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# **The ABC of GMOs, SPS & the WTO: An analysis of the application of the *Agreement on Sanitary and Phytosanitary Measures* within the context of biotechnology and international trade**

**Robert Cunningham\***

This article is situated within the broad framework of “international trade and the environment”. It evaluates the role of the Agreement on Sanitary and Phytosanitary Measures within the context of Genetically Modified Organisms. The article draws upon the recent dispute in EC – Biotech, and specifically explores the interrelationship between the Agreement on Sanitary and Phytosanitary Measures and extra-World Trade Organisation ‘law’ such as the precautionary principle, the Codex Standards, and the Cartagena Protocol. While acknowledging that the World Trade Organisation is not bound by the doctrine of precedent, it draws upon past decisions such as Beef Hormones to ascertain the likely application of critical concepts such as risk assessment in EC – Biotech.

## **Introduction**

This article focuses on the interpretation and application of the *Agreement on Sanitary and Phytosanitary Measures*<sup>1</sup> (*SPS Agreement*) in light of the uncertain scientific information surrounding Genetically Modified Organisms (GMOs). A central theme of the article is the risk assessment process. This is because it is integral to

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<sup>1</sup> Agreement on the Application of Sanitary and Phytosanitary Measures (hereafter “SPS”) Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization available at World Trade Organization, Legal Texts, <[http://www.wto.org/english/docs\\_e/legal\\_e/legal\\_e.htm](http://www.wto.org/english/docs_e/legal_e/legal_e.htm)>, (13 November 2004).

the *SPS Agreement*, and holds importance in relation to the recent dispute in *EC – Biotech*<sup>2</sup> as it influences the interpretation and application of sanitary and phytosanitary measures (SPS measures) generally.

In disputes such as *EC – Biotech*, the World Trade Organisation Panels (WTOP) and World Trade Organisation Appellate Body (WTOAB) will primarily turn to World Trade Organisation ‘law’ which is stipulated in the World Trade Organisation Agreements and the adopted WTOP and WTOAB Reports.<sup>3</sup> In this regard, the article covers provisions such as Articles 2.2, 5.1 and 5.7 of the *SPS Agreement*, as well as relevant decisions such as *Beef Hormones*.<sup>4</sup> Reliance on past decisions is made in full recognition that the World Trade Organisation (WTO) is not bound by the doctrine of precedent.<sup>5</sup>

While WTO ‘law’ is the primary law relied upon within WTO jurisprudence, it is critical to recognise that the WTO does not function within a vacuum. The events surrounding the “Battle of Seattle” are one case in point.<sup>6</sup> As a result, the relationship between WTO law and extra-WTO law such as the precautionary principle, the Codex Alimentarius Commission international standards (Codex Standards), and the Cartagena Protocol on Biosafety (Cartagena Protocol), is of increasing importance. The article attempts to implicitly cover this issue by exploring the relationship between extra-WTO law and the all-important risk assessment process under the *SPS Agreement*. It will be seen that risk assessment raises some interesting

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<sup>2</sup> EC – Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291.

<sup>3</sup> Palmeter D & Mavroidis P, “The WTO Legal System: Sources of Law” (1998) 92 *American Journal of International Law* 398, p 413.

<sup>4</sup> EC – Measures Concerning Meat and Meat Products AB Report, WT/DS26/AB/R (hereafter “Beef Hormones”).

<sup>5</sup> This was made clear by the AB in its decision on Japan – Taxes on Alcoholic Beverages, WT/DS10/AB/R where it was stated at p 15-16 that: “[A]dopted panel reports are an important part of the GATT acquis. They are often considered by subsequent panels. They create legitimate expectations among WTO Members, and, therefore, should be taken into account where they are relevant to any dispute. However, they are not binding, except with respect to resolving the particular dispute between the parties to that dispute.”

<sup>6</sup> See, for example, August R, *International Business Law: Text, Cases and Readings*, 4th Edition, Pearson Prentice Hall, New Jersey, USA, 2004, pp 362-366.

and unavoidable policy-related questions about the decision-making process of the WTO generally.

The article does not proffer a comprehensive overview of *EC – Biotech*, nor does it fully cover the intricacies of biotechnology within the context of international trade. This would be a project for a lengthier dissertation involving, among other matters, an in-depth discussion of the interrelationship between the *SPS Agreement*, the General Agreement on Tariffs and Trade (GATT), and the Technical Barriers to Trade Agreement (TBTA). The article rather seeks to focus on the *SPS Agreement*, and the related risk assessment process, in order to explore their application, as well as their relationship with *EC – Biotech* and the aforementioned extra-WTO law. The article does this by first implicitly discussing the relationship between biotechnology, the precautionary principle, and *EC – Biotech*. There follows a discussion of the application of the *SPS Agreement*, then a discussion of risk assessment and the related notion of risk management. The risk assessment discussion is deepened by drawing upon Articles 2.2, 5.1 and 5.7 of the *SPS Agreement*, the Codex Standards, and the Cartagena Protocol.

### **Biotechnology, the Precautionary Principle, and *EC – Biotech***

The term 'biotechnology' was coined in 1919 by Karl Ereky, a Hungarian engineer.<sup>7</sup> Biotechnology is defined as "the scientific ability to manipulate genetic information within and between species."<sup>8</sup> GMOs are a direct by-product of this technology. While human beings have sought to modify plants, animals and other living organisms for thousands of years, biotechnology or recombinant DNA technology differs in that it allows one or more specific genes to be inserted into a recipient cell's nucleus, leading to more radical changes in the biophysical structure of organic material.<sup>9</sup>

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<sup>7</sup> Centre for Integrated Biotechnology, Washington State University, <[http://www.biotechnology.wsu.edu/definition\\_scope/](http://www.biotechnology.wsu.edu/definition_scope/)>, (13 November 2004).

<sup>8</sup> McNamara C, "Food and the Future" (1999) 24 (6) *Alternative Law Journal* 294.

<sup>9</sup> Lively S, "The ABCs and NTBs of GMOs: The Great European Union-United States Trade Debate-Do European Restrictions on the Trade of Genetically Modified

The pros and cons of GMOs are well documented.<sup>10</sup> Opponents of GMOs point to their uncertainty in relation to health and the environment, the affront to ethical and religious beliefs, and the economic centralisation of power that GMO technologies can potentially grant to multi-national corporations.<sup>11</sup> On the other hand, proponents of GMOs profess that an abundance of economic, environmental and health benefits can be derived from this technology via, for example, the alteration of crops to increase food production and improve the nutritional components of food.<sup>12</sup>

As science is currently incapable of providing *definite* answers to the potential benefits and hazards of GMOs, the role and function of the precautionary principle within the context of international trade will remain important. This is particularly the case in relation to emerging international standards concerning GMOs such as the Codex Standards and the Cartagena Protocol. Principle 15 of the Rio Declaration on Environment and Development (1992) states:

Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The application of the principle in relation to the international trade of biotechnology is fiercely contested ground. Some commentators such as Adler fear a precautionary approach to the regulation of biotechnology would slow its development, increase the costs of products and techniques, and limit the introduction of beneficial crops

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Organisms Violate International Trade Law?" (2002) 23 *Northwestern School of Law Journal of International Law & Business* 239, p 242.

<sup>10</sup> See, for example, Schwartz B, "WTO and GMO's: Analysing the European Community's Recent Regulations Covering the Labelling of Genetically Modified Organisms" (2004) 25 *Michigan Journal of International Law* 771, p 775 and Young-Gyoo S, "Intellectual Property Protection of Biotechnology and Sustainable Development in International Law" (2003) 29 *North Carolina Journal of International Law & Commercial Regulation* 157, pp 174-179.

<sup>11</sup> See, for example, Glass J, "The Merits of Ratifying and Implementing the Cartagena Protocol on Biosafety" (2001) 21 *Northwestern School of Law Journal of International Law & Business* 491, pp 495-497.

<sup>12</sup> See, for example, Schwartz B, note 10.

and foodstuffs.<sup>13</sup> Other commentators such as Kolehmainen, however, suggest that in the name of health and the environment it is critical that states and their agencies have “sufficient time to understand GMO technology and comprehend its full range of possible effects before knowing how to regulate it most effectively.”<sup>14</sup>

Although regulatory approaches vary greatly among countries, many regulatory systems do in fact adopt some form of precautionary approach in relation to GMOs by making the authorisation of GMO products dependent on a case-by-case risk assessment of the product in question. The *Australian Gene Technology Act 2000* (Cth), for example, adopts Principle 15 of the Rio Declaration and necessitates the application of the precautionary principle in “the assessment of environmental risks posed by Genetically Modified Organisms.”<sup>15</sup> New Zealand also engaged with the precautionary principle by enacting a statutory moratorium on commercial releases of GMOs in order to give the government time to research socio-economic, ethical, and environmental concerns.<sup>16</sup>

In the international trade context the GMOs issue is becoming increasingly topical, especially since the advent of *EC – Biotech* where the United States, Canada and Argentina are challenging the *de facto* moratorium by the European Community (EC) and associated bans by

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13 Adler J, “More Sorry than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol” (2000) 35 *Texas International Law Journal* 173.

14 Kolehmainen S, “Precaution Before Profits: An Overview of Issues in Genetically Engineered Food and Crops” (2001) 20 *Virginia Environmental Law Journal* 269, p 288.

15 Senate Committee on Community Affairs, Parliament of the Commonwealth of Australia, *A Cautionary Tale: Fish Don't Lay Tomatoes. A report on the Gene Technology Bill 2000*, November 2000, no.3.57-3.61; document available at <[http://www.aph.gov.au/Senate/committee/clac\\_ctte/gene/report/index.htm](http://www.aph.gov.au/Senate/committee/clac_ctte/gene/report/index.htm)> (13 November 2004).

16 The moratorium, which ended on 29 October 2003, was imposed by the *Hazardous Substances and New Organism (Genetically Modified Organisms) Amendment Act 2002*, (Part 5A) which came into force by Royal Assent on 27 May 2002, available at <[http://www.legislation.govt.nz/browse\\_vw.asp?contentset=pal\\_statutes&clientid=2310743439&viewtype=contents](http://www.legislation.govt.nz/browse_vw.asp?contentset=pal_statutes&clientid=2310743439&viewtype=contents)> (13 November 2004).

EC member states on GMO food and feed.<sup>17</sup> Whether or not the EC's *de facto* moratorium is valid according to international trade rules will depend on at least the partial resolution of a number of important WTO jurisprudential questions, one of which is the role and application of the *SPS Agreement*.

### Application of the *SPS Agreement*

The *SPS Agreement* emerged from the Uruguay Round of the GATT and was implemented in 1995. It addresses the possible use of SPS measures, often referred to as health and safety measures, as scientifically unfounded barriers to the trade of agricultural and food products.<sup>18</sup> The *SPS Agreement* does not create specific standards for SPS measures, it provides a general framework for governments to follow when establishing them. In particular, it mandates that member countries of the WTO base their SPS measures upon science via the risk assessment process so as to prevent SPS measures becoming disguised barriers to trade.<sup>19</sup>

As *EC – Biotech* is the first dispute involving the international trade of GMO products to have actually reached the WTO dispute settlement process, it is not entirely clear which WTO agreement will be used to resolve the dispute. However, some government officials have indicated that they expect disputes over GMO products will be resolved under the *SPS Agreement*.<sup>20</sup> Qualified consensus also exists between the US and the EC in relation to the *application* of the *SPS Agreement*, if not its *role*. In its first submission in *EC – Biotech* the US argued: "The EC's biotech approval regime is unquestionably an SPS measure."<sup>21</sup> To support its argument the US referred to EC

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17 See Morgan D and Goh G, "GM Food Labelling and the WTO Agreements", to be published in forthcoming edition of the *Review of European Community and International Environmental Law*.

18 Stewart T & Johanson D, "A Nexus of Trade and the Environment: The Relationship Between the Cartagena Protocol on Biosafety and the SPS Agreement of the World Trade Organization" (2003) 14 *Colorado Journal of International Environmental Law and Policy* 1, p 32.

19 SPS, Article 5, note 1.

20 See Stewart T & Johanson D, note 18.

21 EC – Measures Affecting the Approval and Marketing of Biotech Products, Executive Summary of the First Submission of the United States, April 30, 2004, pp 4-5, at

Directive 2001/18, one of the objectives of which is “to protect human health and the environment [when] placing on the market genetically modified organisms as or in products within the Community.”<sup>22</sup>

The EC also acknowledges that the *SPS Agreement* will be of *some* significance, although it is more reserved in this context since it believes that the issue is complicated by the interplay between the *SPS Agreement*, the GATT, and the TBTA. For example, the EC points out that the *SPS Agreement* does not actually mention “the environment”, whereas Article 1.5 of the TBTA does, and therefore the EC’s GMO measures cannot be considered to fall entirely within the *SPS Agreement*.<sup>23</sup> In its first submission in *EC – Biotech* the EC stated:

The European Community considers that although some aspects of the alleged measures could be said to fall within the *SPS Agreement* it is plain that other aspects do not.<sup>24</sup>

The determination of the application of the *SPS Agreement* in *EC – Biotech* will ultimately depend on whether the EC’s GMO regulations fall within the definition of an “SPS measure” under Annex A, paragraph 1 of the *SPS Agreement*. Whether this is the case is critical, since a measure obviously cannot be held to be in violation of the *SPS Agreement* if it is not in fact an “SPS measure”. While it is difficult to determine in the abstract whether EC’s measures are in fact compatible with the definition of an SPS measure, the aforementioned commentary does suggest that it is safe to make a qualified assumption that at least some aspects of the EC’s GMO measures will fall within the *SPS Agreement* definition. As this is the case, it therefore becomes an imperative to discuss one of the central themes in Annex A of the *SPS Agreement*: the theme of risk.

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<[http://www.ustr.gov/Trade\\_Agreements/Monitoring\\_Enforcement/Dispute\\_Settlement/WTO/Dispute\\_Settlement\\_Index\\_-\\_Pending.html](http://www.ustr.gov/Trade_Agreements/Monitoring_Enforcement/Dispute_Settlement/WTO/Dispute_Settlement_Index_-_Pending.html)>, (13 November 2004).

22 Note 21.

23 European Communities – Measures Affecting the Approval and Marketing of Biotech Products (DS291, DS292, DS293), First Written Submission by the European Communities, Geneva, 17 May 2004, p 128 para 416, at <[http://trade-info.cec.eu.int/doclib/docs/2004/june/tradoc\\_117687.pdf](http://trade-info.cec.eu.int/doclib/docs/2004/june/tradoc_117687.pdf)> (13 November 2004).

24 Note 23, p 121, para 388.



## Risk Assessment versus Risk Management

Ostrovsky surmised: “GMOs are an extremely divisive issue primarily because of the difficulty of assessing risks associated with GMOs to human health and the environment.”<sup>25</sup> The nature of the science discipline means that there will always be some level of scientific uncertainty. For this reason the *SPS Agreement* has been designed in a manner that allows for the enactment of different provisions depending on the level of this uncertainty. An important tool in this regard is risk assessment. Article 5.1 explicitly refers to risk assessment by requiring that:

[Members'] sanitary or phytosanitary measures [be] based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account *risk assessment* techniques developed by the relevant international organisations. (Emphasis added.)

The “relevant international organisations” will be considered below. At this point it is sufficient to recognise that risk assessment is defined in Annex A, paragraph 4 as either the evaluation of the likelihood of entry, establishment or spread of a pest or disease according to the SPS measures that might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human health from food-borne risks. Different WTO members, however, have taken different approaches to the definition of risk assessment, and it is a matter that is likely to be of considerable significance within *EC – Biotech*.

While the emphasis on traditional scientific methods of risk assessment is internally consistent within WTO jurisprudence, there are lingering questions about whether the WTO is in fact the appropriate forum to be deciding important international policy questions such as the regulation of GMOs. This is especially the case since the WTO lies outside an explicit democratic framework.<sup>26</sup> In this context, the US has suggested that the current emphasis on

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<sup>25</sup> Ostrovsky A, “The New Codex Alimentarius Commission Standards for Food Created with Modern Biotechnology: Implications for the EC GMO Framework’s Compliance with the SPS Agreement” (2004) 25 *Michigan Journal of International Law* 813, p 814.

<sup>26</sup> See, for example, August R, note 6.

science delivers an objective and procedurally fair foundation on which to resolve international trade disputes because of the WTO's 'liberal' approach towards risk assessment and the recognition of the right of members to determine their own levels of protection.<sup>27</sup> The EC on the other hand has referred to limits in 'positivist' science and has called for greater recognition of "risk management" factors such as social values and public opinion in decision-making.<sup>28</sup> The EC has also voiced concerns about the potential politicisation of science and the internationalisation of particular cultural or social values.<sup>29</sup>

The EC advocated the latter arguments in *Beef Hormones* in an attempt to broaden the notion of risk assessment from a purely scientific analysis to include broader "risk management" concepts such as socio-political considerations. Supporting views in this regard have been articulated for many years and are echoed in the following observation by Lowrance:

[D]eciding whether people, with all their peculiarities of need, tolerance and adventurousness might or should be willing to bear the estimated risks is a value judgment that scientists are little better qualified to make than anyone else.<sup>30</sup>

However, the WTOAB in *Beef Hormones* favoured the scientifically based risk assessment process, squashing the EC's attempt to broaden the notion of risk assessment to include the tools of risk management.<sup>31</sup>

In response to the WTO risk assessment policy question, it has been stated that the EC has attempted to broaden the notion of risk assessment to encompass risk management tools. What is the difference between "risk assessment" and "risk management"?

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27 Bohanes J, "Risk regulation in WTO law: a procedure-based approach to the precautionary principle" (2002) 40 *Columbia Journal of Transnational Law* 323, p 341.

28 See *Beef Hormones*, note 4.

29 Goh G, "Precaution, Science and Sovereignty: Protecting Life and Health under the WTO Agreements" (2003) 6(3) *The Journal of World Intellectual Property* 464.

30 Lowrance W, *Of Acceptable Risk: Science and the Determination of Safety*, Los Altos, CA, USA: William Kaufmann, 1976, p 9.

31 Bohanes J, note 27, p 335.

Generally speaking risk assessment portrays “a precise probabilistic estimate of the potentially harmful effect of the intake of or exposure to a substance or activity, determined in accordance with scientifically accepted methodology.”<sup>32</sup> As Bohanes put it, a consequence of a risk assessment might be that the intake of substance B brings with it a probability of 1/10,000 to develop disease C over a certain time horizon.<sup>33</sup> Risk management, on the other hand, is a political and value-based decision, which contemplates the result of a risk assessment and then determines the level of risk society is willing to tolerate and the appropriate measures to draw upon in order to deal with the risk in question.<sup>34</sup> Under risk management, the question becomes whether a probability of 1/10,000 of developing disease C is a risk worth taking and, if so, which measures regulating the use of substance B should be adopted.<sup>35</sup> The risk management question therefore implicitly entails a judgment as to what level of risk is acceptable in a particular society.

Thus, at the heart of the dispute in *EC – Biotech* is the decision-making process of the WTO. It is true that the WTO has demonstrated an occasional willingness to engage with considerations outside the narrow confines of a purely scientific risk assessment. For example, in *Australia – Salmon*<sup>36</sup> the WTOAB partly entertained the arguments of Australia when it drew upon “community values” in determining the appropriate level of quarantine protection.<sup>37</sup> Overall, however, WTO jurisprudence tends to shy away from such risk management tools, focusing rather on the more traditional scientific risk assessment approach as eventually advocated by the WTOAB in the three-prong test in *Australia – Salmon*.<sup>38</sup>

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32 Lowrance W, note 30.

33 Bohanes J, note 27, p 338.

34 Bohanes J, note 27, p 338.

35 Bohanes J, note 27, pp 338-339.

36 *Australia – Measures Affecting Importation of Salmon*, AB Report, WT/DS18/AB/R.

37 See *Australia – Measures Affecting Importation of Salmon*, Note 36 and Goh G, note 29, pp 464-465.

38 Ostrovsky, note 25, pp 833-834.

## The SPS Agreement and Risk Assessment

Returning directly to the notion of risk assessment, it is sometimes not possible to conduct an Annex A, paragraph 4 assessment because of the level of scientific uncertainty. If this is perceived to be the case with GMOs it will become necessary for the WTO to examine the EC's measures under Article 5.7 of the *SPS Agreement*, which is a strictly *provisional* measure. Article 5.7 must be read jointly with Article 2.2:

Article 2.2 Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles, and is not maintained without *sufficient scientific evidence*, except as provided [in article 5.7]. (Emphasis added.)

Article 5.7 In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information. ... In such circumstances, Members shall seek to obtain the additional information necessary for a *more objective assessment of risk* and review the sanitary or phytosanitary measure accordingly within a reasonable period of time. (Emphasis added.)

It is possible that Article 5.7 will apply in *EC – Biotech*, at least to some extent, since Article 16(1) of Directive 90/220/EC provides:

Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received consent under this Directive constitutes a risk to human health or the environment, it may *provisionally* restrict or prohibit the use and/or sale of that product on its territory. (Emphasis added.)<sup>39</sup>

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<sup>39</sup> European Communities – Measures Affecting the Approval and Marketing of Biotech Products (DS291, DS292, DS293), First Written Submission by the European Communities, Geneva, 17 May 2004, p 174 para 590 at <[http://trade-info.cec.eu.int/doclib/docs/2004/june/tradoc\\_117687.pdf](http://trade-info.cec.eu.int/doclib/docs/2004/june/tradoc_117687.pdf)> (13 November 2004).

According to the WTOAB in *Beef Hormones* the risk to be assessed under Article 5.7 is 'ascertainable' risk as opposed to purely theoretical risk. However, the WTOAB did emphasise that risk assessment is not restricted to an examination of only those factors prone to quantitative analysis by empirical or experimental laboratory methods.<sup>40</sup> This point was made via the oft-quoted statement that the risk to be evaluated in a risk assessment under Article 5.1 is risk that has "the actual potential for adverse effects on human health in the real world where people live and work and die."<sup>41</sup>

In relation to the precautionary principle, the WTOAB declined to proffer a precise meaning or legal status of the principle, but rather held that it could not in any case override the explicit wording of Articles 5.1 and 5.2 of the *SPS Agreement*.<sup>42</sup> In particular the WTOAB stressed the point in *Beef Hormones* that the EC had violated the *SPS Agreement* by failing to base its hormone ban on a risk assessment.<sup>43</sup> While the WTOAB did indicate that the precautionary principle "is reflected" in the sixth paragraph of the Preamble to the *SPS Agreement*, in Article 3.3, and in Article 5.7, it also stated that:

[T]he [precautionary] principle has not been written into the *SPS Agreement* as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement.<sup>44</sup>

Importantly, Article 5.7 does not override the requirements of Articles 5.1 and 5.2 of the *SPS Agreement*.<sup>45</sup> Therefore, while a member is not required to use scientific principles as a foundation for provisional measures, nor maintain it with scientific evidence (as is mandated by Article 2.2), it is still required to base the measure on a risk assessment which takes into account available scientific evidence (as stipulated by Articles 5.1 and 5.2).<sup>46</sup> In this regard, the distinction between the

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40 *Beef Hormones*, Note 4, paras 186 and 187.

41 *Beef Hormones*, Note 4, para 187.

42 *Beef Hormones*, Note 4, para 125.

43 *Beef Hormones*, Note 4, para 125.

44 *Beef Hormones*, Note 4, para 124.

45 *Beef Hormones*, Note 4, para 125.

46 Ostrovsky A, note 25, p 839.

application of Articles 5.1 and 5.7 is a delicate one. Indeed, it is not actually clear in any case whether it matters if a measure falls under Article 5.1 or Article 5.7, as Article 5.7 seems to implicitly import the notion of risk assessment by requiring members to seek additional information so as to establish “a more objective assessment of risk.” This point was affirmed by the WTOAB in *Japan – Varietals*<sup>47</sup> where a four-part test for the application of Article 5.7 was spelt out.<sup>48</sup> The third criterion of this test was:

[That] the member must seek to obtain additional information necessary for a more objective assessment of risk [with the] additional information [being] germane to conducting ... a risk assessment.<sup>49</sup>

Thus, it would seem that whichever provision of the *SPS Agreement* is applicable in *EC – Biotech* the notion of risk assessment is inescapable. If the aforementioned *Japan – Varietals* test or a similar test were to be applied in *EC – Biotech*, the WTOAB and/or WTOAB would presumably draw upon extra-WTO ‘law’ such as the Codex Standards and/or the Cartagena Protocol in order to determine the nature of the appropriate “risk assessment” process. We now turn to this extra-WTO law.

## The Codex Standards and Risk Assessment

The *SPS Agreement* encourages countries to harmonise SPS measures with international standards where possible. Annex A, paragraph 3, of the *SPS Agreement* specifically lists the Codex Alimentarius Commission as one of the three international standard-setting organisations that members can rely upon. Thus, if the EC follows Codex Standards in creating its measure, there is a presumption that the measure will be consistent with the *SPS Agreement*.<sup>50</sup> If the EC chooses to create a measure that seeks a higher level of protection than

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47 Japan – Measures Affecting Agricultural Products, WT/DS76/AB/R.

48 Note 47, para 89.

49 Note 47, para 92.

50 SPS, Article 3.2 and 3.3, note 1.

the international standard it must, in accordance with Article 3.3 of the *SPS Agreement*, conduct a risk assessment and justify the more stringent protection on scientific grounds. In this way the Codex Standards for biotechnology represent a baseline for risk assessment of GMOs under the *SPS Agreement*.<sup>51</sup> A critical question then in *EC – Biotech* is how the EC measures compare to the Codex Standards.

The biotechnology guidelines in the Codex Standards outline four standards for assessing the risks to consumers from food derived from GMOs. The relevant guidelines require a risk assessment, risk management, risk communication, information exchange, and a review process.<sup>52</sup> The Codex Guidelines on Food Derived from Biotechnology state at paragraph 15:

[R]isk assessment should take into account all available scientific data and information derived from different testing procedures, provided that the procedures are scientifically sound.<sup>53</sup>

In relation to *EC – Biotech* the guidelines in the Codex Standards and the EC's Deliberate Release Directive have very similar requirements in assessing risks associated with GMOs: they appear to seek a similar level of protection.<sup>54</sup> For example, Annex II of the Deliberate Release Directive refers to an "Environmental Risk Assessment" which has as its objective to evaluate, on a case-by-case basis, "the potential adverse effects of the GMO [to identify] if there is a need for risk management and if so, the appropriate methods to be used."<sup>55</sup> Thus, provided that the WTOAB's interpretation of "conform to" in paragraph 170 of *Beef Hormones* is not taken to mean a verbatim

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<sup>51</sup> These guidelines were established in Rome in 2003 at the 26th Codex session.

<sup>52</sup> Codex Alimentarius Commission, *Report of the Third Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology*, app. II, ALINORM 03/34, June 30-July 5, 2003.

<sup>53</sup> Codex, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, CAC/GL 44-2003, at <[http://www.codexalimentarius.net/web/standard\\_list.do?lang=en](http://www.codexalimentarius.net/web/standard_list.do?lang=en)> (14 November 2004).

<sup>54</sup> For discussion of this issue see Ostrovsky A, note 25, pp 824-827.

<sup>55</sup> Council Directive 2001/18/EEC on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/E.C., art. 4(1), 2001 O.J. (L 106) 1, 5 annex II(A), at 19.

codification of the international standard, the EC's Deliberate Release Directive does *prima facie* sufficiently "conform to" the Codex guidelines for the purposes of Article 3.2 of the *SPS Agreement*.<sup>56</sup> This would amount to a presumption of compliance with the *SPS Agreement*, as is indicated by Howse and Mavroidis who point out that in the determination of whether a measure "conforms to" international standards, "the real issue is whether in all relevant respects the [EC] regulation does not attempt to achieve a higher level of protection than that which would be achieved by international standards."<sup>57</sup>

In *Beef Hormones* the WTOAB suggested that the relevant test in relation to whether a measure "conforms to" international standards is whether there is a "rational relationship" between the measure in question and the risk assessment that led to its adoption.<sup>58</sup> In this regard, the WTOAB recognised that the existence of differing opinions in the scientific community does not of and by itself thwart a rational relationship between the measure in question and the risk assessment, especially where the risk involved is life-threatening in nature and is perceived to constitute a clear and imminent threat to public safety and health.<sup>59</sup> Thus, the question of whether there is such a rational relationship has to be determined on a case-by-case basis "after account is taken of all considerations bearing upon the issue of potential adverse health effects."<sup>60</sup> It transpires from *Beef Hormones* that this "rational relationship" must exist whether the measure falls under Articles 5.1 or 5.7 of the *SPS Agreement*, although it is perhaps less clear what this practically amounts to under Article 5.7 when there is "insufficient scientific evidence".

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<sup>56</sup> Ostrovsky A, note 25, pp 826-827.

<sup>57</sup> Howse R & Mavroidis P, "Europe's Evolving Regulatory Strategy for GMO's - The Issue of Consistency with WTO Law: Of Kine and Brine" (2000) 24 *Fordham International Law Journal* 317, p 356.

<sup>58</sup> *Beef Hormones*, note 4, para 189.

<sup>59</sup> Bentley P, "A Re-Assessment of Article XX, Paragraphs (b) and (g), of GATT 1994 in the Light of Growing Consumer and Environmental Concern About Biotechnology" (2000) 24 *Fordham International Law Journal* 107, p 116.

<sup>60</sup> Bentley P, note 59.



## The Cartagena Protocol and Risk Assessment

As the Codex Standards have yet to govern some aspects of GMOs, the Cartagena Protocol may also play a role in providing the necessary relevant international standards.<sup>61</sup> The Cartagena Protocol came into force on 11 September 2003, ninety days after it secured the requisite 50 signatories. It concerns the international transportation of GMOs produced through modern biotechnology. The Cartagena Protocol was negotiated under the auspices of the Convention on Biological Diversity, and is administered by the United Nations Environment Program.<sup>62</sup> In harmony with the precautionary approach stipulated in Principle 15 of the Rio Declaration, the objective of the Cartagena Protocol is to:

[C]ontribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of [GMOs]<sup>63</sup> resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.<sup>64</sup>

While it is first and foremost an environmental agreement, the Cartagena Protocol addresses the international movement of GMOs, and thus has a major trade component. In this regard it has been noted that the relationship between the trade and environmental aspects of the Cartagena Protocol is the source of considerable confusion.<sup>65</sup> The Cartagena Protocol provides that it and the WTO “are to be mutually supportive”. It also provides that it is not to affect “the rights and obligations of a Party under any existing international agreements [and

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<sup>61</sup> Stewart T & Johanson D, note 18, pp 45-47.

<sup>62</sup> Convention on Biological Diversity, Cartagena Protocol on Biosafety, at <<http://www.biodiv.org/biosafety/>> (13 November 2004), (Cartagena Protocol)

<sup>63</sup> The Protocol actually uses the terminology of Living Modified Organisms (LMO's), but for the purposes of the paper the distinction between GMO's and LMO's is too fine to warrant discussion.

<sup>64</sup> Cartagena Protocol, note 62, Article 1; see also Hagen P & Weiner JB, “The Cartagena Protocol on Biosafety: New Rules for International Trade in Living Modified Organisms” (2000) 12 *Georgetown International Environmental Law Review* 697, p 710.

<sup>65</sup> Stewart T & Johanson D, note 18, p 33.

is not] subordinate ... to other international agreements.”<sup>66</sup> The effect of these provisions is that WTO members, even if they are also parties to the Convention on Biological Diversity, may be able to avoid compliance with it because of its subordinate position.<sup>67</sup>

Importantly, the Cartagena Protocol and the *SPS Agreement* dovetail at the point of risk assessment. For example, in a similar vein to case law relating to SPS measures, Annex III of the Cartagena Protocol promulgates general principles and guidelines with respect to the methodology and factors to be taken into account in risk assessment. Article 16.2 states:

Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of [GMOs] on conservation and sustainable use of biological diversity, taking also into account risk to human health, within the territory, of the Party of import.<sup>68</sup>

As indicated previously in relation to the Codex Standards, “the real issue is whether in all relevant respects the [EC] regulation does not attempt to achieve a higher level of protection than that which would be achieved by international standards.”<sup>69</sup> According to this proviso, the crux of the matter in *EC – Biotech* may be how the EC’s measures compare with the guidelines stipulated under the Cartagena Protocol. In this regard, Howse and Mavroidis draw upon two useful examples.

First, the amended EC Directive 2001/18/EEC,<sup>70</sup> which is the basis of the EC’s GMO measures, requires an environmental risk assessment to be carried out by the notifier, which in turn provides the basis for an assessment report.<sup>71</sup> While not exactly the same, the types of risks and factors to be taken into account in the environmental risk assessment and in the assessment report are very similar to those set

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<sup>66</sup> Cartagena Protocol, note 62, Preamble.

<sup>67</sup> Glass J, note 11, pp 510-511.

<sup>68</sup> Cartagena Protocol, note 62, Article 16.2.

<sup>69</sup> Howse R & Mavroidis P, note 57, p 356.

<sup>70</sup> Council Directive 2001/18/EEC, note 55.

<sup>71</sup> Howse & Mavroidis, note 57, pp 355-356.

out in the Cartagena Protocol.<sup>72</sup> In this regard, the amended EC Directive is more favourable to imports than the Cartagena Protocol since it specifies a shorter time period (90 days) for an initial decision of national authorities on whether release is to be permitted.<sup>73</sup>

Second, the amended EC Directive requires that all appropriate GMO measures be taken to ensure 'safety'. Importantly, this is to be interpreted in a relative manner so that it is compared with existing levels of safety with respect to corresponding non-modified organisms.<sup>74</sup> By contrast, the standard established in the Cartagena Protocol is an absolute one requiring that all necessary measures be taken to prevent harm to the environment from GMOs, regardless of whether a signatory is establishing comparable precautions against environmental harm or human health impacts from non-GMO products and materials. In this sense, it is suggested that the level of protection afforded by the amended EC Directive is actually lower than that provided for in the Cartagena Protocol.<sup>75</sup>

## **Conclusion**

The application of the *SPS Agreement*, and the related risk assessment process, is a complex aspect of WTO jurisprudence. This article has analysed this complexity with reference to the recent dispute in *EC – Biotech*, and extra-WTO law such as the precautionary principle, the Codex Standards and the Cartagena Protocol. Although it is unlikely that *EC – Biotech* will be decided solely on the basis of the *SPS Agreement*, there is at least qualified consensus that it will have some application. This equates in turn to the application of the risk assessment process, as a result of the delicate relationship that exists between pertinent provisions of the *SPS Agreement* such as Articles 5.1 and 5.7, which in turn leaves the door open for the possible importation of the aforementioned extra-WTO law. A further corollary in this regard is the unavoidable WTO policy questions that arise in relation to risk assessment and the related concept of risk management.

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<sup>72</sup> Howse & Mavroidis, note 57, pp 355-356.

<sup>73</sup> Council Directive 2001/18/EEC, note 55.

<sup>74</sup> Howse & Mavroidis, note 57, p 357.

<sup>75</sup> Howse & Mavroidis, note 57, p 357.

In this context *EC – Biotech* represents a symbol within WTO jurisprudence, pointing to the ongoing pressure on the WTO to engage, on some level, with important international policy issues. It also requires the WTO to decipher the relationship between WTO law and extra-WTO law. While there is clear acceptance of the role of explicitly mentioned “international standards organisations” such as the Codex Standards within WTO jurisprudence, the relationship between WTO law and other extra-WTO law such as the precautionary principle and the Cartagena Protocol is less defined. This is likely to be of some significance within *EC – Biotech* since the WTO will be required to determine, within the context of the *SPS Agreement*, how the EC’s measures in relation to GMOs weigh up against “international standards”. The central question in this regard is whether the EC’s measures prescribe a “higher level of protection” than that advocated by international instruments such as the Codex Standards and the Cartagena Protocol. While this question cannot be answered in the abstract, there is currency for the view that, at least as far as the *SPS Agreement* is concerned, the EC’s measures are less onerous than those prescribed by international standards. Ultimately, however, this is one of the many questions for the WTO to answer within the context of *EC – Biotech*.

In summary, while the outcome of *EC – Biotech* is next to impossible to predict, it will undoubtedly require the WTO to engage with some important jurisprudential questions surrounding international trade disputes. In this regard, *EC – Biotech* is sure to contribute to the ongoing evolution of WTO jurisprudence.