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STUDENT NOTE

THE NEW CODEX ALIMENTARIUS COMMISSION STANDARDS FOR FOOD CREATED WITH MODERN BIOTECHNOLOGY: IMPLICATIONS FOR THE EC GMO FRAMEWORK'S COMPLIANCE WITH THE SPS AGREEMENT

Aaron A. Ostrovsky*

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I. INTRODUCTION

Much of the debate in recent years surrounding genetically modified organisms (GMO) has centered on the creation of a formal protocol for regulating the transboundary movement of GMOs as well as what products or processes would be included in the definition of "GMO." One issue which has become increasingly important in regulating the transboundary movement of GMOs is how states assess the dangers associated with GMOs in making regulatory decisions. GMOs are an extremely divisive issue primarily because of the difficulty of assessing the risks associated with GMOs to human health and the environment.

Recently, the Codex Alimentarius Commission (Codex Commission) adopted new standards for assessing risks associated with foods derived from modern biotechnology (Codex guidelines). These standards represent a new baseline for international measures regulating GMOs and will play a significant part in adjudicating international disputes involving assessing risks associated with GMOs, particularly in the World Trade Organization (WTO).

The current dispute brought by the United States in the WTO against the European Community's (E.C.) de facto moratorium on the importation of GMOs has substantial implications for future risk assessment of

1. The debate originally centered around the formation of the Cartagena Biosafety Protocol (CPB) which creates a framework for the regulation of transboundary GMO shipments. See Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027 [hereinafter Biosafety Protocol]. Within the discussions surround the CPB, there was disagreement about whether to regulate only those GMOs which were deliberately released into the environment such as seeds or whether it would apply to all commodities made with GMOs. See, e.g., BRIDGES Weekly Trade News Digest (March 1, 1999), at http://www.ictsd.org/html/story1.01-03-99.htm. This debate was largely outside the context of WTO measures.


2. Codex Alimentarius Commission, ALINORM 03/41, Twenty-sixth Session, FAO Headquarters, Rome Report at 52 (June 30–July 7, 2003). The Codex Alimentarius Commission is an intergovernmental body established by the UN Food and Agriculture Organization and the World Health Organization whose mission is to set international health standards.
GMOs in connection with trade related measures. For the purposes of this Note, the most significant part of the U.S. claim centers around the E.C.'s alleged violations of the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement). Since measures found to "conform to" standard promulgated by the Codex Alimentarius Commission enjoy a presumption of compliance with the SPS Agreement as well as the General Agreement on Tariffs and Trade (GATT), the new Codex Commission standards for biotechnology will play a key role in the WTO dispute.

The E.C. has had three significant measures designed to regulate GMOs. The first, Directive 90/219/EEC was the original instrument for regulating GMOs in the E.C. Directive 90/219/EEC sought to regulate the contained use of genetically modified organisms for research and industrial purposes. It was supplemented by Directive 90/220/EEC which regulated the deliberate release of GMOs into the environment or onto the market. In the face of rapid development of scientific knowledge and new information on GMOs generally, the E.C. repealed Directive 90/220 in 2001 and replaced it with Council Directive 3.


4. Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex I(A), LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 27, at 21,895 (1994) [hereinafter SPS Agreement]; General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194 [hereinafter GATT]. It is important to point out that measures which seek a higher level of protection than that deemed appropriate by the international standard are not deemed to "conform to" that standard and instead must be justified with scientific evidence as well as to comply with SPS Article 5. Id. art. 3, at 21,896-97.


Like the previous directive it replaces, the Deliberate Release Directive has notification requirements for parties seeking to move GMOs across borders, both for when the GMO is going to be released into the environment (e.g., seeds) or placed on the market (e.g., commodities).11 In addition, the releasing party must also submit an environmental risk assessment (ERA).12 The ERA should, "in accordance with the precautionary principle," compare the characteristics of the GMO and its non-modified counterpart, using a "scientifically sound and transparent manner based on available scientific and technical data," with the purpose of "identifying if there is a need for risk management and if so, the most appropriate methods to be used."13

The Deliberate Release Directive also contains a provision for differentiated procedures where there is sufficient knowledge about or experience with the release of GMOs in certain ecosystems.14 This "fast track" decision making process only requires a minimum amount of


10. Id. art. 28(1), at 14. More specifically, the directive states that when a competent authority in the European Commission (Commission) raises objections regarding the risks of GMOs "to human health or to the environment", the Commission shall consult a "relevant Scientific Committee." In addition, the Commission may also consult a scientific committee "on any matter under [Directive 2001/18] that may have an adverse effect on human health and the environment." Id. art. 28(1)-(2), at 14–15.

11. Directive 2001/18, supra note 9, arts. 6(1), 13(1), at 6–7, 9. This notification consists of a technical dossier containing information about the GMO, including its release into and interactions with, the environment, and a plan for monitoring effects of GMOs on human health and the environment. The Deliberate Release Directive requires that for GMOs placed on the market (commodities), the releasing party also have a provide a proposal for labeling the produce. Id. art. 13(2)(f), at 9. For an overview of the compatibility of the E.C.'s labeling requirements with WTO agreements, see Brian Schwartz, Note, WTO and GMOs: Analyzing the European Community's Recent Regulations Covering the Labeling of Genetically Modified Organisms, 25 Mich. J. Int'l L. 771 (2004).

12. Directive 2001/18, supra note 9, annex II, § A, at 19. The objective of the ERA is "on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or placing on the market may have." Id.


14. Id. art. 7, at 7. Note that this provision applies only to GMOs other than those being released onto the market. See id. art. 1, at 4.
technical information to evaluate any foreseeable risks. Finally, the Deliberate Release Directive requires in both the preamble and Article 1 entitled "Objective" that all actions be taken "in accordance with the precautionary principle."

The new Codex guidelines do not require consideration of the Precautionary Principle, indeed they do not mention it anywhere. This is problematic in that if the Precautionary Principle is deemed to allow the Deliberate Release Directive to have a higher level of protection than that prescribed by the Codex guidelines, then it will not enjoy a presumption of compliance with the SPS Agreement and will have to be analyzed under the SPS Agreement in total. Despite the fact that the Precautionary Principle is not actually mentioned in the Codex guidelines, in making the determination of whether the Deliberate Release Directive conforms to the Codex guidelines for the purposes of the SPS Agreement, the key consideration is whether or not the Precautionary Principle can be read into the Codex guidelines, in a sense recognizing an embedded precautionary principle. If it can, then the Deliberate Release Directive can be read to conform to the Codex guidelines, thereby enjoying a presumption of compliance with both the SPS Agreement and the GATT. This question will be the primary focus of Part III and IV.

If the Codex guidelines cannot be read to contain a functional precautionary principle, the Deliberate Release Directive will indeed seek a higher level of protection and will have to be judged for compliance with the entire SPS Agreement independent of any comparison with the Codex guidelines. This analysis will be done in Part V.

This Note makes two assertions. First, despite the fact that the Codex guidelines do not specifically invoke the Precautionary Principle in name, it can indeed be read into the guidelines in the amount of deference given to states in how they assess risk. This in turn means that the E.C.'s Deliberate Release Directive should be enjoy a presumption of compliance with both the SPS Agreement and the GATT. The second assertion is that even if the adjudicating body of the WTO finds that the Deliberate Release Directive, in relying on the Precautionary Principle, prescribes a higher level of protection than the Codex guidelines allow for, it still complies with the SPS Agreement and the GATT in its own right.

15. See id. art. 7(3), at 7. To qualify for the streamlined procedure, the biology of the non-modified organism must be well known and safe for human consumption and interactions with the receiving environment. Id. at annex V, at 34. Additionally, there must be well characterized information about deleted or inserted genetic material. Id. The GMO must not present any additional or increased risks to human health. Id.

16. Id. art. 1, at 4.
Part II provides an overview of the Codex guidelines and establishes why the Deliberate Release Directive should be considered under the Codex guidelines and not an alternative standard. Part III will look at whether generally the Codex guidelines and the Deliberate Release Directive seek the same level of protection in risk assessment procedures. This analysis will be important in determining whether the Deliberate Release Directive "conforms to" the Codex guidelines for the purposes of Article 3 of the SPS Agreement. Part IV looks at how precaution as a principle is used in both instruments. Specifically, Part IV establishes that although the Precautionary Principle is explicitly invoked in the Deliberate Release Directive, but is not in the Codex guidelines, the two instruments still generally seek the same level of protection because the Codex guidelines contains elements of precaution. Part V assumes, arguendo, that a WTO panel would find that the Deliberate Release Directive seeks a higher level of protection than required by the Codex guidelines. In this case, Part V establishes that even if the Deliberate Release Directive does seek a higher level of protection and therefore does not enjoy a presumption of compatibility with the SPS Agreement, it still complies with the SPS Agreement overall.

II. THE RELEVANT INTERNATIONAL STANDARD: THE CODEX ALIMENTARIUS

The Codex Alimentarius Commission held its 26th session in Rome in July of 2003. At the session, the Commission adopted four standards for assessing the risks to consumers from food derived from GMOs: 1) the Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology; 2) the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants; 3) the Draft Guideline for the Conduct of Food Safety Assessment of Recombinant-DNA Microorganisms; and 4) the Proposed Draft Annex on Possible Allergenicity Assessment.

A. The Primary Elements of the New Codex Standards for GMOs

The centerpiece of the new Codex guidelines, the Draft Principles for the Risk Analysis of Food Derived from Modern Biotechnology (Codex guidelines), generally requires a risk assessment, risk management,
risk communication, information exchange and a review process. The safety assessment guidelines for food derived from GM plants and microorganisms serve as complementary pieces, filling out requirements for risk assessments.

The Codex guidelines are a procedural framework. While the guidelines require that risk management be proportional to the assessed risk, they do not define risk in the normative sense, but only offer procedure for assessing risk.

The risk assessment is to be based on a safety assessment, designed to identify a hazard. The safety assessment is not meant to assess absolute risk, but rather relative risk in relation to a conventional counterpart. This method, called substantial equivalence, has benefits over traditional methods of using animal models to determine absolute risk. The comparison of the GM food to its conventional counterpart serves to demonstrate risks which animal models may not reveal, primarily because the substance to be tested in animal studies is well isolated and is not likely to reveal the kind of risks associated with whole foods.

20. Id. app. III(V).
21. Id. app. II, ¶ 2.
22. Id. ¶ 16.
23. Id. ¶ 10.
24. See id. apps. III, IV.

The concept of substantial equivalence has been introduced by WHO (the World Health Organisation) and O.E.C.D (the Organisation for Economic Cooperation and Development) with particular reference to foods produced by modern biotechnology. In the terminology of the O.E.C.D, the concept of substantial equivalence embodies the idea that existing organisms used as foods or as food sources can serve as a basis for comparison when assessing the safety of human consumption of a food or food component that has been modified or is new. If a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety, keeping in mind that establishment of substantial equivalence is not a safety or nutritional assessment in itself, but an approach to compare a potential new food with its conventional counterpart.

Id.
However, the guidelines make clear that substantial equivalence is only a starting point for analysis. It is not intended to imply absolute safety but rather to demonstrate the safety of the GM organism "relative to its conventional counterpart."\(^\text{27}\)

The expressed goal of the safety assessment is to "provide assurance, in the light of the best available scientific knowledge, that the food does not cause harm when prepared, used and/or eaten according to its intended use."\(^\text{28}\) The risk assessment should also enable risk managers to determine if any protective measures are needed and to make well-informed decisions based on that need.\(^\text{29}\)

In addition, the Codex guidelines require risk assessment be done on a case by case basis and focus on the safety and nutritional aspects of foods derived from modern biotechnology.\(^\text{30}\) The guidelines leave the regulating party discretion to define a level of safety and nutritional aspects, however the risk assessment should be limited only to risks to human health and wellbeing.\(^\text{31}\)

The Codex guidelines also require risk management measures taken in response to risk assessment to be "proportional to the risk assessment."\(^\text{32}\) Responses may come in multiple forms, including labeling requirements or marketing approvals.\(^\text{33}\) The guidelines specify that different measures which achieve the same level of protection should be considered equivalent.\(^\text{34}\) The guidelines also specify that risk managers should implement "appropriate measures" to manage uncertainties identified in the risk assessment.\(^\text{35}\)

The third set of elements, risk communication, involves public transparency in the safety assessment and risk management decision-making processes.\(^\text{36}\) This includes a "responsive consultation process" where all reports prepared on safety assessments and other aspects of decision making should be made available to all interested parties.\(^\text{37}\) In addition, the consultation process also provides for an input mechanisms

\(^{27}\) Id. app. III, ¶ 13.  
^{28}\) Id. ¶ 21.  
^{29}\) Id.  
^{30}\) Id. app. II, ¶ 7.  
^{31}\) Indeed, the risk assessment is not to take into account "environmental, ethical, moral and socio-economic aspects." Id.  
^{32}\) Id. app., ¶ 16.  
^{33}\) Id. app., ¶ 16, 19.  
^{34}\) Id. app. II, ¶ 17.  
^{35}\) Id. ¶ 18.  
^{36}\) Id. ¶ 23.  
^{37}\) Id.
whereby the views of all interested parties should be sought.\textsuperscript{38} This implies a public participation element to the risk analysis.

Finally, the Codex guidelines state that regulatory authorities should facilitate "the exchange of information including the information on analytical methods."\textsuperscript{39} Additionally, the guidelines require review of safety assessments "in light of new scientific information that calls into question the conclusion of the original safety assessment."\textsuperscript{40} Implicit in this is an understanding that review should be done whenever new significant scientific data becomes available. This requirement in many ways mirrors the reasoning behind the E.C.'s creation of the Deliberate Release Directive—to keep up with the development of scientific knowledge.\textsuperscript{41} Therefore, in making this requirement, the Codex Commission ensures that the Codex guidelines will keep pace with changes in domestic legislation without needing amendments to the guidelines themselves.

**B. The E.C. Measures Should Be Judged Under the New Codex Guidelines**

International organizations' participation in WTO disputes is varied. In many instances, international organizations, particularly nongovernmental organizations, are limited in their input to submitting \textit{amicus curiae} briefs, with questionable efficacy.\textsuperscript{42} However, there are a few international organizations which enjoy a great deference from WTO adjudicating bodies because they have been specified in various WTO agreements as being authorities in specific areas. Among these are the International Office of Epizootics, the Secretariat of the International Plant Protection Convention, and the Codex Alimentarius Commission.\textsuperscript{43}

The Codex Commission is specifically listed in the SPS Agreement as a "relevant international organization."\textsuperscript{44} Therefore, in terms of creating a measure which regulates food safety under the SPS Agreement, the Codex guidelines on biotechnology represent a baseline procedural requirement for assessing risks associated with GMOs.\textsuperscript{45}

Although it is likely that the new Codex guidelines will apply in the current dispute, there is a \textit{prima facie} issue of timing with respect to the

\textsuperscript{38} Id. ¶ 24.
\textsuperscript{39} Id. ¶ 28.
\textsuperscript{40} Id. app. III, ¶ 59.
\textsuperscript{41} See European Parliament Session Document, \textit{supra} note 8.
\textsuperscript{42} See MICHAEL J. TREBILCOCK & ROBERT HOWSE, \textit{THE REGULATION OF INTERNATIONAL TRADE} 66 (2d ed. 2002) (discussing the decision by the WTO panel in Shrimp Turtle to not accept input from third parties as being inconsistent with Article 11 of the GATT).
\textsuperscript{43} See SPS Agreement, \textit{supra} note 4, annex A, at 21,903--04.
\textsuperscript{44} Id. art. 3(4), at 21897.
Deliberate Release Directive and the Codex guidelines. Since the new Codex guidelines were created after the Deliberate Release Directive, it would have been impossible for the E.C. to consider them in drafting its regulations.\footnote{The Deliberate Release Directive was created in 2001, the Codex guidelines were created in 2003.} In the context of U.S. domestic jurisprudence, considering the Deliberate Release Directive under guidelines which did not exist at the time the directives were drafted would amount to creating retroactive legislation, a practice generally frowned upon by U.S. courts.\footnote{See Usery v. Turner Elkhorn Mining Co., 428 U.S. 1, 17 (1976) (stating that the burden for retroactive legislation for showing constitutionality under the Due Process clause is greater than for prospective legislation).} This, however, is not necessarily the case in WTO jurisprudence.

*European Communities—Trade Description of Sardines (Sardines)* involved such a retroactive application of international standards.\footnote{European Communities—Trade Description of Sardines, May 29, 2002, WTO Doc. WT/DS231/R.} In *Sardines*, the E.C. argued that a regulation should not be considered under international standards which did not exist at the time the regulation was adopted.\footnote{See id.} The Panel in *Sardines* did not agree with the E.C.'s argument, holding that any regulation which still exists at the time of the adoption of a new international standard is bound to comply with that new standard.\footnote{Sardines, supra note 48, ¶ 7.74, (referring to the Vienna Convention on the Law of Treaties, Jan. 27, 1980, art. 28, 1155 U.N.T.S. 331, 339).} The Panel reasoned that, under Article 28 of the Vienna Convention of the Law of Treaties (Vienna Convention), a regulation does not cease to exist before the new international standard is released, and therefore it may be considered under that new standard.\footnote{Id. The Vienna Convention of the Law of Treaties states that a treaty is not retroactive when the situation it governs has ceased to exist before the treaty entered into force.}

*Sardines* dealt specifically with claims made under the Agreement on Technical Barriers to Trade (TBT Agreement) which requires that international standards, where available, be followed.\footnote{See Agreement on Technical Barriers to Trade, Annex 1A, art. 2.4, WTO Agreement, supra note 4, vol. 27, at 22053 [hereinafter TBT Agreement].} While the SPS Agreement does not mandate such compliance,\footnote{See SPS Agreement, supra note 4, art. 3(1) at 21,896.} the reasoning behind the Panel's finding in *Sardines* regarding the TBT Agreement also applies to the SPS Agreement.

More specifically, the relevant language in the SPS Agreement reads: "[m]embers shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist."\footnote{Id.} This requirement does not include any language indicating when a mem-
ber may consider international standards, only that the relevant international standards, where they exist, be followed.55

Using the reasoning from Sardines and Article 28 of the Vienna Convention, since the Deliberate Release Directive continue to exist after the new Codex guidelines have been adopted, a WTO panel should judge it under the new Codex guidelines.

III. E.C. COMPLIANCE WITH THE CODEX GUIDELINES UNDER THE SPS AGREEMENT

The SPS Agreement applies to sanitary and phytosanitary measures which “affect international trade.”56 Since the Deliberate Release Directive seeks to regulate the transboundary movement of products, the Directive falls under the auspices of the SPS Agreement and the WTO in general. Of all the types of measures outlined in the definition of “sanitary or phytosanitary measure” in Annex A of the SPS, the Deliberate Release Directive most likely would be considered under subparagraph (a), a measure protecting against “risks ... of pests, diseases, disease-carrying organisms or disease causing organisms” or subparagraph (c), a measure designed “to protect human life or health within the territory of the member from risks arising ... from the entry, establishment or spread of pests.”57 Since a WTO dispute has never involved GMOs, it is not clear whether they would be considered pests, disease causing organisms or disease carrying organisms.58 Nevertheless, in as much as a GMO can rightly be considered a pest or disease causing organism, the measures should be considered under the SPS agreement.59

Under the SPS Agreement, a member can either create measures which “conform to international standards, guidelines or recommendations” or create their own measures, so long as they result in a “higher level of sanitary or phytosanitary protection” than the international

55. Id.
56. Id.
57. See id. annex A(1), at 21,903 (emphasis added).
58. GMOs were briefly mentioned in WTO Panel Report, Japan-Measures Affecting Agricultural Products, Oct. 27, 1998, DSR 1999:1 315, 442, WTO Doc. WT/DS76/R, ¶ 8.36. This case dealt with Japan’s Plant Protection Law which banned certain plants and plant products from being imported on the grounds that they were potential hosts of codling moth, a pest not found in Japan. GMOs were briefly mentioned in testimony in the panel report saying that genetic modification can lead to differences in plant varieties.
59. Howse & Mavroidis, supra note 1, at 350 (assessing the risks associated with GMOs); see also Julie Teel, Rapporteur’s Summary of the Deliberative Forum: Have NGO’s Distorted or Illuminated the Benefits and Hazards of Genetically Modified Organisms?, 13 COLO. J. INT’L ENVTL. L. & POL’Y 137, 140 (2002) (discussing the problems associated with NGO’s exaggeration of the risks of GMOs).
standard. If a member follows international standards in creating its measure, there is a presumption that the measure will be consistent with the SPS and the GATT 1994. If a member chooses to create a measure which seeks a higher level of protection than the international standard, it must conduct a risk assessment and justify the more stringent protection on scientific grounds.

As stated above, the Codex Commission is specifically listed in the SPS Agreement as a "relevant international organization" meaning that it is a source for international standards. Therefore, the Codex guidelines for biotechnology represent a baseline for risk assessment of GMOs under the SPS agreement.

Furthermore, the Deliberate Release Directive would enjoy a presumption of compliance with the SPS Agreement and the GATT 1994 if it can be shown to "conform to" international standards, in this case the Codex Commissions newly adopted standards for foods derived from biotechnology. The Appellate Body in European Communities—Measures Concerning Meat and Meat Products ("Hormones") determined that for a measure to "conform[] to" an international standard, "such a measure would embody the international standard completely and, for practical purposes, converts it into a municipal standard." This language suggests a close fit between a member's domestic regulation and the international standard but does not state explicitly that there need be a verbatim reproduction of the international standard. Therefore, the above language to be read to mean that the function of the two measures should be similar if not the exact wording.

As stated above, the Codex guidelines call for a risk assessment (and accompanying safety assessment), risk management, risk communication, information exchange and a review process. The risk assessment should be done on a case by case basis and focus only on risks to human

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60. SPS Agreement, supra note 4, arts. 3(2)-(3), at 21,897.
61. Id. art. 3(2), at 21897. While the SPS Agreement specifically mentions the Codex Alimentarius Commission as a source of standards, sources are not limited to the list provided in the SPS Agreement.
62. Id. art. 3(3), at 21,897; see also id. art. 5, at 21,898-99.
63. Id. art. 3(4), at 21,897.
64. See infra § II(B).
65. SPS Agreement, supra note 4, art. 3(2), at 21,897.
66. European Communities—Measures Concerning Meat and Meat Products (Hormones), Jan. 16, 1997, DSR 1998:1 135, 199, WTO Doc. WT/DS26/AB/R ¶ 170. This case dealt with an E.C. ban on the placing on the market and importation of meat and meat products which had been treated with certain growth hormones. The U.S. and Canada claimed the ban violated the SPS Agreement and the TBT Agreement.
67. See infra § II(B).
health and well-being.\textsuperscript{68} The initial question is how well the Deliberate Release Directive match these procedural elements.

Although the stated goals of the Deliberate Release Directive are \textit{prima facie} more broad than those contemplated in the Codex guidelines, this broader scope of coverage is not dispositive in showing non-conformity with the Codex guidelines. Whereas the Deliberate Release Directive seeks to protect "human health and the environment" when GMOs are released into the environment or placed on the market,\textsuperscript{69} the Codex guidelines state specifically that it does not cover risk to the environment.\textsuperscript{70} Moreover, SPS Annex A 3(d) provides that, for matters not covered by the Codex (such as environmental concerns), standards from other international bodies may be used.\textsuperscript{71}

In terms of procedural requirements, the Deliberate Release Directive tracks the Codex guidelines very closely. Like the Codex guidelines, the Deliberate Release Directive requires an environmental risk assessment (ERA) in the application for permission to release a GMO into the environment or the market.\textsuperscript{72} Also like the Codex guidelines, the ERA in the Deliberate Release Directive bases risk assessment on a comparison with conventional products and assesses risk on a case by case basis.\textsuperscript{73}

The Deliberate Release Directive requires that the ERA be carried out in a "scientifically sound ... manner based on available scientific ... data."\textsuperscript{74} This emphasis in the Deliberate Release Directive on relying on available scientific data is mirrored in the Codex guidelines which require that risk assessment "take into account all available scientific data."\textsuperscript{75} In addition, the Codex guidelines require the data submitted for risk assessment to be of a quality "that would withstand scientific peer review."\textsuperscript{76} This requirement speaks to the soundness of the scientific data.

\begin{itemize}
\item \textsuperscript{68} Task Force Report, \textit{supra} note 19, app. II, \S 7.
\item \textsuperscript{69} Directive 2001/18, \textit{supra} note 9, art. 1, at 4.
\item \textsuperscript{70} Task Force Report, \textit{supra} note 19, app. II, \S 7.
\item \textsuperscript{72} See Directive 2001/18, \textit{supra} note 9, arts. 5, 12, at 6, 8.
\item \textsuperscript{73} \textit{Id.} art. 4(3), annex III(B), at 5, 29-31.
\item \textsuperscript{74} \textit{Id.} (emphasis added).
\item \textsuperscript{75} Task Force Report, \textit{supra} note 19, app. II, \S 15 (emphasis added).
\item \textsuperscript{76} \textit{Id.} app. II, \S 12.
\end{itemize}
A similar requirement is found in the Deliberate Release Directive which mandates that an ERA be carried out "in a scientifically sound . . . manner."\(^7\)

The Deliberate Release Directive also provides for a labeling regime, as well as a review process for the release of GMOs which would meet the Codex requirement that risk management be proportional to risk assessment.\(^7\) The Deliberate Release Directive also contains provisions requiring authorities to "consult the public" regarding risks of GMOs, as well as exchange of information between competent authorities within the E.C. as well as the Commission.\(^7\) These provisions meet the requirements of risk communication and information exchange in the Codex guidelines which specifically require that the process be "fully documented at all stages and open to public scrutiny."\(^8\) Finally, the Deliberate Release Directive contains provisions requiring the review of new information regarding risks to human health.\(^8\) These provisions match closely the Codex guidelines' requirement that safety assessments should be reviewed in light of new scientific information.\(^8\)

On the face of the regulations, the Codex guidelines and the Deliberate Release Directive require very similar things in assessing risks associated with GMOs and therefore seem to seek a similar level of protection. Indeed, so long as the Appellate Body's interpretation of "conform to" in *Hormones* is not taken to mean a verbatim codification of the international standard,\(^3\) in which case no deviation from the text would be permitted, the Deliberate Release Directive does sufficiently "conform to" the Codex guidelines for the purposes of SPS Article 3.2, thereby enjoying a presumption of compliance with the SPS in general. However, the specific mention of the Precautionary Principle in the Deliberate Release Directive, and its conspicuous absence from the text of the Codex guidelines, does point to a potential difference in the way these two regimes function. This potential difference, and a determina-

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78. *See id.* arts. 4(5), 21, at 5–6, 13; Task Force Report, *supra* note 19, app. II, ¶¶ 16, 19. There is some controversy in terms of references to labeling regimes and "tracing of products" in the Codex guidelines. Many observers think the mention of traceability systems in the new Codex guidelines is a vindication of the EU's insistence on using labeling and tracing schemes for GMOs. This perception assumes "traceability" and "tracing of products" are the same. The U.S. has insisted the two terms are not equivalent. *UN Food Standards Body Approves GMO Regulations*, *Associated Press*, July 1, 2003; *see also* Brack, *supra* note 71, at 9; Bridges Trade BioRes, June 27, 2002, at http://www.ictsd.org/biores/02-06-27/story3.htm.
81. *Id.* arts. 8, 20.
tion of how much an embedded precautionary principle can be read into the Codex guidelines, will be the subject of Part IV.

IV. DOES THE PRECAUTIONARY PRINCIPLE REQUIRE A HIGHER LEVEL OF PROTECTION?

So far, this Note has discussed the facially similar elements of the Deliberate Release Directive and the Codex guidelines. However, as stated previously, a panel will also examine how a measure actually functions to determine whether it requires or allows a higher level of protection than the international standard. If the Deliberate Release Directive, in function, seeks a higher level of protection than mandated by the Codex guidelines, then it must comply with the relevant SPS provisions.

One of the primary reasons that the Deliberate Release Directive could be argued to seek a higher level of protection than the Codex guidelines is because of the invocation of the Precautionary Principle in Article 1. Nowhere in the Codex guidelines is there mention of the Precautionary Principle by name. Since a precautionary approach would allow a higher degree of protection than relying on hard scientific data, the distinction is important. Although the Codex guidelines make no mention of the Precautionary Principle, ideas of precaution may still be found within the guidelines. This determination requires a comparison of the Deliberate Release Directive and the Codex guidelines to determine if the express invocation of the Precautionary Principle makes the two instruments function significantly differently to warrant a finding that the Deliberate Release Directive seeks a higher level of protection than the Codex guidelines. It is important to point out that, at this level of examination, it is not necessary to gauge how adjudicatory bodies in the WTO treat the Precautionary Principle as a norm of international law in general. This is because the analysis at this stage still focuses only on how the regulations compare with each other and is not concerned with any substantive requirements laid out by specific requirements of the WTO Agreements.

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84. See infra Section II(A).
85. See SPS Agreement, supra note 4, art. 5(1), at 21,898.
86. Directive 2001/18, supra note 9, art. 1, at 4.
87. Of course, this part of the analysis is concerned with Article 3(2) SPS and the requirement that measures "conform to" the international standard but only in as much as it requires a comparison of the specific measure in question and the international standard. See SPS Agreement, supra note 4, art. 3(2), at 21,897.
A. The Precautionary Principle

One of the primary impediments for adequately regulating GMOs is the lack of scientific knowledge surrounding the risks associated with GMOs. This lack of knowledge necessitates that measures seeking to regulate GMOs base risk assessments on other determinations besides science, to ensure adequate protection when scientific data is not available. The Precautionary Principle is one tool regulators may use to justify regulatory measures when scientific data is contradictory or scant.

There is no definitive description of the Precautionary Principle. The most widely accepted elaboration is Principle 15 of the 1992 Rio Declaration: "Where there are threats of serious or irreversible damage, lack of scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." While this definition is limited in scope to environmental degradation (admitting the scope of such a term is potentially enormous), the Precautionary Principle has been acknowledged by the European Court of Justice (ECJ) to also apply to the area of human health protection. Based on these two interpretations, the Precautionary Principle allows that scientific uncertainty should not be used as an excuse to postpone risk management, whether the risk is to human health or the environment. It generally can be understood to apply any time there is a potential grave or irreversible threat to human health or the environment and a risk that the threat will materialize.

B. The Precautionary Principle and the E.C. Measures

With this understanding, the question remains of how does the Precautionary Principle operate within the confines of the Deliberate Release Directive specifically? The Deliberate Release Directive is precautionary on two levels. It is precautionary in that it requires that a risk assessment of a specific GMO be done prior to release. This precautionary step entails scientific analysis of risk. In addition, the Deliberate Release Directive also requires an "assessment of whether the genetic modification has been characterized sufficiently for the purpose of
evaluating any risks to human health.\textsuperscript{94} If a risk assessment is deemed insufficient (for instance because scientific evidence is not determinative), an E.C. member could take precautionary steps to prevent the release of the GMO without scientific analysis. The Deliberate Release Directive requires that E.C. members “in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health . . . which might arise from the deliberate release or the placing on the market of GMOs.”\textsuperscript{95} This language suggests that measures deemed appropriate for protecting human health could be those based on the Precautionary Principle, which by definition allows less adherence to scientific evidence.

While the Codex guidelines contain both the objectives of protecting human health and conducting science-based risk assessments, the inclusion of the precautionary language in the Deliberate Release Directive suggests that an appropriate measure, in accordance with the Precautionary Principle, may not be justified by any existing science but rather by a lack of scientific evidence. This indicates, \textit{prima facie}, that the Deliberate Release Directive seeks a higher level of protection than the Codex guidelines.

\subsection*{C. Ideas of Precaution in the Codex Guidelines}

While the Precautionary Principle is not mentioned by name in the Codex guidelines, ideas of precaution are present. The Precautionary Principle has been invoked in multiple forms in several international agreements involving food safety, the environment, and GMOs.\textsuperscript{96} Based on the prevalence of the Precautionary Principle, or the use of precautionary devices, in international agreements and instruments, one may argue that the conspicuous absence of the Precautionary Principle from the Codex guidelines indicates that the drafters did not intend to include a precautionary device. However, if the Codex guidelines are interpreted only to be guidelines for assessing risk (as indeed they should be) and the Precautionary Principle is understood as an administrative measure used after risk is assessed (as indeed it is), then it makes sense that the Precautionary Principle would be absent from the actual Codex

\begin{itemize}
\item \textsuperscript{94} Id. annex VI(3), at 35.
\item \textsuperscript{95} Id. art. 4, at 5–6 (emphasis added).
\end{itemize}
guidelines. In addition, absence of an actual invocation of the Precautionary Principle does not preclude the existence of precautionary elements in the Codex guidelines which would enable a WTO adjudicating body to read the Precautionary Principle into the text. It is, therefore, essential to examine which parts of the Codex guidelines may include ideas of precaution as a means of determining whether the Deliberate Release Directive really does require a higher level of protection because of the presence of the Precautionary Principle.

The Codex guidelines state “[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.”97 In addition, the pre-market safety assessment should also be based on sound science that “would withstand scientific peer review.”98 This language clearly indicates that a risk assessment should base its findings on science. However, it does not indicate the findings be based on a majority opinion. Indeed, the guidelines are explicit that a risk assessment should take into account “all available scientific data and information derived from different testing procedures.”99 This means that a minority opinion stating high risk due to lack of scientific understanding could be permissible.

The clearest expression of a precautionary idea in the Codex guidelines appears in the risk management section. Paragraph 18 states “[r]isk managers should take into account the uncertainties identified in the risk assessment and implement appropriate measures to manage these uncertainties.”100 While this language by no means runs contrary to the provisions of the guidelines which require that risk assessment be based on sound science, it does seem to contemplate a situation where uncertainties in a risk assessment, which cannot be assuaged by scientific review, may be deemed dangerous enough to justify preventing the release of the specific GMO.

The Codex guidelines also require safety assessments should be reviewed when necessary to ensure that emerging scientific information is incorporated into the risk analysis.101 Further, when new scientific information becomes available, it should be reviewed and “risk management measures adapted accordingly.”102 This language could be interpreted in two ways: either as specifically requiring that the latest scientific information be used in assessing risk or as implicitly allowing a risk

98. Id. app. I, ¶ 12.
99. Id. ¶ 15.
100. Id. ¶ 18.
101. Id. ¶ 30.
102. Id.
assessment to be based on an emerging but minority scientific opinion. This second interpretation, that risk assessment can be based initially on minority scientific opinions, necessitates taking into account uncertainties as per Paragraph 18, with the forward looking view that later scientific discovery may clarify current unknowns about the risks of GMOs. Viewing the language in this way, it is apparent that some situations would warrant justifying a non-release on precautionary grounds exclusively.

Based on this assessment, despite the fact that an explicit invocation of the Precautionary Principle is absent from the Codex guidelines, the guidelines do allow the use of precautionary measures when scientific information is lacking and risk is substantial. Therefore, since, as determined previously, the Codex guidelines and the Deliberate Release Directive are facially similar and both contain elements of precaution in their function, the Deliberate Release Directive does "conform to" the Codex guidelines and does not seek a higher level of protection. For the purposes of the SPS Agreement, this would mean a presumption of compliance with the SPS Agreement as well as the GATT.103

V. THE DELIBERATE RELEASE DIRECTIVE COMPLIES WITH THE SPS AGREEMENT EVEN IF THEY SEEK A HIGHER LEVEL OF PROTECTION THAN THE INTERNATIONAL STANDARD.

The above assertion that the Deliberate Release Directive conforms to the Codex guidelines relies on a finding by the panel that elements of precaution can be read into the Codex guidelines such that the Deliberate Release Directive does not seek a higher level of protection than the Codex guidelines. However, this may not be the case which leads to the second assertion of this Note; even if a WTO panel finds that the Deliberate Release Directive does seek a higher level of protection than the Codex guidelines and that it does not sufficiently "conform to" the Codex guidelines to enjoy a presumption of compliance with the SPS agreement and the GATT, the Deliberate Release directive still complies with the relevant articles of the SPS Agreement.

The SPS Agreement requires that, if a measure is deemed to seek a higher level of protection than the relevant international standard demands, it must comply with Article 5 of the SPS.104 SPS Article 5 generally requires measures be based on a risk assessment,105 the risk

103. See SPS Agreement, supra note 4, art. 3(2), at 21,897.
104. Id. art. 5, at 21898–99; see also Howse & Mavroidis, supra note 1, at 327 (discussing the relationship between domestic SPS regulations and international standards).
105. SPS Agreement, supra note 4, art. 5(1), at 21,898.
assessment must take into account available scientific evidence, the member should seek to minimize negative trade effects when determining the appropriate level of protection, and the measure must not be more trade restrictive than required to achieve the appropriate level of protection.

A. The Measure Must Be Based on a Risk Assessment and May Not Be Maintained Without Sufficient Scientific Evidence—SPS Articles 5.1, 5.2 and 2.2

Domestic sanitary and phytosanitary measures which seek a higher level of protection than that required by an international standard must generally comply with the procedural requirements in SPS Article 5 and the substantive requirements in SPS Article 2.2. Articles 5.1 and 5.2 require that a member base its sanitary and phytosanitary measures on risk assessment, and that this assessment take into account available scientific evidence. SPS Article 2.2 requires that a measure itself be based on scientific principles and may not be maintained without sufficient scientific evidence.

The SPS agreement initially requires that a member base its measure on an assessment of "the risks to human, animal or plant life or health." The Appellate Body in Hormones made clear that while a risk assessment cannot be based merely on "theoretical uncertainty," the SPS Agreement does not require that a member establish a magnitude of risk. Therefore, a member could in theory seek to reduce ascertainable risks to zero.

After determining the existence of risk, the member must conduct a risk assessment based on scientific principles. "Risk assessment" is defined in Annex A of the SPS agreement as:

The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing member according to the sanitary or phytosanitary measures

106. Id. art. 5(2), at 21,898.
107. Id. art. 5(4), at 21,898.
108. Id. art. 5(6), at 21,898.
109. See id. arts. 5(1–2), at 21,898.
110. Howse and Mavroidis have provided an extensive analysis of the general compliance of previous E.C. GMO measures with these requirements of the SPS. However, it is useful to recount the analysis in light of the fact that Directive 2001/18 effectively repeals Directive 90/220 by adding new requirements. See Howse & Mavroidis, supra note 1.
111. SPS Agreement, supra note 4, art. 5(1), at 21,898.
113. Howse & Mavroidis, supra note 1, at 329.
114. See SPS Agreement, supra note 4, art. 5(2), at 21,898.
which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.\textsuperscript{115}

The Panel in \textit{Hormones} interpreted this definition as requiring "at least for risks to human life or health, a scientific examination of data and factual studies; it is not a policy exercise involving social value judgments made by political bodies."\textsuperscript{116} However, the Appellate Body in \textit{Australia—Measures Affecting Importation of Salmon (Salmon)} stated that it is not necessary for the risk assessment to establish any threshold degree of risk to justify the SPS measure.\textsuperscript{117} A risk assessment need not be quantitative, but may be expressed "quantitatively or qualitatively."\textsuperscript{118}

The Appellate Body in \textit{Salmon} developed a three prong test for risk assessments, determining that a risk assessment must:

\begin{enumerate}
\item \textit{identify} the disease whose entry, establishment or spread a member wants to prevent within its territory . . .
\item \textit{evaluate the likelihood} of entry, establishment or spread of these diseases, as well as the associated potential biological and economic consequences, and
\item evaluate the likelihood of entry, establishment or spread of these diseases \textit{according to the SPS measures which might be applied.}\textsuperscript{119}
\end{enumerate}

In establishing the above three criteria, the Appellate Body made clear that a risk assessment cannot simply determine there is a possibility of entry; the risk assessment must affirmatively determine the likelihood or probability of entry.\textsuperscript{120}

Howse and Mavroidis point out that since there is only a qualitative requirement to the risk assessment, and not a quantitative one, the only threshold for scientific certainty required by the SPS is the threshold of not being maintained without "sufficient scientific evidence" contained

\textsuperscript{115} SPS Agreement, \textit{ supra} note 4, annex A(4), at 21,904
\textsuperscript{116} Howse & Mavroidis, \textit{ supra} note 1, at 330 (quoting European Communities—Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States, Aug. 18, 1997, WTO Doc. WT/DS26/R/U.S.A \textsection 8.94).
\textsuperscript{118} \textit{Id.}
\textsuperscript{119} \textit{Id.} \textsection 121.
\textsuperscript{120} \textit{Id.} \textsection 123.
in SPS Article 2.2. This means that regulators could act to prevent serious harm even where a risk assessment is uncertain so long as the uncertainty was based on sufficient scientific evidence and further examination was unwarranted due to excessive costs or delay resulting in irreparable harm.

The Principles of Environmental Risk Assessment outlined in Annex II of the Deliberate Release Directive generally track the requirements set out in SPS Articles 5.1 and 5.2. The overall objective of the ERA is 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." This language complies with the procedural requirements laid out in Salmon that a risk assessment identify the organism, evaluate the likelihood of the spread of the organism (and associated consequences) and the potential effectiveness of the measure proposed. In addition, the Deliberate Release Directive requires that the ERA be "carried out in a scientifically sound ... manner based on available scientific ... data." Requiring a sound scientific basis for the ERA is in keeping with the panel’s requirement in Hormones that a risk assessment necessarily entail a scientific examination of data and factual studies.

However, Article 28 of the Deliberate Release Directive also requires a scientific committee be consulted when there is an objection raised by the E.C. member authority or the Commission regarding the risks of GMOs, when a risk assessment report indicates that a GMO should not be placed on the market, or at the discretion of the Commission or the relevant authority of the E.C. member. This framework provides for a further examination of the scientific justification for an action in almost every situation where precaution may necessitate denying a release application. While Article 28 does not specify exactly what the Scientific Committee is to find, if they are indeed required to find anything at all regarding the risk assessment, this extra step does seem to address the requirements or SPS Article 2.2. In addition, consultation of the Scien-

121. Howse & Mavroidis, supra note 1, at 362; see also Salmon, DSR 1998:VIII at 3365, WTO Doc. WT/DS18/AB/R ¶ 130.
122. Howse & Mavroidis, supra note 1, at 362.
123. See Howse & Mavroidis, supra note 1, at 363.
126. Directive 2001/18, supra note 9, annex II.
129. See Howse & Mavroidis, supra note 1, at 363.
The New Codex Alimentarius

B. Members Should Minimize Negative Trade Effects and Measures Should Not Be More Trade Restrictive Than Necessary—Arts. 5.4 and 5.6 SPS

Article 5.6 SPS requires generally that a member’s measures are not more trade restrictive than required to provide the “appropriate level of sanitary and phytosanitary protection.” In determining this level of protection, under SPS Article 5.4, a member must “take into account the objective of minimizing negative trade effects.”

The Appellate Body in Salmon noted that the footnote to SPS Article 5.6 creates a three part test for ensuring that a measure is no more trade-restrictive than required. A measure is considered more trade-restrictive than required if there is another measure which: is “reasonably available taking into account technical and economic feasibility,” “achieves the appropriate level of sanitary . . . protection”; and is “significantly less restrictive to trade” than the sanitary measure contested.

The Salmon test does not examine the member’s chosen level of protection. Indeed, a WTO adjudicating body will not question the level of the objective sought; they will review the means and not the ends of a measure. However, the Panel in Japan—Measures Affecting Agricultural Products (“Varietals Panel”) determined that Article 5.6 of the SPS agreement must be read in the context of Article 2.2; namely that the measure is applied only to the extent “necessary to protect human . . . life or health.” The Varietals Panel indicated that an adjudicating body may examine a member’s ends, and if a measure was over protective of human health, it would be deemed more trade restrictive than required. Therefore, a test for compliance with SPS Article 5.6 would characterize a member’s appropriate level of protection, deem whether that level is necessary to protect human life or health, and assess what other

131. SPS Agreement, supra note 4, art. 5(6), at 21,898.
132. Id. art. 5(4), at 21898.
133. See id. art. 5(6), at 21898 n.3.
135. Howse & Mavroidis, supra note 1, at 337.
137. Id.
measures which are less trade restrictive may be reasonably available based on this level of protection.

In terms of the level of protection sought by the Deliberate Release Directive, safety of a GM product is determined relative to its conventional counterpart. In essence, this means that any margin of risk beyond that posed by the non-genetically modified equivalent could potentially be deemed inadequate. This regime establishes a baseline (the safety of the conventional counterpart) which is, by its nature, minimally trade restrictive since the safety of a conventional counterpart is already an accepted norm in the market which trading partners can be reasonably excepted to meet. In addition, scientific committees could demonstrate the level of protection is necessary to protect human health. This would address the requirement outlined in Varietals that a measure not be over protective of human health.

The fast track procedures outlined in Article 7 of the Deliberate Release Directive could address the requirement that the measure “take into account the objective of minimizing negative trade effects” if it indeed can be shown that sufficient experience with a GMO has lead to a conclusion that it is safe for human consumption. However, Article 7 could be little more than window dressing for all but the most well known and widely used products.

An important question relating to Article 7 of the Deliberate Release Directive is the source of the experience with the GMO. Article 7 requires interactions with the sending and receiving environments. This could limit trading partners’ market access. A member desiring to export a specific GMO to the E.C. could have substantial experience with that GMO in its own country but be denied the fast track process because it has no information regarding interactions with an E.C. environment. If an exporting member in this situation were still required to go through the E.C.’s standard regulatory approval process, instead of the fast track approval process, this could be considered more trade restrictive than necessary, in light of the fact that the particular GMO is safe for use in the exporting country. While it is difficult to determine in the abstract how advantageous differentiated procedures would be, it is clear that having a number of different methods for approving GMOs, each with varying requirements, goes a longer way towards compliance with SPS Articles 5.6 and 5.4.

138. Howse & Mavroidis, supra note 1, at 364.
139. See Howse & Mavroidis, supra note 1, at 364.
141. SPS Agreement, supra note 4, art. 5(4), at 21,898.
142. Directive 2001/18, supra note 9, annex V(2), at 34.
143. See id.
C. Checking Compliance With A Measure Must Be Done Without Undue Delay—SPS Article 8

Another aspect of the Deliberate Release Directive which will be of crucial importance to a WTO panel is the “moratorium” on approval of all GMO products seeking admission into the E.C. The U.S. complaint centers on the E.C. suspension of applications for and approval of biotech products under the E.C. system as well as national marketing and import bans on biotech products of E.C. member states.144

SPS Article 8 and Annex C require that approval procedures be undertaken and completed “without undue delay.”145 The Appellate Body in *Hormones* established that SPS Article 2.3, which requires that member’s measures not constitute a disguised restriction on trade146, provides context for reading other SPS articles.147 Therefore, if a member were to violate Article 8 in terms of causing an undue delay in the approval process, this would also be a violation of Article 2.3. It is important to consider, in assessing compliance with SPS Articles 8 and 2.3, whether the moratorium is outside the scope of the Deliberate Release Directive or is considered legal within the scope of the framework.

With respect to E.C. member states’ individual regulations, the European Court of Justice (ECJ) recently held that an E.C. member state may suspend the trade in GMOs within its territory if, as a result of new information or a reassessment of existing information, the product endangers human health.148 This case dealt with Italy’s suspension of the use of transgenic maize manufactured by Monsanto, which Monsanto claimed should have been allowed under the fast track provisions in Article 5 Novel Foods.149 The court found that Article 5 Novel Foods did not prevent a member from implementing measures under Article 12 Novel Foods, which generally provides that when new or additional...
information regarding food safety indicates a danger to human health, a member may temporarily restrict or suspend trade or use of a product.\footnote{150. Council Regulation 258/97 on Novel Foods and Novel Food Ingredients, art. 1, 1997 O.J. (L 43) 1, 1–6 [hereinafter Novel Foods].}

Those measures can be adopted only if the member State has first carried out a risk assessment which is as complete as possible given the particular circumstances of the individual case, from which it is apparent that, in the light of the precautionary principle, the implementation of such measures is necessary in order to ensure that novel foods do not present a danger for the consumer.\footnote{151. Case 236/01, supra note 148.}

The Deliberate Release Directive also contains a safeguard provision with language that mirrors Article 12 of Novel Foods almost exactly.\footnote{152. See Directive 2001/18, supra note 9, art. 23, at 13.}

Therefore, even though the ECJ did not consider the Deliberate Release Directive, it is reasonable to assess both measures' compliance with SPS Article 8 together.

The U.S. included the Italian suspension of Monsanto maize in its WTO complaint. However, in terms of compliance with the SPS agreement, the question for the WTO panel will not be one of substantial equivalence (as it was for the ECJ in the Italian Case), but whether the indefinite suspension of GM maize could be considered an undue delay under SPS Article 8 and a disguised restriction on trade under SPS Article 2.3.

The ECJ decision in the Italian Case indicates that suspensions of approval of GMOs are legal within the E.C. regulations. In addition, since the fast track procedures outlined in Article 5 Novel Foods do not affect a state's ability to implement safeguards under Article 12 Novel Foods, the decision also indicates that safeguards fall outside of the scope of procedural approval requirements in Novel Foods. While this decision is certainly not binding on a WTO panel, it could be instructive in determining whether the provisional measures in Article 12 Novel Foods, as well as those in Article 23 of the Deliberate Release Directive, are outside the scope of the procedural requirements under SPS Article 8.\footnote{153. See generally India—Patent Protection for Pharmaceutical And Agricultural Chemical Products, Dec. 19, 1997, DSR 1998:1 9, 30–31, WTO Doc. WT/DS50/AB/R ¶ 66 (discussing the application of domestic decisions to WTO rulings).}

Using the ECJ's ruling as a basis, the E.C. moratorium would not be considered a procedural violation under SPS Article 8 since any suspension of the approval process would be outside the normal scope of the normal approval process. A provisional measure such as a moratorium is more appropriately considered under SPS Article 5.7.
D. Measures Adopted on Precaution—SPS Article 5.7

SPS Article 5.7 allows a member to provisionally adopt sanitary measures in cases where scientific evidence is insufficient. While generally, SPS Article 2.2 prevents a member from implementing measures without scientific justification, SPS Article 5.7 operates as a qualified exemption from obligations under SPS Article 2.2. However, SPS Article 5.7 does not override the requirements of SPS Articles 5.1 and 5.2. Therefore, while a member does not have to base a provisional measure on scientific principles, nor maintain it with scientific evidence (as required by SPS Article 2.2), it still must base the measure on a risk assessment which takes into account available scientific evidence (as required by SPS Articles 5.1 and 5.2).

In this vein, the Appellate Body in Varietals determined that the two sentences of SPS Article 5.7 read together constitute a four part test. First, the relevant scientific information must be insufficient. Second, the measure must be adopted on the basis of available pertinent information. Third, the member must seek to obtain additional information necessary for a more objective assessment of risk. This information must be “germane to conducting . . . a risk assessment.” Finally, the member must seek to review the measure within a reasonable period of time. This period of time is established on a case by case basis. If any one of these four requirements is not met, a measure is not consistent with Article 5.7.

The Appellate Body did not illuminate the meaning of “available pertinent information.” This term is potentially the most important in SPS Article 5.7, however, in terms of understanding how much information is enough to justify a precautionary measure.

Howse and Mavroidis point out that the Deliberate Release Directive is precautionary in the sense that the it takes a precautionary approach by not approving a GMO until it is shown to be safe. This implies a...
reliance on a scientific determination of safety (or lack thereof). However, SPS Article 5.7 only requires that a member’s risk assessment take into account scientific evidence, not base a decision on scientific evidence. Therefore, the E.C. could invoke SPS Article 5.7 if a provisional measure was put in place because a “genetic modification has [not] been characterized sufficiently for the purpose of evaluating any risks to human health” as required by the Deliberate Release Directive.

The current moratorium seems to be exactly this kind of situation. For reasons which are not sufficiently supported by available science, the E.C. and its member states have chosen to suspend trade in certain GMOs because they have not been sufficiently characterized in terms of human safety.

In applying the four part test from Varietals, the first two parts are clearly met. The scientific information in this case is insufficient to establish a hard line of acceptable risk and the measure is being adopted on the basis of the information which is available. In regards to the third part, that the member must seek additional information necessary for a more objective assessment, Howse and Mavroidis point out that in the old measure, Directive 90/220/EEC, there was only a duty to seek new information in situations where the GMO was approved. Howse and Mavroidis make the argument, however, that in denying an application, an applicant can always reapply with new information and so in a sense the third prong of SPS Article 5.7 is met. Expanding upon Howse and Mavroidis’ reasoning, this is true when there is nothing to prejudice reapplication (as there is not of the face of the Deliberate Release Directive). However, in a situation such as the current one, in which a moratorium may prejudice reapplication, or a requirement to collect new information may be seen as a disguised barrier to trade, it is not so clear that the third prong is met.

The third prong may be met however by the requirement under the Deliberate Release Directive to consult a scientific committee in situations where an application has been refused. Part of the Scientific Committee’s charge is to “draw the Commission’s attention to any specific or emerging problem falling within their remit in matters of . . .

167. SPS Agreement, supra note 4, art. 5(7), at 21,898.
169. Indeed, the Scientific Committee on Plants found many of the temporary bans instituted by E.C. member states under article 16 of Council Directive unjustified based on scientific evidence. See Facts on GMOs in the EU, supra note 6 at 4.
170. Howse & Mavroidis, supra note 1, at 368.
171. Id. at 369.
food safety.\textsuperscript{173} This examination by the Scientific Committee seeks new information as per the third prong of the \textit{Varietals} test.\textsuperscript{174} However, the language of Article 28 of the Deliberate Release Directive indicates that a Scientific Committee is consulted in a situation where permission is refused, not where permission is stayed.\textsuperscript{175} Therefore, the Deliberate Release Directive does not seem to fulfill the third prong of the test.

However, even though the E.C. has suspended applications and decisions, investigation into risk assessment continues. Just recently the European Food Safety Authority (EFSA) issued a favorable scientific opinion on Monsanto’s NK603 Roundup Ready Maize, one of the products listed in the U.S. complaint.\textsuperscript{176} This determination by the EFSA was the last step before final approval under the Deliberate Release Directive.\textsuperscript{177} Therefore, while the process may be moving slowly (the pace of the review would then be the fourth consideration of the \textit{Varietals} test), it is by no means stagnant.\textsuperscript{178}

E. One Final Consideration—\textit{GATT} Article XX

If the moratorium cannot be justified in terms of scientific assessment of risk, the most appropriate instrument for review of legality under WTO may be \textit{GATT} Article III.4.\textsuperscript{179} \textit{GATT} Article III.4 forbids members from giving less favorable treatment to products which are considered the same or directly competitive. The difficult determination in this situation would be likeness. The Appellate Body, in \textit{E.C.—Measures Affecting Asbestos And Asbestos Containing Products} ("Asbestos") found "likeness" can be determined using physical properties, end uses, consumer perceptions and tariff classification, but other considerations are

\textsuperscript{175}. Directive 2001/18, supra note 9, at 14–15.
\textsuperscript{177}. See Monsanto Press Release, supra note 176.
\textsuperscript{179}. \textit{GATT}, supra note 4, art. III(4), 55 U.N.T.S. at 206.
not outside the scope of GATT Article III.4.\textsuperscript{180} The \textit{Asbestos} opinion used consumer perceptions to justify differentiating products in terms of health risks or perceived health risks. In the same way, GMOs may be determined to be different from conventional products because of the public perception of the dangers of GMOs.

However, if the Deliberate Release Directive is deemed to be inconsistent with GATT Article III.4, they could still be justified either under GATT Article XX(a) or (b), exemptions for public morals or protecting human health. The Deliberate Release Directive provides for a consultation of a Committee on Ethics where issues on the ethical implications of biotechnology arise.\textsuperscript{181} This would provide a basis either for determining unlikeness of products or justifying the moratorium under GATT Article XX(a).\textsuperscript{182}

The moratorium may also be justifiable under subparagraph (b) or GATT Article XX which allows members to violate GATT Article III if it is necessary to protect human health.\textsuperscript{183} The Appellate Body in \textit{Asbestos} determined that a member, in justifying a measure under GATT Article XX(b), may rely on scientific sources which represent a divergent opinion.\textsuperscript{184} In addition, the Appellate Body also stated that a panel need not rely on the preponderant weight of the evidence to deem an action is justifiable under GATT Article XX(b). This indicates that an action could potentially be based on a minority scientific opinion which advocated for precaution but could only back up that opinion with a \textit{lack} of clear evidence of safety.

The Appellate Body also made clear that the term “necessary” means there is no less trade restrictive measure available.\textsuperscript{185} If the E.C. can show via a scientific opinion, potentially from a Scientific Committee, that there is a potential risk in the future from GMOs, then the moratorium could be considered the least trade restrictive means of protecting human health.

\textsuperscript{180} European Communities—Measures Affecting Asbestos And Asbestos Containing Products, March 12, 2001, WTO Doc. WT/DS135/AB/R ¶ 102.

\textsuperscript{181} Directive 2001/18, supra note 9, art. 29, at 14–15.

\textsuperscript{182} See Howse & Mavroidis, supra note 1, at 370. At this point, the Public Morals exception in Article XX(a) GATT has not been interpreted in WTO adjudication, so it is not clear how the “necessity” requirement would be met.

\textsuperscript{183} See GATT, supra note 4, art. XX(b), 55 U.N.T.S. at 262.

\textsuperscript{184} Asbestos, WTO Doc. WT/DS135/AB/R ¶ 178.

\textsuperscript{185} Id. ¶ 171.
The current GMO dispute is one of the WTO’s greatest adjudicating challenges to date. From a legal standpoint, multiple levels of legal framework within the WTO as well as in the E.C. risk turning the adjudication process into a morass. From a societal standpoint, the challenge is greater. This dispute is more politically charged than Shrimp Turtle, which to date has been the WTO’s highest profile case. While the legal regime may advise a specific outcome, going counter to the will of either the United States or the E.C. risks putting into question the legitimacy of the entire WTO.

The new Codex guidelines are a small part of the overall dispute, but since they represent the baseline by which the E.C. may judge the risks of GMOs, the guidelines are a critical element. The new Codex guidelines provide a procedural framework for regulators to assess the risks associated with foods derived from biotechnology. In as much as the Deliberate Release Directive currently being challenged in the WTO is also a procedural framework for E.C. member states to create domestic regulatory policy for managing risks associated with GMOs, the directive clearly conforms to the international standard as required in SPS Article 3.2. In addition, even though the Deliberate Release Directive bases its implementation on the Precautionary Principle, the directives does not seek a higher level of protection than sought in the Codex guidelines as elements of precaution are included in them as well.

Even if the Deliberate Release Directive is deemed to be more protective than the Codex guidelines, and therefore does not enjoy the presumption of compliance granted by SPS Article 3.2, it is more than likely that it will be found to comply with SPS Article 5. In addition, the moratorium could be considered a provisional measure under SPS Article 5.7 if it can be shown that as part of the application process, there is an ongoing examination of the potential safety of the GMO. Indeed, the recent permission granted to Mansanto Roundup Ready maize indicates this to be the case.


187. See SPS Agreement, supra note 4, art. 3(2), at 21,896.