE contamination, consumers in the EU are very suspicious about GMOs. To the uninformed, "genetic modification" sounds much more dangerous than forcing cannibalism on bovine animals. Frankenstein horrors spring to mind at the very thought of tinkering with the genetic make-up of living organisms. The debate launched by new technologies is not limited to genetically modified plants, but extends to cloning experiments with animals and recent UK government policy to pro-

32. *See, e.g.*, Commission Decision No. 2001/2/EEC, O.J. L 6/16 (2000); *see also* the earlier measures referred to in the recitals to that decision. Other measures are in the legislative pipeline.

mote legislation to allow the use of human embryos for medical applications. The public issue is not just one of food safety but of the ethical approach we have to human, animal, and plant life.

EU legislation on genetically modified plants provides a legal testing ground for issues that will later arise for other new products of biotechnology. From a strict legal point of view, Article XX applies in the same way to all products of new biotechnology, whether they be GMOs or products resulting from genetic manipulation of animals or of human embryos, yet from an ethical point of view, these cases will be seen by many as being quite different. The different ethical considerations play a role in determining what the legal position *should be*, but they do *not* themselves constitute legal rules.

The genetic modification of plants, it should be observed, is not like feeding bovine animals with feedstuffs made up from bovine meat and bones. Natural cross-fertilization of plants is continually producing new varieties. This process can be encouraged and controlled by so-called "natural" cross-fertilization techniques. Modern biotechnology enables one to make the step change in a more controlled fashion. In all cases it is necessary to ensure that the new strain of plant is safe for human consumption.

One may wonder how or why a different strain of, for example, tomatoes, should not be safe for human consumption in the same way as tomatoes are generally. The point is that the process of genetic modification can create new proteins to which some consumers might be allergic. It is therefore necessary to ensure that the new plant product is safe for human consumption, in the same way as one would proceed if tomorrow a new exotic naturally occurring equatorial fruit was discovered.

Human safety is not the only concern. The creation of a herbicide resistant variety of maize would a boon for farmers, but if, cross-pollenization, the herbicide resistant characteristic were transferred to thistles, that would be the farmer's scourge. There is therefore a recognizable threat to the environment that has to be managed when genetically modified organisms are cultivated in the soil.

There is nothing novel about the two objectives just discussed: ensuring that food is safe for human consumption and

ensuring that the biodiversity of the environment is not harmed. All new inventions have good and bad uses. Modern history is full of examples where man has had to manage the advantages and disadvantages of new discoveries. The first steam carriages had to be preceded by a man carrying a red flag whereas today's motor cars hurtle along densely packed motorways at speeds unimaginable by those first red flag carriers. People have freedom of choice, and certain communities choose to let technological progress pass them by. The point is that individual choice as to a particular style of life is not a reason for stifling free trade and the economic efficiencies that flow therefrom.

Thus we can conclude that there is no justified reason to obstruct trade in GMOs provided the two objectives—protection of human health and protection of the environment combined with justified information for the public—can be achieved. This is an objective scientific question. It will have to be recognized that there will be occasions when things go wrong, just as in the past there have been outbreaks of salmonella in eggs or pollution of agricultural plantations from lead emissions from car exhausts. The way to avoid these mistakes is though vigilant non-discriminatory domestic controls within the domestic territory, not by preventing free trade. It is true that this approach does not deal with the problems of damage caused to the environment outside the importing Member Country. This is a matter that can only be solved through a new round of trade negotiations.[33]

VI. *EU LAW ON GENETICALLY MODIFIED ORGANISMS*

In 1987 the EU Council adopted its Fourth Environmental Action Programme,[34] in which it recognized that the evaluation and best use of biotechnology with respect to the environment was a priority action on which the European Community should

33. *See* Héctor Rogelio Torres, *The Trade and Environment Interaction in the WTO—How can a "New Round" Contribute?* 33 J. WORLD TRADE 153 (1999); Matthew A. Cole, *Examining the Environmental Case Against Free Trade*, 33 J. WORLD TRADE 183 (1999), examines the argument that free trade contributes to economic growth which in turn leads to a reduction in pollutants. This argument, if valid, does not appear to apply in the case of GMOs where the issue is not pollution by waste, but "pollution" by the end product.

34. O.J. C 328, at 1 (1987). In fact, in 1987 it was the Council of the European Communities which subsequently became, in 1994, the Council of the European Union.

concentrate. In relation to GMOs the Council subsequently adopted Directive 90/219/EEC on the contained use of GMOs,[35] Directive 90/220/EEC on the deliberate release into the environment of GMOs,[36] and Regulation (EC) No 258/97 on novel foods and novel food ingredients.[37] For trade purposes the only provisions of these measures that interest us are those of Directive 90/220/EEC on the placing on the market of GMOs and those in Regulation (EC) No 258/97 on the placing on the market of foods and food ingredients containing, or consisting of, GMOs or produced from, but not containing, GMOs.

A. *Placing of GMOs on the Market*

The procedure for authorization to place a GMO on the EU market is complex because it is designed to allow Member States to play their individual roles, while ensuring that the end result is a common EU approach. The procedure begins with an application made to a Member State authority. Such application must contain a risk analysis similar to that required for a release into the environment,[38] the conditions for the placing of the GMO on the market (which must comply with the relevant EU product legislation), and an environmental risk assessment.

Upon receipt of a complete application, the concerned Member State authority has ninety days in which either to reject the application for non-compliance with Directive 90/220/EEC, or to forward the application to the European Commission with a favourable opinion. The Commission then forwards copies of the file to all the other Member States. The other Member States have sixty days in which to raise objections. In the absence of any objections within the sixty days, the notifying Member State must issue its consent to the placing of the GMO on the market and must notify the Commission and all the other Member States. As a result of such notification, the GMO may be used without further notification throughout the EU in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly ad-

35. Council Directive No. 90/219/EEC, O.J. L 117, at 1 (1990).

36. *Id.* O.J. L 117, at 15 (1990).

37. Council Regulation No. 258/97, O.J. L 43, at 1 (1997). This directive was adopted by the EU Council jointly with the European Parliament.

38. For a controlled release into the environment for the purposes of field trials, see Council Directive No. 90/220, O.J. L 117/8, at 15 (1990).

hered to.[39]

Where a Member State raises an objection in sixty day period, the application is subjected to what is known in the EU as a "comitology procedure." The details of this procedure need not be explained here. Suffice it to observe that the Commission can propose and adopt a solution after consulting a committee of Member State representatives, unless the Member States vote unanimously in favour of a different solution or in favour of no action at all. The point about the "comitology procedure" is that it introduces an element of unpredictability in the EU decision-making process, which is sometimes difficult for third countries to understand.

B. *Placing on the Market Foods or Food Ingredients Containing or Consisting of GMOs, or Food or Food Ingredients Produced From but not Containing GMOs*

The placing on the market of foods or food ingredients containing or consisting of GMOs is governed by Regulation (EC) No 258/97, referred to above. The authorization procedure is similar, but not identical, to that under Directive 90/220/EEC. This procedure applies also to the placing on the market of foods or food ingredients produced from, *but not containing*, GMOs.

Such products would include, for example, maize flour produced from genetically modified maize. Such products are no longer organisms capable of reproducing themselves and so the risk assessment concentrates more on the food safety aspects than on the environmental risks. There is also a simplified authorization procedure for food or food ingredients produced from but not containing GMOs.[40]

Where it can be shown that the novel food or food ingredient is substantially equivalent to an existing food or food ingredient in regard to composition, nutritional value, metabolism, intended use, and the level of undesirable substances contained therein, the applicant may simply notify the Commission that it is placing the product on the market. Such notification must be accompanied with the documentary proof that the food or food ingredient is substantially equivalent to an existing food or food

39. Council Directive No. 90/220, art. 13(5), O.J. L 117/8/5 (1990).
40. Commission Regulation No. 258/97, art. 3(4), O.J. L 043 (1997).

ingredient. Such proof may consist of generally recognized scientific evidence, or an opinion of the competent food authority of a Member State. In practice, a company making such notification will seek an opinion from the food authority of a Member State and that authority will base its opinion on generally recognized scientific evidence.

C. *Member States' Concerns About EU GMO Legislation*

Member States are concerned about the potential risks to human health and to biodiversity from the placing on the market of GMOs and food products derived from GMOs. In addition, there is the political issue of transparency and freedom of choice for consumers. As a result, a *de facto* moratorium has been applied by the Member States with the result that no new approvals have been granted under Directive 90/220/EEC or Regulation (EC) No. 258/97 since October 1998. Moreover, several Member States have already taken safeguard measures against specific approved GM products. An additional problem arises under Regulation (EC) No. 258/97 in that some Member States consider that the simplified procedure for the approval of GMO-derived foods and food ingredients does not give all Member States an adequate say in the approval procedure.

As a result of these concerns, the Commission proposed an amendment to Directive 90/220/EEC. The EU Council and the European Parliament finally came to agreement on December 22, 2000, on the text of the required amendments to Directive 90/220/EEC. The amendments provide for improved information to the public at the time of field trials, for a tightening of the approval procedure and for a widening of the scope of the safeguard clause. Member States will be allowed to take safeguard action where they have "additional" information, as opposed to the current requirement of "new" information on the basis of which there is a risk to human health or the environment. In addition, the Commission has undertaken to bring forward its proposal for implementation of the Cartagena Protocol on Biosafety[41] and to submit to the Council and to the Parlia-

41. Although potential conflicts of this Protocol with GATT 1994 will bring their own set of problems. For a review of these conflicts, see Peter W.B. Phillips and William A. Kerr, *Alternative Paradigms: The WTO versus the Biosafety Protocol for Trade in Genetically Modified Organisms*, 34 J. WORLD TRADE 63 (2000).

ment a proposed directive on the labeling and tractability of GMOs. It remains to be seen whether all this will have the effect of unblocking the Member States' *de facto* moratorium on new approvals under Directive 90/220/EEC. Moreover, the simplified authorization procedure under Regulation (EC) No 258/97 for GMO derived foods remains a source of discontent. Respect for the rule of law is ultimately going to lie with the EU and national courts.

Directive 90/220/EEC and Regulation (EC) No 258/97 contain a safeguard clause,[42] which the Member States have not hesitated to invoke in order to ban EU-approved GMO products in their national territory and thereby put political pressure on the Commission to hasten amendments to EU GMO legislation. So far there has been no court judgment on the legality of the Member States' use of the safeguard clause.

Some judicial guidance is available, however, from a recent decision of the European Court of Justice upon a referral of a preliminary question of law from the French Conseil d'Etat. The European Court of Justice rendered a subtle ruling[43] in which it recognized the duty of a Member State to be concerned about new information that might cast doubts on a Commission decision authorizing the placing of a GMO on the market. In such a case the Court ruled that the Member State in question should suspend any implementation of the Commission's decision, but should immediately invoke the safeguard clause and notify the Commission and the other Member States. The Court also recalled its earlier case-law[44] according to which only the Court of Justice has jurisdiction to rule on the invalidity of a measure adopted by an EU institution, such as a measure authorizing the placing of a GMO on the market. The Court did not give any guidance as to what sort of irregularities at the national level might lead to invalidity at the EU level nor did it rule on what would or would not constitute new information justifying the use of the safeguard clause.[45]

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42. Council Directive No. 90/220, art. 16, O.J. L 117/8/5 (1990); Commission Regulation No. 258/97, art. 12, O.J. L 043 (1997).

43. *Association Greenpeace France et al. v. Ministère de l'Agriculture et de la Pêche et al.*, Case C-6/99, (ECJ Mar. 21, 2000) (not yet reported).

44. *Foto-frost v HZ Lübeck-Öst*, Case 314/85, [1987] E.C.R. 4199.

45. It is not surprising that the Court of Justice, with its very busy timetable, did not seek to rule on theoretical considerations. For a criticism of the failure to give any

This latter question is currently before at least one national court. It is, therefore, an unanswered question whether the European Court of Justice will allow the Member States a wide or a narrow interpretation of the safeguard clause in GMO matters. Whatever the Court of Justice decides in this matter, it will have to ensure that its ruling does not place the Community in a situation where it would be in breach of its WTO/GATT obligations.

VII. *DO PARAGRAPHS (B) AND (G) OF ARTICLE XX GIVE THE EU ADEQUATE PROTECTION?*

We come now to the question whether Article XX provides the EU with adequate protection for its consumer protection and environmental concerns in the biotechnology area.

In the *Shrimp/Turtle* dispute the Appellate Body held that the sea turtle was "an exhaustible natural resource" within the meaning of Article XX(g) (although, as observed above, the US measures were found to be arbitrary and discriminatory and therefore incompatible with GATT 1994 obligations). How does trade in GMOs threaten exhaustible natural resources? Arguably, the release of GMOs into the environment could result in gradual cross-fertilization with all known plant varieties in their present form. If it is accepted that the non-genetically modified variety is a different "resource" than the non-modified variety, then it is possible that introduction of a genetically modified variety into the environment would endanger the survival of the non-modified "resource." Logically this question should be resolved using the same approach as already used in the introduction of new (unmodified) hybrids. It could also be said that the introduction of a new variety could endanger the life or health of existing species within the meaning of Article XX(b). This is true, but again, it is a consideration that is already applied under phytosanitary legislation and so would fall to be dealt with under the SPS Agreement. From the point of view of protection of plant life and health there is no ground for over-reacting to trade in GMOs: their introduction into the environment should be approached in the same way as the introduction of new plant species obtained by hybrid techniques.

As far as concerns the health and life of consumers, the nor-

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guidelines, see Andrea Mastromatteo, *A Lost Opportunity for European Regulation of Genetically Modified Organisms*, 25 EUR. L. REV. 425 (2000).

mal procedures for protecting human health can be applied within the limits defined by the SPS Agreement. As has already been argued, the question is not one of banning food products in which consumers have no confidence for one reason or another, but in ensuring objectively that the public will be safe. However rigorous the public food safety checks, there will occasionally be cases where unsafe food enters the food chain, for the simple reason that human beings are fallible. The more dangerous the product, the more rigorous should be the efforts taken to prevent it entering the food chain. Given that GMOs are now in the environment, traces of them will turn up in the food chain from time to time, even where the production chain has been managed so as to be GMO free.[46] It is rather like lead, cadmium, and many synthetic fertilizers. Traces of them turn up inevitably in the food chain.[47] No one has sought to ban imports because they contain traces of lead, and yet there is no reason to suppose that traces of lead are less dangerous than traces of GMO.

It has to be concluded that there is no valid reason for singling out GMOs for treatment in any manner different from the way questions of authorized food additives have been dealt with since the beginnings of the GATT. One country may authorize the use of a particular additive and another may prohibit the use of this additive but authorize another. The normal procedures for recognition of products in the WTO apply here, based on objective scientific evidence.

VIII. *THE "ETHICAL" OBJECTION*

By ethical here we mean a value judgment made by an individual or even by the public as a whole, as to whether use of a certain sort of product is a good action or a bad action. Such a consideration does not fall within Article XX(a) on the protection of public morals. The objective of this provision is to allow Member Countries to ensure that vulnerable sections of the pop-

46. An example is the recent case of traces of unauthorised GMO derived products turning up in tortillas on the shelves of UK supermarkets, even though the products had been produced in a theoretically GMO-free environment.

47. An illustration of this can be found in the judgment of the European Court of Justice concerning the question whether jam could be described as "natural" if it contained traces of lead, cadmium and pesticides. *See* Case C-465/98, *Verein gegen Unwesen in Handel und Gewerbe Köln eV v Adolf Darbo AG*, 2000 E.C.R. 4.

ulation are not morally depraved through exposure, for example, to pornographic material. No one would seriously suggest that sections of the population would be morally depraved through eating GMOs or GMO derived food. The only ethical consideration here is that consumers should be allowed to choose what they eat.

Traditional regulations on labeling as to ingredients already meet this objective and are compatible with WTO/GATT obligations provided the labeling requirements are not discriminatory and are not so disproportionate as to amount to a barrier to trade. For example, a labeling requirement that the list of ingredients should also show the name and address of the supplier of each of those ingredients would be disproportionate because it would serve no useful purpose in furthering the protection of human health. By analogy, one could pose the question, "is the requirement that a distinction be made between ingredients containing GMOs or derived from GMOs and other ingredients disproportionate once it is established that there is no health risk from consuming the ingredients containing or derived from GMOs?" Logically, if there is absolutely no health risk, such a labeling requirement would not be justified since, like the information about the suppliers of all the ingredients, it does not serve any useful purpose. It is here, perhaps, that our regulators are guilty of a kind of "double-think." "There is no health risk, but just in case there is a risk, we will require that the product be labelled so that you can choose for yourself."[48] For the time being, at least, this double-think is generally accepted as a legitimate approach. In WTO/GATT terms, such labelling requirements must be non-discriminatory and must not have the effect of rendering it more difficult for exporters than for domestic producers to market products.

The issue then is whether a Member Country can impose a negative labeling or a positive labeling obligation. A negative labeling obligation is the obligation to label a product "GMO

48. C. Ford Runge & Lee Ann Jackson, *Labelling, Trade and Genetically Modified Organisms—A Proposed Solution*, 34 J. WORLD TRADE 111, 119 (2000), are more candid, and affirm that "there is a legitimate need to conduct monitoring and research to assure the safety of GMO foods, notwithstanding claims to the contrary." *See also* Fiona MacMillan & Michael Blakeney, *Regulating GMOs: Is the WTO Agreement on Sanitary and Phytosanitary Measures Hormonally Challenged?* 2 I.T.L.R. 161, 167 (2000) (discussing the interface between science and regulation).

free" if one wants to target that section of the market desirous of eating GMO free products. Negative labeling is therefore an optional system of labeling. The problem is that voluntary use of negative labeling could mislead consumers into believing that products containing or derived from GMOs are less safe, thereby creating a barrier to trade, unless the label was accompanied by a statement such as "no significant difference has yet been shown between foods with and without GMOs."[49] A positive labeling obligation is the obligation to label a product "Contains GMOs" or "Derived from GMOs" when the product contains or is derived from GMOs. Where positive labeling obligations are imposed without any exceptions for adventitious presence,[50] producers who do not operate in a hermetically closed environment are practically obliged to label everything "may contain GMOs or GMO derived material." Once this occurs, the positive label is totally devalued.

The ethical consideration in relation to GMOs in food is simply that producers should not be allowed to give novel foods to consumers without telling them that the foods contain or are derived from GMOs. There is no vociferous section of the population that affirms that it is unethical to modify plants genetically. Some animal lovers might be more vociferous in objecting, on ethical or moral grounds, to genetic engineering in animals, and others[51] object very strongly to the prospect of products obtained through research carried out on human embryos.

It is beyond the scope of this Essay to argue the ethical or moral case against genetic engineering in animals or research on human embryos. Whatever the point of view of the reader, it should be possible to understand that there are some activities and practices that are seen by certain segments of the population not just as unethical, but as morally wrong. At this level, labeling does not solve the problem. The consumer considers that it is wrong that products should be manufactured in a certain way. That is a political reality that regulators will have to take account of in the near future, and in taking account of it

49. *See id.*

50. I.e., the presence of GMOs in food or food ingredients, even where operators have taken appropriate steps to avoid using GMOs or products derived therefrom.

51. Of which the author is one.

they are inevitably going to find that Article XX of the GATT 1994, in its present formulation, does not provide them with any defence.

CONCLUSION

It is understandable why environmental and consumer protection groups think that free trade in accordance with GATT 1994 rules constitutes a serious danger to the environment and to consumers. The proponents of free trade, on the other hand, have valid reasons to fear that environmental and consumer protection regulations very soon become disguised obstacles to free trade. It is not that they support free trade to the detriment of all other considerations, but that they believe that through free trade all the world's trading nations will develop economically and will have greater resources to deal with environmental problems, problems that ultimately have to be handled globally through multilateral conventions. As far as consumer protection is concerned, it is not that the free traders want to expose the consumer to unnecessary risk, but that measures to protect public health must be based on objective scientific evidence. National politicians can make errors of judgment in the handling of threats to food safety, as the mad cow case has shown. Arguably the consumer has a greater interest in seeing his food safety interests ruled by international organizations such as the WHO, under the watchful surveillance of the WTO, than by the complexities of national politics.

In the polyvalent society of the Global Market Place there is, of course, small room for individual ethics. Ethics are not a permitted ground for restricting trade pursuant to Article XX of GATT 1994. The reason for this is simply the potential for abuse. Member countries who wish to meet ethical concerns of sections of their populations may achieve this through non-discriminatory proportionate labeling requirements. In the GMO field, meaningful and truthful labeling should meet consumer concerns in relation to consumption of food containing or derived from GMOs. On the other hand, it is predicted that labeling cannot meet the more serious ethical concerns of sections of the population arising out of new technologies involving genetic modification of animals or manipulation of human embryos. We conclude that, in its present form, Article XX provides the

necessary safeguards for the local environment and for human health in relation to GMOs; the burden lies on importing Member Countries to ensure that non-discriminatory, proportionate and effective action is taken to protect the consumer and the local environment. The "external," or international environment is a matter for multinational agreement, not domestic regulation. On the other hand, Article XX provides no comfort to the ethical and moral questions posed by other technologies such as genetic engineering in animals and research carried out on the human embryo.