

Vol. 21 No. 38

December 8, 2006

WTO RULING ON BIOTECH FOODS ADDRESSES “PRECAUTIONARY PRINCIPLE”

by

Lawrence A. Kogan

On September 29, 2006, the World Trade Organization (‘WTO’) released its final decision in the long-standing dispute between the United States and Europe over the regulation of genetically modified (‘GM’ or ‘biotech’) food and seed. The WTO Dispute Resolution Panel found that because the European Community (‘EC’) and several European Union member states had acted primarily out of *political* rather than *scientific* concerns to justify their trade-restrictive food safety measures, they clearly violated the tightly drafted provisions of the WTO Sanitary and Phytosanitary (‘SPS’) Agreement. This decision is significant because it clarifies the central role of science in evaluating the presence of health and environmental risks prior to the adoption of national food safety regulations not otherwise based on relevant international standards.

The EU Commission had, from 1998 to 2004, refused to approve outright, and/or unduly delayed approval of, various new biotech crop varieties for cultivation or consumption on health and environmental ‘safety’ grounds. Argentina, Canada and the U.S. sought legal recourse at the WTO in May 2003. Their complaints alleged that these bans constituted an unjustified and illegal denial of access to European markets under WTO SPS law, and that such bans had unnecessarily caused their farmers to incur hundreds of millions of dollars of economic losses each year. The Panel focused on the type of evidence that a WTO member government is permitted to rely on as justification for the imposition of national/regional health and environmental regulatory restrictions which have a substantial impact on international trade flows.

The Fundamental Requirement of an ‘Adequate’ Science-Based Risk Assessment – SPS Article 5.1 and Annex A (4). In its decision, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (hereinafter ‘*EC Biotech Products*’),¹ the Panel reaffirmed that WTO member countries concerned about the safety of specific biotech food-related imports must follow the specific terms of the WTO SPS Agreement. Pursuant to the SPS Agreement, countries may restrict imports of certain products in order to safeguard human or animal health, or to protect the environment, provided the regulations they enact either are in accordance with existing relevant international standards, or are narrowly drafted in order to protect against a

¹*European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, Report of the Panel, WT/DS291/R, WT/DS292/R and WT/DS293/R, final report issued Sept. 29, 2006, at http://www.wto.org/english/news_e/news06_e/291r_e.htm.

Lawrence A. Kogan is an international business, trade, and regulatory attorney. He is CEO of the Institute for Trade, Standards and Sustainable Development, Inc. (ITSSD), a Princeton, NJ-based non-partisan non-profit international legal research and educational organization. The author would like to thank Gregory Conko for his assistance in the preparation of this article. A longer analysis of the WTO decision by Mr. Kogan will be published in *Global Trade and Customs Journal*, Vol. 2 No. 3 (Kluwer Mar. 2007).

genuine ascertainable risk, as determined by the application of best available science.

This most recent WTO Panel decision makes clear that in the absence of relevant international standards, or a national government's refusal to adopt them, a concerned WTO member bears the burden of conducting an objective, empirically-based scientific risk assessment. And this must be done *before* a WTO member promulgates regulations that have the effect of denying or restricting market access to those products. The Panel looked to whether the EC and several EU member states had fulfilled their threshold task: to undertake an 'adequate risk assessment.' In this regard, the Panel found that while the EC and several EU member states had endeavored to conduct *a* risk assessment, what they performed failed to qualify as an *adequate* risk assessment within the meaning of SPS Article 5.1 and Annex A(4).

The WTO Panel reasoned that the EC and EU member states could not rely on either non-expert nongovernmental organization reports or general scientific studies appearing in peer-reviewed journals which did not otherwise provide an assessment of specific context-based health or environmental risks pursuant to specifically defined scientific protocols. Indeed, in the Panel's view, these sources did not constitute an 'adequate' risk assessment because, *prima facie*, they did not look to or take "into account risk assessment techniques [protocols] developed by the relevant international organizations." These organizations and their protocols include the general risk analysis and more specific biotech foods standards prepared by the Food and Agricultural Organization's Codex Alimentarius Commission ('Codex'); the International Standards for Phytosanitary Measures ('ISPMs'); and the animal health standards prepared by the Office International des Epizooties (International Epizootic Office 'OIE').

The Panel proceeded to explain in more detail how the EC and EU member states had failed to undertake an 'adequate risk assessment' of their own. While doing so, the Panel also distinguished between the environmental and health concerns of scientists, which are typically substantiated through application of scientific method, and those of legislators, which are often based on unverifiable facts and public fears. In the Panel's view, legislators' concerns are relevant primarily for *managing* potential product risks whose degree of 'safety' scientists have already assessed in gauging how to arrive at the 'appropriate level of regulatory protection' (i.e., fulfilling the legislators' protection goals). Legislators' concerns may even "have a bearing on the question of which risks a Member decides to assess with a view to taking regulatory action, if necessary," on safety grounds. Scientists' concerns are relevant for identifying and evaluating (i.e., *assessing*), in the first instance, the existence and magnitude of potential health and/or environmental safety risks posed by a specific product. In effect, the Panel rejected the argument, and focused on how neither the language of the SPS Agreement, nor relevant WTO jurisprudence "suggest[s] that a risk assessment had to be adequate *for the purposes of a Member's legislator*" (emphasis added). According to the Panel, there is "only one relevant relationship: that between the scientific evidence and the obligation to perform a risk assessment under Article 5.1"

The Unavailability of SPS Article 5.7 Safeguard (Precautionary) Measures. The *EC Biotech Products* decision is especially significant for its discussion of the Precautionary Principle's legal status within the confines of WTO law. The broad Precautionary Principle (as opposed to a more limited, provisional and facts-oriented Precautionary Approach) is a general European 'better-safe-than-sorry' philosophy of regulation that has assumed the status of regional law within the EC, and perhaps, even the status of international environmental law. The EC has based regulations on the Precautionary Principle to ban or severely restrict the market access of substances, products and activities if they are merely believed to pose uncertain hypothetical health and environmental hazards, as opposed to specific risks. The EC has repeatedly argued that scientific uncertainty as to cause and effect, magnitude, or severity is not an excuse to avoid employing precautionary measures, and that the conventional science-based risk assessments required by SPS Article 5.1 are not enough, and must be bypassed, to prevent such hazards from materializing in the first place. The Appellate Body previously acknowledged that SPS Article 5.7 reflects a Precautionary Approach as opposed to the Precautionary Principle.

The WTO Panel, in the *EC Biotech Products* case, found that the EU and the EU member states were ineligible to invoke the limited and provisional safeguard measures (a Precautionary Approach) afforded by SPS Article 5.7. Apparently, these parties had claimed that SPS Article 5.7 entitled them to employ the broader Precautionary Principle because of the 'scientific uncertainty' surrounding the health and environmental risks about which their legislators were concerned. They also argued that in any event, the concepts of 'scientific

uncertainty' (relating to the Precautionary Principle) and 'insufficient scientific evidence' (relating to a Precautionary Approach) as defined by SPS Article 5.7 were interchangeable as a matter of WTO law, thereby rendering the requirement of a science-based risk assessment inapposite.

The Panel rejected each of these claims, relying on the clear language of Article 5.7. According to the Panel, a WTO member must satisfy all four of Article 5.7's *cumulative* requirements in order to invoke its provisions. "Whenever one of these four requirements is not met, the measure at issue is inconsistent with SPS Article 5.7."

The Panel's decision then proceeded to focus on the first of these requirements, as it set forth the following factual and legal bases explaining why Article 5.7 was unavailable to the EC and the several EU member states.

Insufficient Scientific Evidence Does Not Excuse the Requirement to Conduct a Risk Assessment.

First, the Panel determined, as a matter of law, that the 'insufficient scientific evidence' language of Article 5.7 does *not* permit WTO member states to bypass the SPS Article 5.1 requirement to conduct an adequate science-based risk assessment. It based its determination on the previous Appellate Body ruling in the *Japan-Varietals* case. In effect, the Panel embraced the proposition that, "if a measure is not based on a 'risk assessment', it can be presumed *not* to be based either on 'scientific principles', within the meaning of SPS Article 2.2, or to be maintained without 'sufficient scientific evidence'" as required by SPS Article 5.1.

The EC and EU Member States Actually Possessed Sufficient Scientific Evidence to Conduct a Risk Assessment. Next, the Panel found that the EC and EU member states had failed to show that there was 'insufficient scientific evidence' to conduct a science-based risk assessment on each product, with respect to each risk in question. Indeed, much to the contrary, the WTO Panel determined that the EC's relevant scientific committees had, in fact, reviewed and evaluated the human health and environmental risk information provided by both the Community and the various EU member states. The relevant EC scientific committees had not even considered whether any EU member state's information called into question their previous conclusions. Consequently, the Panel ruled that 'sufficient scientific evidence' existed.

'Scientific Uncertainty' and 'Insufficient Scientific Evidence' Are Not the Same. Third, the WTO Panel specifically rejected as a matter of law the EC's and EU member states' argument that the extra-WTO Precautionary Principle permitted them to ignore their own scientific risk assessments because of the existence of 'scientific uncertainty.' The WTO Panel ruled that a risk assessment otherwise satisfying the conditions imposed by SPS Article 5.1 and Annex A4 would not cease being a credible risk assessment, merely because WTO member legislators lacked absolute confidence in it. Furthermore, it stated that to the extent a WTO member harbors any scientific uncertainties or political discomfort with its risk assessment, that member should consider those factors when determining how to *manage* the health and environmental risk(s) about which it is concerned.

However, the kind of broad scientific uncertainty relied upon by the EC and EU member states is *not* the same thing as having 'insufficient' scientific evidence to make a regulatory decision. In this regard, the Panel distinguished, as a matter of law, between the narrowly defined standard of 'insufficient scientific evidence' referenced in SPS Articles 5.1 and 5.7 (indicating a Precautionary Approach), and the broader Precautionary Principle-based notion of 'scientific uncertainty,' which the EC and the EU member states endeavored to have *read into* SPS Article 5.7. The Panel supported this distinction by referencing the Appellate Body's conclusion in the prior *EC-Hormones* case.² In *EC-Hormones* the Appellate Body ruled that although Article 5.7 may reflect a Precautionary Approach, "the [P]recautionary [P]rinciple, as such, was *not* written into the SPS Agreement as a ground for justifying an SPS measure *that is otherwise inconsistent with the Agreement*" (emphasis added).

Passing on the Status of the Precautionary Principle as a Matter of Customary International Law. Moreover, the Panel refused to embroil itself in the continuing international debate over the legal status of the Precautionary Principle. That debate has persisted since at least January 1998, when the *Beef Hormones* case was decided. As the *EC Biotech Products* decision noted, "there has, to date, been no authoritative decision by an

²See the Appellate Body Report on '*EC Measures Concerning Meat and Meat Products (Hormones)*', hereinafter '*EC Hormones*', adopted on Feb. 13, 1998, WT/DS26/AB/R; WT/DS48/AB/R.

international court or tribunal which recognizes the [P]recautionary [P]rinciple as a principle of general or customary international law.” The Panel also noted that there was not even a single, definitive formulation of the principle. After finding that the principle’s legal status outside the boundaries of international trade law was irrelevant to the case at hand, the Panel passed on offering its own opinion on this matter.

UN Biosafety Protocol Norms Do Not Govern Interpretation of WTO Law for Non-Biosafety Protocol Treaty Parties. Finally, the WTO Panel rejected the EC’s and EU member states’ efforts to invoke the Precautionary Principle as an applicable non-WTO treaty norm that could serve as a viable defense of its regulatory system. The EC had alleged, for example, that the Precautionary Principle plays a central role within the 2000 Cartagena Protocol on Biosafety to the United Nations Convention on Biological Diversity (commonly known as the Biosafety Protocol), even though referring to a ‘Precautionary Approach’ rather than the ‘Precautionary Principle’ appears within the text of the Protocol. The EU sought to obtain this result even though Argentina, Canada, and the U.S. have neither ratified the Biosafety Protocol nor interpreted it in this manner, and although the U.S. has not ratified its parent, the Convention on Biological Diversity.

The Last Word. Given the 2005 speech made by EU Enterprise and Industry Commissioner Gunter Verheugen before EuropaBio, the European association for bio-industries, it would appear that some EU Commission officials believe that the successful promotion of biotechnology depends on the regulatory debate remaining ‘science-based.’³ However, neither Commissioner Verheugen, nor the WTO, nor the plaintiffs in this *EC Biotech Products* case are likely to have the last word. At least one NGO, the Institute for Agriculture and Trade Policy (IATP), has already alleged that the Panel’s final decision had been substantively revised from its earlier interim (Feb. 2005) decision, as the result of strong political pressure applied by the plaintiffs. And, in an effort to confuse policymakers, the IATP has claimed that these changes will expose “the precautionary approach to regulation” (what they really mean to say, is, the Precautionary Principle) to an indefinite “threat of further litigation.” Considering the growing trade distortions that the EU’s new regulatory regime for food biotech products has triggered, both within and outside the European region, this is far from a remote possibility.

Anticipating the WTO Panel’s decision and the continuing uncertainty over the relationship between the Precautionary Principle and WTO law, its supporters, including both activist groups and governments, have enlisted the assistance of the United Nations University Institute of Advanced Studies. Their goal is to incorporate the broad-based Precautionary Principle within WTO jurisprudence. The UNU-IAS, for example, has undertaken a series of studies, the first of which was released during November 2005, “to explore the role of precaution in the WTO Agreements...[in an effort]...to shed light on proposals to enhance the incorporation of this principle in the rules of the multilateral trading system and to diminish tensions in this regard between the WTO and MEAs.”⁴ In particular, these reports seek to define precisely under what circumstances the *extra*-WTO Precautionary Principle would constitute disguised trade protectionism, and which party bears the scientific burden of proof when there is a disagreement about a product’s safety, *within* the WTO regime. According to A.H. Zakri, Director of the UNU-IAS, they aim to develop a common international definition of the Precautionary Principle, a common international threshold for risk and/or a common practice of risk assessment that is applicable under WTO law, in order to “highlight[] similarities and differences between agreements and organizations with respect to precaution” for purposes of resolving these regulatory debates.

Skepticism notwithstanding, it is difficult to imagine how calls to avoid the international acrimony and debate surrounding the Precautionary Principle, particularly, allegations that it is being used as a new form of disguised protectionism, are not actually intended themselves as a disguised effort to weave divisive cultural differences into the WTO Agreements.

³See Gunter Verheugen, “The Commission’s New Biotechnology Policy”, Biotechnology Policy Day High Level Roundtable (9/22/05) at 4, cited in “Biotechnology Debate Must Remain Science-Based, Says Verheugen” Latest News (9/29/05) at http://www.checkbiotech.org/root/index.cfm?fuseaction=news&doc_id=11324&start=1&control=221&page_start=1&page_nr=101&pg=1.

⁴See Sabrina Shaw and Risa Schwartz. “Trading Precaution: The Precautionary Principle and the WTO” at 1, at <http://www.ias.unu.edu/binaries2/Precautionary%20Principle%20and%20WTO.pdf>.