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# Science and Precaution in EC - Biotech: A Brief Analysis of the first US Submission

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## I. Introduction

In 2003, the United States launched one of the most awaited cases in WTO history. European Communities – Measures Affecting the Approval and Marketing of Biotech Products (*EC – Biotech*)[2] was anticipated, with eagerness or trepidation, by national governments all over the world, environmentalists, consumers, farmers, biotech companies, and many others. While the potential significance of its effects was clear, however, only with the first US submission, presented on April 21st, 2004, did the legal contours of the case begin to be elucidated.

The present note will briefly examine some of the arguments presented by the United States, particularly in light of WTO jurisprudence and other relevant rules of international law. Section II will provide an overview of the first US submission. Section III will focus on the US arguments regarding Articles 2.2 and 5.1 of the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), as well on Article 5.7 of the SPS Agreement, which was not addressed by the United States but could be pivotal in the case. Section IV will then look at the potential role and influence of the Cartagena Protocol on Biosafety[3] (Biosafety Protocol) on the case.

## II. Overview of the First US Submission

Science, not surprisingly, is the focus of the US submission. While the request for consultations mentioned that the EC measures at issue appeared to be inconsistent with a number of WTO agreements, the US submission deals exclusively with claims under the SPS Agreement. This was expected for two reasons. First, the SPS Agreement clearly governs any measure applied by a WTO Member to protect human, animal or plant life or health from risks arising from the pests, disease-carrying organisms, additives, toxins, etcetera, that may affect international trade.[4] Second, and more importantly in this case, it is the only WTO instrument that requires measures to be based on scientific evidence, thus establishing a higher burden of proof for the EC than might have resulted from the other agreements.[5]

While the US submission pursues several types of claims on the basis the SPS Agreement, the present note will focus on the claims related to Article 5.1, which establishes the obligation to base SPS measures on a risk assessment (RA), and hence Article 2.2, which is the general obligation to base SPS measures on scientific principles. These articles are at the core of the science-based SPS Agreement and will likely be critical in the case. Moreover, it will look at Article 5.7, which is the sole exception to the Article 2.2 requirements.

## III. Science and Precaution in the SPS Agreement

Given the nature of the SPS Agreement, proving that its measures are based on sound science will be a crucial challenge for the EC. In its submission, the United States claims that the EC measures are not based on a RA as required by Article 5.1 of the SPS Agreement, making them also inconsistent with Article 2.2. As mentioned, it is not considered an easy standard to meet. Moreover, the US submission emphasizes recent WTO dispute settlement developments that may further raise RA standards. The Panel's interpretation of the scope of a RA under Article 5.1 will thus be a significant issue in the case.

In addition, although the United States does not address the issue of whether such an approach is possible or likely, the EC may choose to invoke the only exception provided for by Article 2.2. Article 5.7 allows Members, in situations where relevant scientific evidence is insufficient, to adopt measures based not on scientific principles but on "available pertinent information." The other decisive issue in this case, therefore, will be the interpretation of the conditions that trigger Article 5.7. Both Articles 5.1 and 5.7 issues are analyzed below.

### A. Article 5.1 of the SPS Agreement

As mentioned, Article 5.1 requires SPS measures to be based on RA. The United States claims that no RA were put forth by the EC in regards to its general moratorium and some of its product-specific moratoria and, even in other cases where RA were provided, the final decisions were not "based on" those assessments. The viability and strength of these claims,

however, can only be established after determining what a RA is under Article 5.1 and when Article 5.1 considers measures to be based on a RA.

### 1. What is a risk assessment?

Though the United States asserts that there is no evidence of a scientific assessment "whatsoever," the concrete challenge is that there is no RA as defined by the SPS Agreement in Annex A, paragraph 4. What is, then, the scope of a RA under the SPS Agreement? WTO jurisprudence has, in effect, established a broad scope for RA. In the *EC – Hormones* case, for instance, the Appellate Body (AB), also interpreting the term "RA" on the basis of Annex A, affirmed that the fact that RA were a "scientific process" did mean all matters not susceptible of quantitative analysis were excluded from its scope. The risk evaluated, the AB said, had to be the "risk in human societies as they actually exist"[6]. The *EC – Hormones* case also established that a RA is not a "minimum procedural requirement:" Members are not obliged to carry out their own RA nor are they required to prove that the study was effectively considered by the decision-makers.[7]

The scope of RA established by cases such as *EC – Hormones* was not necessarily restricted by the examination of RA on the basis of the Annex A definitions in the *Australia – Salmon* case, which the US Submission cites.[8] On the contrary, in *Australia – Salmon* the AB highlighted some of its previous statements. For instance, it confirmed that the fundamental element sough in a risk assessment is the objective relationship between the science and the measure, rather than compliance with burdensome procedural requirements.[9] In that sense, the US emphasis on the distinction between "scientific assessments" in general and "risk assessments," referred to in the previous paragraph, may constitute an over-restrictive notion of RA.

Nevertheless, *Australia – Salmon* did contain some elements that could be interpreted to restrict the scope of RA and other cases, such as *Japan – Apples*, are seen by some as following this trend.[10] In the context of biotech products, however, the issue may play out differently. For one thing, Article 5.1 establishes that the RA must be "appropriate to the circumstances," providing for a certain degree of flexibility.[11] The space for the WTO dispute settlement system to consider "product, origin and destination, including, in particular, country specific situations" is crucial not only in light of the unique challenges posed by biotech products, but also in relation to the exceptional challenges facing the EC in the regulation of such a sensitive issue.[12] In this regard, Busch and Howse consider that the WTO is likely to prove somewhat deferential to the EC as the US complaint calls into question its domestic regulatory politics at a fundamental level.[13]

Moreover, the precautionary principle becomes critical in determining the scope of risk assessments, especially in the biotechnology context. After all, Article 5.7 does not exhaust the relevance of the principle in the SPS Agreement and the WTO dispute settlement system has affirmed that a Panel charged with determining whether "sufficient scientific evidence" exists to warrant the maintenance by a Member of a particular SPS measure "may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution.[14]"

### 2. When is a measure based on a risk assessment?

The United States claims that, while the EC did undertake some RA, the decisions eventually made were not based on these assessments. In fact, both at the European and national levels, decisions banned products identified as not posing a risk to human or animal health or the environment by previous assessments. What, then, does it mean for a measure to be "based on" a risk assessment. In *EC – Hormones*, the relationship referred to by the United States (between the scientific conclusion yielded by a risk assessment and the scientific conclusions implicit in the measure), was indeed considered relevant, but not "to the exclusion of everything else."[15] What "everything else" entails is still unclear. However, one thing is clear and particularly important in *EC - Biotech* in light of the on-going debate in the scientific community as to the positive and negative consequences of biotechnology. According to the AB, countries can base their measures on minority scientific opinions without eliminating the reasonable relationship between the measure and the RA.[16]

## B. Article 5.7 of the SPS Agreement

As mentioned, even if the EC cannot fulfill the requirements of Articles 5.1 and 2.2, it has the possibility of invoking Article 5.7.[17] Article 5.7 allows Members to provisionally adopt SPS measures in cases where relevant scientific evidence is insufficient, and as such has been interpreted to establish a formulation of the precautionary principle. However, Article 5.7 constitutes a *qualified* exemption from Article 2.2. That is, it only justifies provisional SPS measures if four cumulative requirements are met: on one hand, the measure must be imposed in a situation where "relevant scientific information is insufficient" and adopted "on the basis of available pertinent information;" and on the other, the measure may not be maintained unless the Member which adopted it attempts "to obtain the additional information necessary for a more objective assessment of risk" and reviews the "measure accordingly within a reasonable period of time."

Since the EC measures are in fact only a temporary step in a complex and comprehensive process of regulating biotechnology products in the European Union, which is nearly at the

point of overcoming the US complaints, the EC is likely to raise this provision in its defense. The EC has continued to gather relevant information and the threshold of "available pertinent information" does not seem particularly high. The issue of "relevant scientific information is insufficient," however, could prove trickier.

While in the 1992 Rio Declaration on Environment and Development it is "lack of full scientific certainty" that triggers the precautionary principle, according to *Japan – Apples*, Article 5.7 is NOT triggered by scientific uncertainty, but rather by the insufficiency of scientific evidence. That is, Article 5.7 applies in situations where little, or no, reliable evidence was available on the subject matter at issue.[18] The considerable amount of scientific studies conducted on biotechnology products, as inconclusive as they may be, could thus prove a challenge for the EC. Since the four requirements are cumulative in nature, failing to surpass this condition would cause the measure at issue to be inconsistent with Article 5.7. Nevertheless, a broader formulation of the precautionary principle for biotech products in other international law rules, as will be analyzed below, could prove a compelling element in favor of the EC.

## IV. Cartagena Protocol on Biosafety: Role and Potential Influence

The present note would be incomplete, as would any Panel or AB decision, without consideration of other relevant international law rules. As trade rules increasingly interact with other systems of international law, there has been growing recognition of the need for the WTO, including its dispute settlement system, to situate and apply WTO rules in the broader context of international law. Cases such as Reformulated Gasoline[19], Shrimp-Turtle[20] and the Shrimp-Turtle implementation review decision[21] confirm the acknowledgment of the role of international law in WTO dispute settlement.

In the EC – Biotech case, consideration of international law will be particularly significant. The Biosafety Protocol, which recently entered into force, is a comprehensive agreement with the specific objective of promoting the safe transfer, handling and use of living modified organisms resulting from modern biotechnology and with a focus on transboundary movements.[22] As the only multilateral agreement specifically dealing with biotech products, the Biosafety Protocol is likely to play an important role both as a source of factual information and as a reference for the proper interpretation of the SPS Agreement. Both of these roles, as well as the potential influence that the Protocol could have on the case if it is considered, will be analyzed below.

### The Protocol as a Source of Factual Information

One of the potential ways in which the Biosafety Protocol could be considered in *EC – Biotech* is as a source of factual information. Within the WTO dispute settlement system, a WTO Member may turn to information implicit in or generated by other international rules and institutions to prove factual circumstances related to compliance with WTO rules. In this sense, while the information gathered through the Biosafety Protocol's Advanced Informed Agreement (AIA) procedure and Biosafety Clearinghouse could be valuable in future cases, the early stages of the Protocol will most likely hinder any such role in *EC – Biotech*. Nevertheless, the very existence of a Protocol attempting to deal with the potential adverse effects of biotechnology products may be considered proof of any EC allegations as to the risks they present. In that way, the Biosafety Protocol could strengthen the EC's defense to the US claims under Article 5.1.

### The Protocol as a Source for Interpretation

Perhaps the most important role that international law has played in the WTO dispute settlement so far, and certainly the most significant role that the Biosafety Protocol will have on *EC – Biotech*, is in giving meaning to the terms of the WTO agreements. Customary rules of interpretation of public international law, recognized by the WTO dispute settlement system, establish that in cases where several international instruments interact, "any relevant rules of international law applicable in the relations between the parties" must be taken into account.[23] Such consideration has proved fundamental for achieving balanced and coherent results in a number of WTO cases.

In *EC – Biotech* there is even further reason for the Biosafety Protocol to be considered. The SPS Agreement's references to international standards and organizations clearly contemplate that the SPS Agreement's obligations must be interpreted in light of relevant international law. [24] In that sense, the Biosafety Protocol could be relevant to several issues raised by this case. For example, the Biosafety Protocol's RA provisions give the party of import significant room to manage and control the risks identified in the assessment, including the possibility of considering socio-economic factors. Such elements could be important in the interpretation of the scope of Article 5.1, although the Biosafety Protocol's reference to other international obligations on this point may limit its usefulness. The Biosafety Protocol's precautionary principle, stating that lack of scientific certainty does not impede a party from making an appropriate decision with regard to the import of the GMOs, is another element that could be important to the case.[25] As the articulation of the precautionary principle in the Biosafety Protocol is specifically designed for

biotech products, it could provide critical guidance, particularly on the interpretation of the triggering conditions of Article 5.7.

## V. Conclusion

Predicting the outcome of EC – Biotech is, at this early stage, impossible. However, the first US submission does provide some elements to further define the key issues at stake. Articles 5.1 and 2.2 of the SPS Agreement, as the core of its science-based decision-making, will certainly figure prominently in any decision. In that sense, *EC – Biotech* will be one of a line of cases to further define the scope of RA, hopefully reflecting the importance granted to the inclusiveness of the concept by earlier decisions. The pivotal issue, however, is likely to be Article 5.7, with the controversial yet essential issue of precaution. The context and history of the case not only suggest that the EC will invoke Article 5.7, but also demand that the Panel consider the issue with great care. As a set of relevant international law rules, the Biosafety Protocol may play, in this regard, a crucial function. The consideration of the objective and structure of the Biosafety Protocol, as well as its formulation of the precautionary principle, should strongly advocate the recognition of the fundamental role of precaution in the context of biotechnology.

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**ENDNOTES**

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[2] European Communities – Measures Affecting the Approval and Marketing of Biotech Products (*EC – Biotech*), WT/DS291.

[3] Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Biosafety Protocol), adopted in Montreal on January 29, 2000, available on www.biodiv.org.

[4] Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), Annex A, paragraph 1, *available at* http://www.wto.org/english/docs_e/legal_e/15-sps.pdf.

[5] *Id.* at Article 2.2.

[6] See EC - Measures Concerning Meat and Meat Products (*EC - Hormones*), WTO Docs. WT/DS26/AB/R, WT/DS48/AB/R, (January 16, 1998), at para. 187.

[7] I*d,* at para. 189.

[8] Australia - Measures Affecting Importation of Salmon (*Australia – Salmon*), WTO Docs. WT/DS18/AB/R, (October 20, 1998), at para. 124.

[9] The Panel on *Australia – Salmon* held that a risk assessment need not be an official government report: "We note that these reports do not form part of Australia's formal risk assessment nor represent Australia's official government policy. However, to the extent they constitute relevant available scientific information which was submitted to the Panel, we consider it our task to take this evidence into account. We consider that, for purposes of our examination, the scientific and technical content of these reports and studies is relevant, not their administrative status (i.e., whether they are official government reports or not)".

[10] *See* Japan - Measures Affecting the Importation of Apples (*Japan Apples*) WTO Docs. WT/DS245/AB/R, (November 26, 2003), at para. 163. In *Japan – Apples*, for instance, the AB accepted the Panel's approach of exhausting the analysis of scientific justification by contrasting the extent of the risk established by the assessment and the nature of the measure, disregarding any other factors.

[11] EC - Hormones, supra note 6, at para. 190.

[12] *See* Australia - Measures Affecting Importation of Salmon, WTO Docs. WT/DS18/R, (June 12, 1998), at para. 8.71.

[13] Marc Busch and Robert Howse, "A (Genetically Modified) Food Fight: Canada's WTO Challenge to Europe's Ban on GM Food," C.D. Howe Institute Commentary, No. 186, September 2003.

[14] EC - Hormones, supra note 6, at para. 124.

[15] *Id,* at para. 193.

[16] *Id,* at para. 194.

[17] The EC may choose to not argue it alternatively, however, due to consequences on the burden of proof (see *Japan Apples*).

Japan – Measures Affecting Agricultural Products WTO Docs. WT/DS76/AB/R, ( February 22, 199) at para. 80.

*Id.* at para 91.

[18] Japan - Measures Affecting the Importation of Apples, supra note 10, at para. 184.

[19] See United States – Standards for Reformulated and Conventional Gasoline, WTO Docs. WT/DS2/AB/R, (April 29, 1996).

[20] See United States – Import Prohibition of Certain Shrimp and Shrimp Products, WTO Docs. WT/DS58/AB/R, (October 12, 1998).

[21] See United States - Import Prohibition of Cetain Shrimp and Shrimp Products, Recourse to article 21.5 by Malasya, WTO Docs. WT/DS58/AB/RW, (October 22, 2001).

[22] Biosafety Protocol, supra note 3, at Article 1. The Biosafety Protocol came into force on September 11, 2003.

[23] See the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), available on www.wto.org, Art 3.2 and Article 31 (3) (c) of Vienna Convention. The WTO DSU, however, establishes that "the panel and Appellate Body cannot add to or diminish the rights and obligations provided in the covered agreements."

[24] SPS Agreement, supra note 4, at Art.3.

[25] *Id.* at Art. 10.6.