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The WTO Biotechnology Dispute

by

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THE WTO BIOTECHNOLOGY DISPUTE

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INTRODUCTION

The routine sounding GATT 1994 disputes before the World Trade Organization concerning the European Communities' regulation of genetically modified or biotech foods hide the agricultural revolution that engendered the disputes and the ongoing international policy debate.[2] Argentina, Canada and the United States argue in essence that the European Communities (hereinafter "EC") have used non-tariff measures - a moratorium on their procedures - to thwart access to the EC market for genetically modified agricultural and food products that have been approved in the respective exporting territory. The resort to the World Trade Organization (hereinafter "WTO") dispute settlement process changes a public policy debate about a new technology into an international economic law issue, which is subject to the rules of the GATT 1994. This is intended to de-politicize the intense debate about the genetic modification of what we eat. While the dispute primarily pits the United States against the European Communities, the debate in reality involves the world and will not be resolved by these cases. In fact, because the three requests for the establishment of WTO panels, the EC has revised its law.[3] However, even the new EC rules create concerns among U.S. exporters, who are concerned most about the new traceability and labeling rules.[4]

These disputes are about market access for products in the food supply that have been modified using the new biotechnology.[5] The three Members argue that the EC and some of its Member States un-

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[2] General Agreement on Tariffs and Trade 1994, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, April 15, 1994, Annex IA, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND Vol. 1 (1994), 33 I.L.M. 1125 (1995) [hereinafter GATT 1994].

[3] The new rules are Regulations 1829/2003 and 1830/2003.

[4] *See* the November 25, 2003 letter sent by a group of U.S. trade associations, including the American Farm Bureau Federation, the Biotechnology Industry Association and the Grocery Manufacturers of America, to Ambassador Robert Zoellick) (arguing that the new regulations violate the EC's WTO obligations) (Letter on file with the author)...

[5] Organisms, seeds, plants, ingredients, processing aids and enzymes, and foods can be genetically modified. Often, the applicable national and model approaches differ depending on the nature of the food. In this article, the generic term "food" will be used unless the context requires more specificity.

justifiably restrict imports on safety and non-safety grounds in contravention of specific provisions of the GATT 1947, the Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter "SPS Agreement"), the Agreement on Technical Barriers to Trade (hereinafter "TBT Agreement") and the Agreement on Agriculture. Also in dispute are Member States' (Austria, France, Greece, Italy and Luxembourg) prohibitions on importation, marketing or sale of EC approved biotech foods are also in dispute.[6] Each request also claims the nullification and impairment of benefits accruing to the Member under the cited agreements and/or the GATT 1994.

PUBLIC POLICY AND THE NEW BIOTECHNOLOGY

The new biotechnology is a scientific milestone that has been received with vastly different reactions among policymakers and the public. While genetically modified pharmaceuticals have been accepted without controversy and while the quiet use of a few genetically modified foods have been in use for some time,[7] the application of the technology to staples like corn and soybeans triggered questions about the long-term safety and consequences of the new biotechnology. Colorful protests took place in Seattle, Washington D.C., Genoa and Cancun, among many other locations. If biotech animals, like fish, are approved the debate is likely to intensify.[8]

A few circumstances illustrate the sensitivities involved in this issue. First, there is a great divide among governments and within the public about the acceptability of biotech foods. The U.S. production of genetically modified crops has increased dramatically in recent years. Argentina, Canada, China, and Brazil are among the other producers. In contrast, the fifteen (soon to be twenty five) Member States of the EC and Japan have restricted the production and/or marketing of biotech foods for reasons of food safety, consumers' right to know what is being marketed and/or consumer choice. Recently, several southern African countries were drawn into the debate. Whether it is because biotech foods might play a positive role in improving conditions of food security in Africa, because an economically healthier Africa is potentially a vast market for the products or because both the EC and the U.S. would like Africa to support their perspective toward biotech foods, the confrontation occurred and resulted in a split response from the southern African governments. Eventually their re-

[6] There are few differences about the WTO rules cited in the three Requests. Canada refers to Annex C(1)(c)(regarding information requirements) of the SPS Agreement, all of Article 5.1 and Article 5.2.3 (regarding information requirements).

[7] Beer, wine and cheese producers and manufacturers have used genetically modified processing aids for several years.

[8] The U.S. Food and Drug Administration has received an application to market biotech fish.

gional trading organization, the Southern African Development Conference, created a task force, which has not yet reported. They also agreed upon a resolution that recognizes that the choice of whether to plant and/or import biotech food is a sovereign decision. That position was supported by the Director General of the World Health Organization (hereinafter "WHO") during a tour of Africa to the disappointment of many in the United States.

At the intergovernmental level, the debate has been primarily in support of the new biotechnology; the Organization for Economic Cooperation and Development (hereinafter "OECD") and the Codex Alimentarius Commission (hereinafter "Codex") have been involved in the safety assessment of biotech food for many years. More recently, a Codex task force successfully resolved issues regarding terminology, risk analysis and other previously contentious questions.

Second, the proliferation of nongovernmental organizations with recommendations regarding the treatment of the technology and products derived from it testify to the sensitivity of the public policy debate. The debate among nongovernmental organizations has been intense, with the most vocal being groups from Europe and India who oppose biotech foods on safety and/or environmental protection grounds. Views range from those of Consumers International, Greenpeace and Oxfam to the usually contrary perspectives of the International Chamber of Commerce, the Brussels-based European Confederation of Food and Drink Industries, the Grocery Manufacturers of America and the Biotechnology Industry Organization in the United States. The International Organization for Standardization and the United Nations-backed International Food Policy Research Institute have also played roles, as have the Rockefeller Foundation and the Pew Foundation in the United States. Also, it is worth noting that the debate about the production and marketing of genetically modified foods is an issue that has ignited many in the consumer movement and has magnified the attention paid to the WTO as an institution and as a set of rules, notably after the WTO ruling in *Beef Hormones*.[9]

Third, the technology is so sensitive that there has been a policy debate about what to call the process that is being applied to foods. Biotechnology, modern biotechnology, gene technology, genetic engineering, genetic modification and recombinant DNA technology[10]

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[9] European Communities – Measures Concerning Meat and Meat Products (Hormones), WT/DS58/AB/R and WT/DS48/AB/R. WTO dispute reports are available on the WTO web site, *http://www.wto.org/disputes*. In *Beef Hormones,* Canada and the United States successfully challenged the EC's restrictions on imports of beef raised with the use of certain growth hormones. That case also involved a production process and a European public that was largely critical of products resulting from the production process. *See also* Michael Paulson, *WTO Case File: The Beef Hormone Case*, Nov. 22, 1999 *at* http://seattlepi.nwsource.com/national/case22.shtml.

[10] In its *Statement of Policy: Foods Derived from New Plant Varieties*, the U.S. Food and

are among the terms used to describe the process of creating what are termed genetically modified organisms,[11] novel foods[12] or food[13].

A fourth sensitivity is the result of differing views about whether food should be regulated on the basis of its characteristics or the (agricultural) production process by which it was produced. *Beef Hormones* was a dispute about a measure that regulated a product on the basis of its production process.[14]

THE STATE OF PLAY REGARDING EC AND MEMBER STATE APPROVALS

Few biotech food products have been authorized for the retail market[15] or deliberate release into the environment. A few were approved before 1998, when the policy of suspending consideration or approval of applications began. According to the United States, twenty two other applications were filed[16] and four applications were

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Drug Administration referred to new methods of genetically modifying plants, such as recombinant DNA techniques and cell fusion techniques. 57 Fed.Reg. 22,984 (May 29, 1992) [hereinafter, "Statement of Policy"]. Since 1992 several new techniques have been developed.

[11] Directive 2001/18 states, "For the purposes of this Directive: (1) 'organism' means any biological entity capable of replication or of transferring genetic material; (2) 'genetically modified organism (GMO)' means an organism. . . in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination." Human beings are not covered by the definition. Art. 2(1)-(2), Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, 2001 O.J. (L 106) [hereinafter Directive 2001/18].

[12] Under EC rules, novel foods are certain categories "of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community." Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, Art. 1.2, 1997 O.J. (L 043) [hereinafter Reg. 258/97]. One of the categories is "foods and food ingredients containing or consisting of genetically modified organisms[,]" [and another category includes those] foods and food ingredients produced from, but not containing, genetically modified organisms." *Id.* paras. a) and,(b), respectively.

[13] In its *Statement of Policy,* the United States announced that it would regulate genetically modified plants and foods derived from them like traditional foods. The United States focuses on the characteristics of the food rather than the process of production. 57 Fed. Reg. 22,984 (May 29, 1992). Although the *Statement* mentioned "genetically modifying" plants and "genetic modifications" in plants, subsequently the United States used the descriptor "biotechnology", the term that was adopted later by the Codex Task Force.

[14] *See* Michael Paulson, *WTO Case File: The Beef Hormone Case*, Nov. 22, 1999 *at* http://seattlepi.nwsource.com/national/case22.shtml.

[15] Placing on the market and deliberate release are defined in Directive 2001/18 but not in Reg. 258/97. "'[P]lacing on the market' means making available to third parties,whether in return for payment or free of charge[.]" Directive 2001/18, Art. 2(4). "'[D]eliberate release' means any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment". *Id.* at Art. 2(3).

[16] Memo/02/160 (Oct. 15, 2002). Most (seven) were filed in Spain, which in January 2003 gave a favorable assessment of Monsanto's application to place on the market Roundup Ready corn (NK603), on the same day that the SNIF was published. France re-

withdrawn. The Commission admits, in its 2002 *Questions and Answers on the regulation of GMOs in the EU,* that no authorizations have been granted for deliberate release since 1998.[17]

Argentina, Canada and the United States argue that the EC has blocked all applications for approval and has not considered any application for final approval since 1998.[18] According to the United States, the U.S. companies' applications, under the deliberate release rule, date back to 1994 when Bejo Zaden filed in the Netherlands for an approval for red-hearted chicory for food and feed use.[19] In 1995, Bayer applied in France to import and process oilseed rape and hybrid oilseed rape under Directive 90/220.[20] Eighteen GMO's have been approved under the Directives on deliberate release of GMO's into the environment. Maize, oil seed rape, soybean and chicory varieties are permitted for cultivation, import and processing, feed or food.[21] One soy and one maize were approved under the novel foods and novel feed ingredients rule.

According to the EC Commission, in 2002 twenty two applications were pending under Directive 2001/18. The pending applications requested authorization for environmental release, placing a product on the market, or both. For example, after reviewing the conclusions regarding very large United Kingdom farm-scale trials and assessing the impact of modified crops on the environment and other data, Belgium recently denied an application for the deliberate release of genetically modified spring-sown oilseed rape on the basis that the modified variety is more damaging to wildlife than conventionally grown varieties.[22] On the other hand, having denied its approval to grow the plants, Belgium approved the application to import and place the rape on the market.[23] Soon after, the United Kingdom approved an environmental release, in spite of public opposition and a report from the Environmental audit Committee of the House of Commons, which recommended that approval be delayed pending more results from the United States experience.

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ceived the second highest number of applications (five). *Id* Ten applications were filed between 1995 and 1996, and nine between 1998 and 1999. *Id.*

[17] Until that time, eighteen GMOs had been approved for commercial release but two Member States had not implemented the Decisions. citation The Commission said that thirteen (13) applications were pending.

[18] WT/DS291/23, at 1.

[19] Seed production had already been approved. citation

[20] Seed production had already been approved. citation

[21] These approvals were obtained under Directive 2001/18/EC and its predecessor, Directive 90/220/EC.

[22] The denial will be reviewed by the other member states and might be appealed in Belgium.

[23] John Mason, *Belgium rejects GM oilseed rape over fears for wildlife*, FIN. TIMES, Feb. 3, 2004, at 6.

The current "suspension" or "moratorium" is expected to end with the approval by the European Commission of one European and one United States biotech food in the spring of 2004. One of the products is Monsanto's NK603, a maize, which the company hopes to export to the EC and process there. The Monsanto product received a favorable opinion from the European Food Safety Authority (hereinafter "EFSA"), which permits the European Commission to issue a Decision of approval.

The European Commission admits that although eleven applications are pending, no foods consisting of or containing live GMOs have been approved under the full procedure of the Novel Foods Regulation, although two plants of maize and soybean varieties were authorized previously under Directive 90/220. The producers of another group of foods filed under the simplified procedure of the novel foods regulation that is available for foods that are "substantially equivalent" to existing foods. Thirteen products can be marketed in the EC as novel foods that are substantially equivalent to existing foods. [24] The notifiers only give notice of their intention to market the product, coupled with scientific support for that conclusion or an opinion of substantial equivalence from a Member State.

THE DISPUTE SETTLEMENT PROCESS

Since the consultations under Article 4.11 of the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes (hereinafter "DSU")[25] were unsuccessful, the dispute will be conducted under the procedures and timetable of the. DSU. Disputes are given a twelve (12) month timetable, although that timeframe is often exceeded. First, a three person Panel is selected or appointed and given terms of reference.[26] The panelists assist the Dispute Settlement Body [hereinafter "DSB"] to make an objective assessment of the matter, "including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements."[27] In principle the three reach a decision within six (6) months, although the calendar can be changed in light of "unforeseen developments."[28] When a measure is inconsistent with the GATT

[24] A food is substantially equivalent when the composition, nutritional value, metabolism, intended use and level of undesirable substances is substantially equivalent to traditional foods.

[25] Australia, Brazil, Canada, India, Mexico, New Zealand and the United States consulted with the EC. European Communities – Measures Affecting the Approval and Marketing of Biotech Products: Acceptance by the European Communities of the Requests to Join Consultations, WT/DS293/16 (June 19, 2003) *available at* http://docsonline.wto.org.

[26] DSU Understanding, art. VII (giving the standard text for terms of reference).

[27] *Id* at art. XI.

[28] *Id.* app. III. One circumstance that can affect the schedule is the decision by the Panel to seek information and technical advice, as occurred in the Beef Hormones dispute. *Id.*

1994, the recommendation is that the Member bring its measure into conformity. [29] The offending Member is expected to do so within fifteen (15) months, although that period is often extended, e.g., because of a dispute about whether the revised measure conforms. In sensitive disputes, implementation has not been stellar. The suspension of concessions, as provided under Article 22, is to be a temporary solution but has turned out to be the end result in politically sensitive disputes, such as *Bananas* and *Beef Hormones*, among others. In fact, there are calls from the business community and others to recognize that the DSU Understanding needs more flexibility and a return to more diplomatic solutions than the approach taken under the DSU.

The Panel's report is presented to the DSB for adoption within sixty days of the circulation of the report to Members. A party may appeal to the seven member Appellate Body on the law and legal interpretations embodied in the report of the Panel. The DSU sets a timetable of sixty days from the appeal.[30] The Appellate Body report and its recommendations are then considered by the DSB for adoption.[31]

Since the complaints concern inaction, an initial issue will be how to define the measures to be examined. The substance of the EC's rules are not the issue. Rather it is the blockage in the approval process that is being challenged. Nothing in European Communities law requires or condones a "moratorium." In fact, the Novel Foods Directive, for example, contains specific procedural time limits,[32] as does Directive 2001/18 on deliberate release.[33] The EC is expected to argue that there was a "suspension" while new legislation was being developed, but not a moratorium. According to the this line of argument, the spring 2004 approvals show that the suspension is no longer in place, rendering the disputes moot. [34]

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at art. XIII. However, since this dispute does not involve the question of risk or another scientific issue, the Panel probably will have no reason to seek advice from exports.

[29] *Id.* art. XIX, para. 1.

[30] DSU Understanding, Art. XVII, para. 5.

[31] *Id.* art. XVII, para. 14.

[32] Council Regulation 258/97, art. 6, 1997 O.J. (LO43) ("[t]he initial assessment report shall be drawn up within a period of three months"); and *id.* art. 13 (mandating action by the European Commission if the Council of Ministers has not acted in three months).

[33] Council Directive 2001/18/EC, art. 6, 2001 O.J. (L 106) concerning deadlines in the standard authorization procedure.

[34] This was the preliminary characterization of the EC position offered by Paola Testori Coggi, Director, Directorate-General for Health and Consumer Protection, European Commission, at Conference on *The Regulation of Food Safety and the Use of Traceability/Trace-Back in the EU and the USA: Convergence or Divergence?*, Washington, D.C., (Mar. 19, 2004).

THE CLAIMS

In its Request for the Establishment of a Panel, the United States said the EC "has applied a moratorium on the approval of products of agricultural biotechnology,"[35] e.g., the suspension of reviews and approvals, on the one hand, and the failure to consider certain applications for approval. The specific EC measures being challenged include the "suspension" of consideration of applications for, or granting of, approval of biotech products and the failure to consider certain applications for approval. The Member States's measures being challenged by the United States are "national marketing and import bans," which were introduced although the EC had approved the products for importation and placing on the market.[36] As explained by the Office of the U.S. Trade Representative, for "five years, the EU has kept in place a ban on biotech approvals – a ban which is unsupported even by the EU's own scientific studies."[37]

Argentina, in its Request for the Establishment of a Panel, referred to a "*de facto* moratorium" on the approval of biotechnology products since October 1998. It says that the moratorium led to "[t]he suspension of consideration of applications for approval of GM products" and "[t]he failure to consider for approval applications for the specific GM products notified under relevant EC legislation."[38] It also contests the "bans" on four maize imports imposed by Austria, Germany, Italy and Luxembourg. The Canadian Request for the Establishment of a Panel is similar to the other two. It also says that the EC maintains a "moratorium" and "effectively has suspended the consideration of applications . . . and the granting of approvals . . . under the relevant EC approvals processes."[39]

Either could involve several reviewing entities. The approval process for authorization to market a GMO involves both the Commission and the Member States and can also include a referral to the Scientific Committees, the Regulatory Committee and the Council of Ministers.

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[35] Report of the Appellate Body, European Communities-Measures Affecting the Approval and Marketing of Biotech Products, Request for the Establishment of a Panel by the United States (Aug. 2003) *available at* www.law.georgetown.edu/current/9mos/documents/DS291-23.doc.

[36] *See*, Press Release, Office of the U.S. Trade Representative *United States Requests Dispute Panel in WTO Challenge to EU Biotech Moratorium* (Aug. 7, 2003) *available at* www.ustr.gov/releases/2003/08/03-54.pdf.

[37] *Id.*

[38] www.law.georgetown.edu/iiel/current/gmos/gmos_wto.html

[39] Report of the Appellate body, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, Request for the Establishment of a Panel by Canada, WT/DS292/17 (Aug. 8, 2003), *available at* www.law.georgetown.edu/iiel/current/gmos/documents/DS292-17.doc.

THE MEASURES

Two different approval processes are under challenge, although the Requests make no distinction between them. Directive 2001/18 concerns the deliberate release into the environment of genetically modified organisms and their placing on the market. According to the Preambular language, "the protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of genetically modified organisms (GMOs)."[40] The Preamble also refers to both preventive action and the precautionary principle.

Regarding the deliberate release of GMOs in the EC, the process begins with an application (including an environmental risk assessment) to a competent authority in the Member State where the product will first be placed on the market [41] The competent authority may determine that the EC criteria for deliberate release have not been met and may reject the application.[42] No deliberate release is authorized unless the competent authority gives its written consent.[43]

Over the years, the Member States have retained the authority to take safeguard measures. They could invoke Article 16 of Directive 90/220, which authorized Member States to restrict provisionally or to prohibit the use and/or sale of a product in its territory in spite of the Commission's written consent, whenever the Member State justifiably considers that the product presents a risk to human health or the environment. Austria, France, Germany, Greece and Luxembourg invoked this safeguard clause of Directive 90/220. However, their justifications were not such as to allow the Scientific Committees to support the restrictions. The Commission asked the five Member States to withdraw their safeguard measures, lift the prohibitions and submit them under the (then) new safeguard provisions of Article 23 of new Directive 2001/18.[44]

The procedure for the approval of an experimental release is somewhat different. The application is still made to the national authorities and must include an environmental risk assessment. If the Member State gives a favorable opinion, it so notifies the other Member States through the European Commission. The other Member States may object, but if neither does, the first Member State grants consent to place the product on the market. That authorization oper-

[40] Council Directive 2001/18, preamble (7).
[41] Council Directive 2001/18, art. 6.1.
[42] *Id.* at art. 6.5(b).
[43] *Id.* at art. 6.8..
[44] Article 23 permits the provisional restriction or prohibition on the use and/or sale of a GMO on its territory when there is new or additional information providing a basis for considering that a GMO as or in a product constitutes a risk to human health or the environment. *Id.* at art. 23.1.

ates to make the product marketable throughout the single market.

On the other hand, when a Member State objects, the process shifts to the Community level. The European Commission requests an opinion from the Scientific Committees. If their opinion is favorable, the Commission prepares a draft Decision and submits it to the Regulatory Committee for its opinion. When that opinion is favorable, the Commission adopts the Decision. When their opinion is not favorable, the Commission presents its draft Decision to the Council of Ministers, which may adopt it by a qualified majority or reject it. However, if the Council fails to act within three (3) months, then the Commission may adopt the Decision. It is under this 90 day procedure that the Commission decided to go forward with its spring 2004 approvals, obviating what would have been a politically charged, qualified majority process.

Novel foods, e.g., those containing, consisting or produced from GMOs, undergo a separate authorization process Regulation (EC) No 258/97[45] governs the placing on the market of finished products like tomato paste "derived" from a GMO. Under EC perceptions, these novel foods raise not environmental, but consumer protection and food safety concerns, as made clear in Article 3.1. Novel foods must not present a "danger" for the consumer, mislead the consumer or "differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer."[46] The approval process includes a review of the product's label.[47]

The process begins in a Member State and includes the transmittal of any favorable opinion to the other Member States through the Commission.[48] Unlike the deliberate release rule, however, if there are no objections, the original Member State may authorize the product to be placed on the single market.[49] On the other hand, if there are objections, the Commission must consult the Scientific Committees and the Regulatory Committee.[50] Following a favorable opinion from the latter body, the Commission may adopt a Decision. A simplified procedure may be used for foods like cooking oils that are derived from but no longer contain GMOs and that are substantially equivalent to existing foods.[51] For these products there is a notification rather than an application process, with the notification made to the

[45] Commission Regulation 258/97, 1997 O.J. (L 43) 1; also *available at* http://www.biosafety.be/GB/FF/Dir.Eur.GB/258-97/258-97.html.
[46] *Id.* at art. 3.1.
[47] *Id.* at art. 8.
[48] *Id.* at art. 4.
[49] *Id.* at art. 4.2.
[50] *Id.* at art. 7.
[51] *Id.* at art. 5.

Commission rather than to a Member State.[52]

A Member State may invoke the safeguard clause of Article 12 of the Novel Food Directive when, as a result of new information or a reassessment of existing information, it has "detailed grounds" for considering that the "use" of the GM food endangers human health or the environment.[53] Italy took such an action concerning four GM maize varieties that had been notified under the procedure for products claimed to be substantially equivalent to existing foods.

LEGAL ISSUES

The three governments cite both the SPS and TBT Agreements as the basis for their claims. In theory the two are mutually exclusive, with the former applying to food safety measures and the latter to other GATT Article IIII:4 type barriers, including those related to the trade/environment link. Which agreement guides the analysis should depend on the rationale underlying the measure. There are conditions for the imposition of either an SPS or a TBT measure. The conditions restricting the exercise of food safety measures are more onerous and include the requirement of an analysis of the risk. Consequently, the characterization of the EC's measures is fundamental to the analysis of the disputes. The United States insists that these are food safety measures. The EC asserts that it has determined that the foods are safe and has lifted the suspension. The consequence is assumed to be that it is inappropriate to judge the dispute under the SPS Agreement.

Each request for a Panel cites the Agreement on the Application of Sanitary and Phytosanitary Measures, the Agreement on Technical Barriers to Trade, the Agreement on Agriculture and certain Articles of GATT 1947 in support of the Request. Under the first two agreements, which are the heart of the claims, the panel will examine the measure(s) taken by the EC. If the measures are considered food safety measures, then the SPS Agreement applies. That Agreement was interpreted in WTO disputes concerning *Beef Hormones*,[54] *Salmon*[55] and *Varietals*.[56] On the other hand, if the measures are not food safety measures, they are governed by the TBT Agreement, which was considered in *Asbestos*. The defense against a TBT claim is easier than the defense against an SPS claim. In the three SPS disputes and in *Asbestos* the choice between agreements was not an is-

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[52] *Id.*

[53] *Id.* at art. 12.1.

[54] *See* Michael Paulson, WTO Case File: *The Beef Hormone Case*, Nov. 22, 1999 *at* http://seattlepi.nwsource.com/national/case22.shtml.

[55] Report of the Appellate Body, Australia – Measures Affecting Importation of Salmon, WT/DS18/AB/R, *at* http://www.wto.org, (Oct. 20, 1998) [hereinafter Salmon].

[56] Report of the Appellate Body, Japan – Measures Affecting Agricultural Products, WT/DS/AB/R *at* http://www.wto.org,(adopted Mar. 19, 1999) [hereinafter Varietals].

sue.

In *Asbestos* the Appellate Body, when considering Canada's argument that the full text of a decree should have been considered as a whole, said that the "proper legal character of the measure at issue cannot be determined unless the measure is examined as a whole .... [T]o characterize the measure simply as a general prohibition, and to examine it as such, overlooks the complexities of the measure, which include both prohibitive and permissive elements."[57]

It is not clear whether a measure may fall under more than one Agreement. Perhaps this would be possible if the underlying text were considered and analyzed as independent articles, with each considered independently. The Requests complain about a process, however, not about specific articles of the EC laws. The process implements measures whose purposes seems to cut across the SPS and TBT Agreements raises novel issues.

After determining whether the SPS or TBT Agreement applies, it is likely that the biotech disputes will turn on defenses, since the fact of an effective ban on imports is difficult to dispute. Is there a justification for the inaction under the GATT 1947 or either of the agreements cited?[58] The possible responses vary by agreement.

The WTO Agreements and Federal Systems

Member States retain authority to restrict imports, under Articles 16/23 of the deliberate release rule[59] and Article 12[60] of the Novel Foods Directive. Although their actions have an effect on international commerce, the WTO rules have limited applicability to states in federal systems or to the Member States in these disputes. In fact, although the U.S. Request for a Panel mentions the failure of some Member States to approve applications, the Request does not refer to Article 7 of the TBT Agreement or to Article 13 of the SPS Agreement.

The SPS Agreement

The United States will try to make this an SPS dispute, because the rules of the SPS Agreement impose a high burden on the Member seeking to apply an SPS measure.[61] The EC is likely to argue that its

[57] Report of the Appellate Body, European Communities – Measures Affecting Asbestos and Asbestos Containing Products, para. 64, WT/DS135/AB/R, *at* http://www.wto.org (Mar. 12, 2001).

[58] Based on Appellate Body reports, apparently a measure whose substance falls under the SPS or TBT Agreement and is contrary to the Agreement, is not saved by Article XX.

[59] Council Directive 2001/18/EC, arts. 16, 23, 2001 O.J. (L 106) 1.

[60] Commission Regulation 258/97.

[61] The U.S. Request for a Panel cites Articles 2.2, 2.3, 5.1, 5.2, 5.5, 5.6, 7 and 8, as well as Annexes B(1), B(2), B(5), C(1)(a), C(1)(b) and C(1)(e) of the SPS Agreement.

measures must be judged under the TBT Agreement and might argue that neither agreement covers the Member State actions.[62]

An action to protect human health will be judged under the rules of the SPS Agreement.[63] The agreement was included among the Uruguay Round trade agreements to complement the Agreement on Agriculture. The negotiators believed that Members might try to use non-tariff measures, especially sanitary and phytosanitary measures, to thwart the market access opportunities built into the Agreement on Agriculture. The SPS Agreement contains standard GATT rules, such as the requirements that the measure be necessary,[64] may not be applied in a manner that would constitute a disguised restriction on international trade,[65] and may be applied only to the extent necessary to protect human health.[66] However, it is notable for several new rules. Foremost is that there must be sufficient scientific evidence to support the measure. A food safety measure must be based on scientific principles,[67] may not be maintained without sufficient scientific evidence in general,[68] and must be based on a risk assessment.[69] There are other new ideas in the agreement. It requires Members to lean towards harmonization of food safety standards by requiring them to base their measures on an international standard (most likely a Codex standard in the case of food safety measures) unless that standard is contrary to the Member's chosen appropriate level of protection.[70] A restrictive import measure must apply only to the geographical area that presents a hazard, even if that is only one region and not the entire country of export. There is a rather opaque equivalence requirement, which is still being deciphered by Codex. These rules were interpreted in *Beef Hormones, Salmon and Varietals*. [71]

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[62] The EC Commission has had its own difficulties with Member States and biotech rules. *See, e.g.*, Case C-296/01, Minister of Econ. Affairs, Fin.and Indus.v. GEMO SA (Nov. 20, 2003). The Court of Justice of the European Communities ruled that France had not fulfilled its obligation to transpose Directive 90/220/EEC before the deadline for implementation.

[63] To exclude doubt, the TBT Agreement notes that it does not apply to sanitary and phytosanitary measures as they are defined under the SPS Agreement. TBT Agreement, Art. 1.5.

[64] SPS Agreement, Art. 2:2.

[65] SPS Agreement, Art. 2.3.

[66] SPS Agreement, Art. 2:1.

[67] SPS Agreement, Art. 2.2.

[68] SPS Agreement, Art. 2.2.

[69] SPS Agreement, Art. 5. Article 5 was explored in Beef Hormones and Salmon.

[70] S6 SPS Agreement Art. 3.1 and 3.3.

See also, Marsha A. Echols, FOOD SAFETY AND THE WTO: THE INTERPLAY OF CULTURE, SCIENCE AND TECHNOLOGY, The Hague: Kluwer Law International (2001)

The TBT Agreement

The requests for a Panel make claims under the TBT Agreement.[71] Measures that fall under the TBT Agreement are called technical reglations, standards[72] and conformity assessment procedures.[73] The US/EC dispute involves a technical regulation, since the measures in dispute lay down "product characteristics or their related processes and production methods, *including the applicable administrative provisions,* with which compliance is mandatory."[74]

Consumer and environmental protection measures are judged under the TBT Agreement, which requires that a technical regulation not be "applied with a view to or with the effect of creating unnecessary obstacles to international trade,"[75] among other criteria. The relationship between the WTO and environmental protection has been confronted by the Cartegena Protocol on Biosafety to the Convention on Biological Diversity.[76] These issues might form the turning point of the disputes, overshadowing the food safety analysis. They would present new issues for the WTO and would involve a consideration of two contentious issues, the precautionary principle (or approach) and other legitimate factors. The precautionary principle and the role of other legitimate factors could be among the most contentious issues.[77] Article 1 of the Directive (Objective) and Article 4 (General obligations) refer to the precautionary principle. Both would be considered

[71] The U.S. Request for a Panel cites Articles 2.1, 2.2, 2.8, 2.9, 2.11, 2.12, 5.1.1, 5.1.2, 5.2.1, 5.2.2, 5.6 and 5.8.

[72] A standard is a voluntary rule, guideline or statement of characteristics for a product or "related processes and production methods." TBT Agreement, Annex I, para. 2.

[73] A conformity assessment procedure is any procedure "used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.." TBT Agreement, Annex I, para. 3.

[74] TBT Agreement, Annex I, para. 1 (emphasis added).

[75] TBT Agreement, Art. 2.2.

[76] Article XX contains general exceptions to the rules promoting free and nondiscriminatory trade. Subsection (g) permits certain restrictive measures relating to the conservation of exhaustible natural resources.

[77] In its preamble, Directive 2001/18 refers to the Treaty Establishing the European Community, which says that environmental action must be based on the principle that preventive action should be taken. More specifically, the preamble states that the "precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it." Article 5.7 of the SPS Agreement is considered a reference to the exercise of precaution, as recognized in *Beef Hormones* and *Varietals.* However, it is less well developed in trade law than in environmental law. *See, e.g.*, the Rio Declaration on Development and the Environment, whose Principle 15 states that "lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" and the Cartegena Protocol. The Protocol regulates trade in living modified organisms (LMO's). It is possible that this highly divisive issue will be avoided by the U.S. and EC, which seem intent on backing away from political disputes.

not as they apply to a substantive measure, but to a process.

The TBT Agreement applies to measures taken for environmental reasons. The environmental issues might be at issue because of the EC's Directive regarding experimental release.[78] The environmental consequences of the release of biotech organisms is replacing food safety as the principle concern of European consumers.[79] Under that Directive there was a case by case assessment of the risks to human health and to the environment before a GMO (e.g., insects, microorganisms, organisms) or a food product, (e.g., maize, soybeans), can be released into the environment or placed on the market.[80] In addition, the last sentence of the Preamble to the Agreement on Agriculture notes that the agricultural commitments in the Agreement "should be made in an equitable way among all Members, having regard to non-trade concerns, including . . . the need to protect the environment."[81]

In addition to requiring most favored nation and national treatment, [82] the TBT Agreement contains general rules against creating unnecessary obstacles to international trade, i.e., the technical regulation must not be more restrictive than necessary to fulfill a legitimate objective,[83] requiring the use of some or all of an international standard to be the basis for the measure, [84] and requiring, whenever appropriate, that the technical regulation be based on product performance standards rather than design or descriptive characteristics,[85] and the "right to an assessment of conformity."[86] Importantly, conformity assessment procedures may not be applied more strictly than "necessary to give the importing Member adequate confidence that products

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[78] Council Directive 2001/18, O.J. L 106 of April 17, 2001 and Commission Regulation 258/97, O.J. L 043 of February 14, 1997 are the primary rules being challenged as crucial to blocking the approval process. Part B of the Directive concerns deliberate release of GMOs, while Part C contains the rules and procedures regarding the placing on the market of GMOs as or in products. However, the U.S. request for a panel also cites the rule prior to Directive 2001/18, i.e., Council Directive 90/220, O.J. L 117 of May 8, 1990, as amended by Council Directive 94/16 O.J. L 103, April 22, 1994.

[79] [127] European Commissioner for Health and Consumer Protection, David Byrne, Address at the Conference on The Regulation of Food Safety and the Use of Traceability/Tracing in the EU and the USA: Convergence or Divergence (March 19, 2004), *available at* http://www.eurunion.org/News/speeches/2004/040319db.htm.

[80] Council Directive 90/220 was repealed and updated by Directive 2001/18 of the European Parliament and Council.

[81] Agreement on Agriculture, Apr. 15, 1994.

[82] TBT Agreement, Art. 2.1.

[83] TBT Agreement, Art. 2.2. Although this Agreement does not apply to sanitary (food safety) measures, "protection of human health or safety" is one of the legitimate objectives. *Id.* Protection of the environment is another. *Id.*

[84] TBT Agreement, Art. 2.4.

[85] TBT Agreement, Art. 2.8.

[86] TBT Agreement, Art. 5.1.1.

conform" with the technical regulation.[87] The Agreement also contains procedural rules, including the procedures for assessment of conformity in Articles 5 (by central government bodies) and Article 7 (by local government bodies) as well as several notification and publication rules.[88] For example, Members must ensure that conformity assessment procedures are "undertaken *and completed* as expeditiously as possible."[89]

The text of Article 2.2 gives a clue to what the EC might argue, i.e., that it is pursuing a legitimate objective, "taking account of the risks non-fulfillment would create."[90] Consequently, the EC might argue that it is not creating an unnecessary obstacle to trade. The protection of the environment is explicitly mentioned as a legitimate objective. The list is non-exhaustive, however, leaving room for the EC's possible argument that responding to consumer concerns and the exercise of precaution are legitimate objectives.

The Agreement on Agriculture

The only reference in the Requests to the Agreement on Agriculture is to its Article 4 (Market Access).[91] Article 4 of the Agreement on Agriculture contains a specific market access commitment, which cross-references the Schedules of concessions.[92] Subsection 2 prohibits its Members from maintaining, resorting to or reverting to any measures that were converted to customs duties from quantitative import restrictions.[93] The U.S. Request specifically refers to Article 4.2: "Members shall not maintain, resort to, or revert to any measure of the kind which have been required to be converted into ordinary customs duties," such as quantitative import restrictions.[94]

The GATT 1947 Claims

Although it is clear that the three Members base their claims primarily on the new Agreements, they also make claims under rules that pre-date the WTO.

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[87] TBT Agreement, Art. 5.1.2.

[88] *See, e.g.*, TBT Agreement, Art. 5, Art. 7.

[89] TBT Agreement, Art. 5.2.1(emphasis added).

[90] *Id.* at Art. 2.2.

[91] Agreement on Agriculture, Apr. 15, 1994, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Art. 4.2, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND vol. 5 (1994), 33 I.L.M. 1125 (1994) [hereinafter Final Act].

[92] *Id.*

[93] *Id.* at Art. 4.2

[94] Final Act, Art. 4.2.

Nondiscrimination

Several of the GATT 1947 rules on which the complainants rely concern non-discrimination among the products of various Members and between an imported product and local production. The Article I:1 claim concerns discrimination among the products of competing exporters. Article I of the GATT 1947, the most-favored-nation rule, states that: ". . . with[95] respect to all rules and formalities in connection with importation . . ., and with respect to all matters referred to in paragraphs . . . 4 of Article III, any advantage, favour, privilege or immunity granted . . . to any product originating in . . . any other country shall be accorded immediately and unconditionally to the like product originating in. . .the territories of all other contracting parties."[96] The Article III:4 claim, in contrast, prohibits a different type of favoritism - this time one that favors domestic production. Article III, the national treatment rule, requires in part "treatment no less favourable than 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."[97]

Quantitative Restrictions

The complainants argue that the measures have the effect of restricting the volume of goods shipped to the EC in contravention of Articles X:1 and XI:1 of the GATT 1947. Article X Article XI of the GATT c1947 contain prohibitions on quantitative restrictions, which has many exceptions. Its intent is that Members should use financial controls to regulate the flow of imports, rather than quotas, licenses or other measures.

Nullification and Impairment

The complainants argue that the EC measures nullify and impair benefits from the agreements, without specifically citing Article 3.8 of the DSU. Argentina made the point that, "[a]s a global producer and exporter of biotechnology products, for Argentina the systemic and trade implications of the . . . measures constitute a clear nullification or impairment of its rights under the WTO Agreements."[98] The three Members appear to raise Articles XXIII:1(a) claims of violations of WTO obligations that lead to a nullification or impairment of

[95] General Agreement on Tariffs and Trade, Oct. 30, 1947, Art. I, para. I [hereinafter GATT 1947]. The note at Article III explains that the rule applies even when the measure is applied at the time or, point of importation.

[96] GATT 1947, at Art. III, para. 4.

[97] *Id.* at Art. III.

[98] Request for Consultations by Argentina, European Communities – Measures Affecting the Approval and Marketing of Biotech Products, *at http://www.wto.org*, at 1 (May 21, 2003).

benefits. In its Request, the United States asserts that the EC measures appear to be inconsistent with the Agreements. Argentina states that the measures infringe WTO rules and Community legislation. Canada states that the measures are inconsistent with the EC's obligations under the three agreements and the GATT 1994. The initial theory then seems to be Article XXIII:1(a), although the language used by the United States leaves open the possibility of an Article XXIII:1(b) nonviolation nullification and impairment argument.

In *Asbestos,* the Appellate Body explained the distinction between the two parts of Article XXIII:1.

> A claim under Article XXIII:1(a), therefore, lies when a Member is alleged to have acted inconsistently with a provision of the GATT 1994. Article XXIII:1(b) sets forth a separate cause of action for a claim that, through the application of a measure, a Member has 'nullified or 'impaired' 'benefits' accruing to another Member, 'whether or not that measure conflicts with the provisions' of the GATT 1994.[99]

IMPLEMENTATION

Since the public policy and democratic principles aspects of these disputes are considerable, it can be expected that if the EC is unsuccessful in its defenses, the implementation of DSB recommendations will not be immediate. In fact, the EC might argue that implementation would be contrary to democratic principles.[100]

The WTO has not been successful in the implementation of DSB recommendations in politically sensitive cases. The offending Member has either delayed carrying out the recommendation, as in *European Communities – Bananas*[101] and *United States - Foreign Sales Corporations,*[102] or has failed to comply, as in *European Communities – Beef Hormones.*[103] The DSU offers no alternative to acceptance of the recommendation,[104] making a diplomatic or compromise result

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[99] Report of the Appellate Body, European Communities – Measures Affecting Asbestos and Asbestos-Containing Products *at* http://www.wto.org, at 66-67 (Mar. 12, 2001).

[100] According to Commissioner David Byrne, consumers are becoming more comfortable with biotech foods, in part because of the new labeling and traceability rules. Consequently, the European Commission is able to ground the Spring 2004 rules on notions of consumer choice, instead of food safety.

[101] *See* Report of the Appellate Body, European Communities – Regime for the Importation, Sale and Distribution of Bananas, *at* http://www.wto.org (Sept. 9, 1997).

[102] *See* Report of the Appellate Body, United States-Tax Treatment for "Foreign Sales Corporations" *at* http://www.wto.org, (Nov. 17, 2000).

[103] *See* Report of the Appellate Body, EC Measures Concerning Meat and Meat Products (Hormones), *at* http://www.wto.org , (Jan. 16, 1998).

[104] The general rule states that "[a]n Appellate Body report shall be adopted by the DSB and unconditionally accepted by the parties[.]" Final Act Annex 2, para. 17.14, Apr. 15, 1994, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND vol. 5 (1994), 33 I.L.M. 1125 (1994). The flexibility offered by compensation and the suspension of concessions are only "temporary measures available in the event that the recom-

impossible. Of course, this outcome was desired by the United States and several other countries, which insisted on a degree of certainty, structure,[105] and a new form of consensus to make firm the ultimate findings.[106] Some sovereignty and traditions were sacrificed to trade liberalization. These changes were considered necessary to avoid the delays and other problems that arose in several contentious Article XXIII disputes before the Uruguay Round of Multilateral Trade Negotiations. According to a former Legal Counsel to the WTO, "[t]he principal argument in favor of a relatively more legalistic system is that it would better promote compliance with GATT rules than would a negotiation/consensus system."[107]

However, governments should have some flexibility in their trade and domestic policy. For example, a democratically elected government should be able to take into account and possibly to give priority to genuine popular concerns. This is not possible under DSU Paragraph 22.1.[108] The voices questioning this system are increasing.[109]

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mendations and rulings are not implemented within a reasonable period of time." Final Act, Annex 2, para. 22.1.

[105] *See* Final Act, Annex 2, para. 12.9-10; Final Act, Annex 2, para. 17.5; Final Act, Annex 2, para. 20.1.

[106] A negative consensus is required to block the adoption of the Appellate Body report, thus providing greater assurance that the losing member will be held accountable; "[a]n Appellate Body report shall be adopted by the DSB and unconditionally accepted by the parties to the dispute unless the DSB decides by consensus not to adopt the Appellate Body report within 30 days following its circulation to the Members." Final Act, Annex 2, para. 17.14.

[107] William J. Davey, *Dispute Settlement in GATT*, 11 FORDHAM INT'L L.J. 51 (1987).

[108] The DSU states that, "[c]ompensation and the suspension of concessions or other obligations are temporary measures available in the event that the recommendations and rulings are not implemented within a reasonable period of time. However, neither compensation nor the suspension of concessions or other obligations is preferred to full implementation of a recommendation to bring a measure into conformity with the covered agreements. Compensation is voluntary and, if granted, shall be consistent with the covered agreements." Final Act, Annex 2, para. 22.1.

[109] Echols *supra*, note 118 at pp. 153-154. "The process envisioned by Article 22 of the DSU should be amended and shortened. A Member would (without the DSU Article 22 arbitration on implementation date that delayed *Beef Hormones*) notify the WTO that it will not be able to bring its regulations into conformity with the [SPS] Agreement. The governments involved would immediately begin discussions to develop a mutually acceptable compensation package. If they are unable to reach a mutually acceptable result, *e.g.*, regarding the value of the compensation package or the product coverage, an arbitrator would decide." *Id.* The burden should be placed on the Member opting to compensate instead of comply, for example, in the product coverage or by increasing the value of the compensation package.

CONCLUSIONS

It is too early to know the precise contours of the parties' claims and the EC's responses in these disputes or whether there will be a settlement. An initial consideration of the claims and the relevant EC law leads to the preliminary conclusion that the rulings in the disputes will turn primarily on an analysis of the TBT Agreement rather than the SPS Agreement. This will be the likely result if, for example, the WTO panel decides to consider the link between biotech foods (especially organisms and seeds) and the environment in the importing Member. Given environmental law's reliance on precaution and the flexible language of the TBT Agreement, the exercise of precaution might be judged differently and more flexibly in a TBT case than in an SPS case. However, it is not clear that a panel would import this principle of environmental law into a market access case.

Consumer protection probably will be less important as a justification for the EC measures, although its use also opens another possibility for a case of first impression.

Whichever approach is taken by the WTO, if the EC loses, it is likely to argue that its approval to market a biotech food and its new laws bring it into compliance with WTO obligations. This response could lead to the second set of GMO disputes.