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*US—Continued Suspension of Obligations
in the EC-Hormones Dispute*

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Introduction

When WTO member states seek to restrict imports on the grounds of protecting public health and safety, those trade-restricting measures must be justified under the provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures (“SPS Agreement”),¹ one of the agreements that make up the WTO system. The SPS Agreement is, by its nature, a compromise between two principles: the desire of WTO members to reduce barriers to international trade, and the desire of those members nonetheless to pass the national laws that each deems necessary to safeguard public health and welfare.

Several fundamental questions underlie disputes over trade-restricting SPS measures. How much discretion should each member have within the WTO framework to define the nature and gravity of public health risks they seek to ensure against? Does such discretion undermine the central purpose of the WTO, which is to harmonize national legislation to permit the free flow of goods across borders? To what extent can scientifically-based risk assessments provide an objective measure of risk that applies globally? What level of scientific knowledge and consensus should be required to strike down a divergent SPS measure as scientifically unsupported? Where scientific knowledge or consensus is lacking, may a member maintain a trade-restricting measure on the basis of the precautionary principle, which endorses human and environmental protection against potential risks in the absence of complete scientific understanding?

The WTO’s dispute resolution arm has struggled to answer these questions in a series of cases interpreting the SPS Agreement. In two previous WTO decisions – *European Communities—Measures Concerning Meat and Meat Products (Hormones)* (“EC-Hormones”)² and *European Communities—Measures Affecting the Approval and Marketing of Biotech Products* (“EC-Biotech”)³—the Appellate Body and a WTO panel rejected attempts by the European Communities (“EC”) and some of its member states to justify restrictions on hormone-treated

¹ Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter SPS Agreement].

² Appellate Body Report, *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R (Oct. 16, 2008) [hereinafter *EC-Hormones*].

³ Panel Report, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS293/R (Sep. 29, 2006) [hereinafter *EC-Biotech*].

beef, and on biotech products, without the support of risk assessments establishing a causal link between the public health concern and the products that the EC and some of its member states sought to restrict. While those cases established that a vague recitation of the precautionary principle would not suffice to defend an SPS measure, the more difficult questions presented by the SPS Agreement remained largely unanswered.

In *United States—Continued Suspension of Obligations in the EC-Hormones Dispute*, (“*US-Continued Suspension*”),⁴ the Appellate Body considered a more sophisticated attempt by the EC to implement and support an SPS measure. The EC appealed a decision of the Panel that favored a strict approach to scientific evidence and risk assessment, relying heavily on standards set in risk assessments by international bodies, which would likely result in greater consistency of SPS measures among WTO member states. The Appellate Body rejected this approach as too rigid, announcing instead a standard that permits greater individuality of SPS measures among WTO members, while balancing that freedom with standards that seek to ensure rigorous scientific review of even the most nation-specific solutions.

US-Continued Suspension: Factual Background

The case has a long procedural history, beginning with the *EC-Hormones* dispute. In that case, the United States (“U.S.”) and Canada had challenged the ban imposed by the EC on meat from cattle treated with six hormones – oestradiol-17 β , progesterone, testosterone, trenbolone acetate, zeranol, and melengestrol acetate (“MGA”).⁵ The U.S. and Canada challenged the measures under Article 5.1 and Article 5.7 of the SPS Agreement, which permit SPS measures only when they are based on a risk assessment (Art. 5.1), or, on a provisional basis, where scientific evidence is insufficient to conduct a risk assessment (Art. 5.7). The WTO Appellate Body held that the scientific studies relied on by the EC as risk assessments to justify the bans were not “sufficiently specific to the case at hand” because they were “general studies which do indeed show the existence of a general risk of cancer; but they do not focus on and do not address the particular kind of risk here at stake.”⁶

Following the *EC-Hormones* ruling, the EC authorized seventeen additional scientific studies on the effects of the hormones at issue.⁷ Based on the first group of studies, the EC on May 12, 1999 informed the Dispute Settlement Body of the WTO (“DSB”) that it would not lift its import ban.⁸ The U.S. and Canada on July 26, 1999, obtained authorization from the DSB to “suspend concessions and other obligations” to the EC and imposed import and ad valorem duties on certain EC imports.⁹

The EC received the results of the seventeen scientific studies at different times over the next few years. At the request of the EC, the Scientific Committee on Veterinary Measures relating to Public Health (“SCVPH”) of the EC issued three separate opinions (in 1999, 2000, and 2002)

⁴ Appellate Body Report, *United States—Continued Suspension of Obligations in the EC-Hormones Dispute* WT/DS320/AB/R (Sep. 19, 2008) [hereinafter *US-Continued Suspension*].

⁵ *US-Continued Suspension* ¶ 2.

⁶ *Id.* ¶ 5.

⁷ *Id.* ¶ 10.

⁸ *Id.* ¶ 7.

⁹ *Id.* ¶¶ 8-9.

evaluating the scientific data.¹⁰ In light of the SCVPH's conclusions, the EC adopted Directive 2003/74/EC on September 22, 2003, which maintained the EC's permanent prohibition on meat and meat products from animals treated with oestradiol-17 β , and which provisionally continued the bans on the other five hormones until "more complete scientific information" could be collected with regard to the risks of those hormones to consumers.¹¹

The EC informed the DSB of Directive 2003/74/EC, as well as the 1999, 2000 and 2002 opinions of the SCVPH, which it considered to be risk assessments justifying the measures. The EC claimed that it had fully complied with the ruling in *EC-Hormones* and that the U.S. and Canada's suspension of concessions were no longer justified. The U.S. and Canada refused to lift the import and ad valorem duties. The EC requested consultations with the U.S. and Canada, and a Panel was established on February 17, 2005.¹²

Before the Panel, the EC argued that it had removed the inconsistent measure,¹³ and that the U.S. and Canada had violated the dispute settlement provisions of the WTO by maintaining the suspension of obligations without having recourse to the DSB to determine whether the new EC directive satisfied the Panel's ruling in *EC-Hormones*.¹⁴

In its report, the Panel considered the sufficiency of the new EC directive in meeting the EC's obligations under the SPS Agreement.¹⁵ The Panel ruled that the EC had not shown that the new measures were consistent with its obligations.¹⁶ The Panel also held that the U.S. and Canada violated the Dispute Settlement Understanding ("DSU") of the WTO¹⁷ by maintaining concessions after the enactment of Directive 2003/74/EC rather than initiating WTO proceedings to determine the sufficiency of the new Directive.¹⁸ The EC and the U.S. and Canada appealed the Panel's rulings.¹⁹ The oral hearing on the appeal took place on July 28-29, 2008.²⁰

The Ruling of the Appellate Body

The Appellate Body issued its report on September 19, 2008.²¹ With regard to the procedural issues, the Appellate Body held that the U.S. and Canada were not required to initiate proceedings concerning the sufficiency of Directive 2003/74/EC and therefore did not violate the DSU by maintaining concessions after the enactment of that Directive.²² However, the

¹⁰ *Id.* ¶ 10.

¹¹ *Id.* ¶ 11.

¹² *Id.* ¶ 12.

¹³ *Id.* ¶ 14.

¹⁴ *Id.* ¶ 13.

¹⁵ Panel Reports, *US-Continued Suspension*, WT/DS320/R (U.S.) and WT/DS321/R (Canada) (March 21, 2008).

¹⁶ *Id.* ¶¶ 7.579, 7.835, 7.847 (U.S.); ¶¶ 7.548, 7.822, 7.832 (Canada).

¹⁷ Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter DSU].

¹⁸ *Id.* ¶ 7.856 (U.S.); ¶ 7.841 (Canada).

¹⁹ Appellate Body Report, *US-Continued Suspension* ¶¶ 26-28.

²⁰ *Id.* ¶ 33.

²¹ *Id.* p. 310.

²² *Id.* ¶ 736(a). In addition to deciding numerous issues under the SPS Agreement, the Appellate Body Report dealt extensively with the procedural issues raised in the post-suspension stages of a dispute. See ¶¶ 265-409. In general,

Appellate Body found that the Panel had erred in several respects in reviewing the EC's risk assessment and the sufficiency of Directive 2003/74/EC under the SPS Agreement.²³ In light of these errors, the Appellate Body reversed the Panel's decision that the Directive was not based on a risk assessment under the SPS Agreement.²⁴ Finding that it lacked sufficient information to complete the analysis itself, the Appellate Body recommended that the parties initiate new proceedings to determine whether the Directive complied with the EC's obligations under the SPS Agreement.²⁵

This section reviews three of the Appellate Body's most significant conclusions with regard to the SPS Agreement: the relationship between risk assessment and risk management; the standard of review that a panel should observe in considering a risk assessment under Art. 5.1; and the quantity and quality of scientific evidence needed to render a previous scientific conclusion "insufficient" to conduct a risk assessment under Art. 5.7.

A. Defining the Relationship Between Risk Assessment and Risk Management: Higher Level of Protection May Be Relevant to Scope and Methodology of Risk Assessment

Article 2.2 of the SPS Agreement provides that an SPS measure must be based on scientific principles and sufficient scientific evidence.²⁶ This standard informs the requirement in Art. 5.1 that an SPS measure must be based on a risk assessment.²⁷ The scientific evidence requirement of Art. 2.2 also imparts meaning to the provision of Art. 5.7 that WTO members may adopt SPS measures on a provisional basis where certain conditions are fulfilled, including where the relevant scientific evidence is insufficient to perform a risk assessment.²⁸ Whether a member can maintain an SPS measure under Art. 5.1 or Art. 5.7, then, turns on whether the inquiry justifying the measure is considered an adequate "risk assessment" under the SPS Agreement.²⁹

the Appellate Body ruled that the EC was not entitled to a presumption that Directive 2003/74/EC satisfied its obligations under SPS Agreement. Because the enactment of Directive 2003/74/EC did not, by itself, remove the measure found to be inconsistent with the SPS Agreement in the original *EC-Hormones* dispute, the U.S. and Canada could not be said to have violated Articles 22.8, 23.1 or 3.7 of the DSU by maintaining suspension of concessions without recourse to further proceedings under the DSU. The Appellate Body ruled that either party could initiate such proceedings to resolve any issues regarding the sufficiency of a new measure. *See id.* ¶ 736.

²³ *Id.* ¶ 736(b)-(d).

²⁴ *Id.* ¶¶ 736(c)(vi), 736(d)(vi).

²⁵ *Id.* ¶ 737.

²⁶ "Members shall ensure that any [SPS] 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 provide for in [Art. 5.7]." SPS Agreement, Art. 2.2.

²⁷ "Members shall ensure that their [SPS] measures are 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 organizations." SPS Agreement, Art. 5.1.

²⁸ "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt [SPS measures] on the basis of available pertinent information, including that from the relevant international organizations as well as from [SPS measures] applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the [SPS measure] accordingly within a reasonable period of time." SPS Agreement, Art. 5.7.

²⁹ The SPS Agreement defines a "risk assessment" as "[t]he evaluation of the likelihood of entry, establishment or spread of a pest or disease with the territory of an importing Member according to the [SPS measures] 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." SPS Agreement, Annex A, ¶ 4.

While the SPS Agreement encourages members to rely on relevant international standards to protect against risks,³⁰ the SPS Agreement recognizes that a country may choose to guarantee its citizens a higher level of protection than afforded by the international standards.³¹ The level of protection chosen by a member falls under the heading of “risk management,” which has been defined as “the process, distinct from risk assessment, of weighing policy alternatives ... considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.”³² Such higher levels of protection must still be based on a risk assessment.³³

The WTO Appellate Body and WTO panels have in recent cases begun to articulate the distinction between risk assessment and risk management. One particularly thorny question has been whether the sufficiency of a “risk assessment” must be viewed as entirely separate from countries’ decisions concerning “risk management.” Under one view, risk assessment is a purely factual, scientific inquiry into the existence and magnitude of risk, and cannot be affected by the types of policy judgments that risk management is concerned with.³⁴ A competing view holds that risk assessment is never purely empirical, but rather involves judgments affecting the scope and nature of the risk assessment.³⁵ Under this view, risk management concerns can, and indeed inevitably will, affect the framing of the risk assessment. Proponents of this view argue that risk assessment thus cannot be meaningfully understood in complete isolation from risk management considerations.³⁶

In *US-Continued Suspension*, this question arose in two instances. First, the EC argued that its ban on oestradiol-17 β was justified by a risk assessment under Art. 5.1 in part because the studies showed the likelihood of misuse or abuse of actual veterinary practices, resulting in unsafe levels of the hormone being present in treated animals.³⁷ The U.S. and Canada argued that the consideration of misuse or abuse was a matter for the risk management stage, and could not serve to justify the ban as based on a risk assessment.³⁸ Second, the question arose with regard to the provisional ban on the other hormones under Art. 5.7. The EC argued that the existence of international risk assessments for the provisionally-banned hormones did not preclude the EC’s provisional bans, because there was insufficient scientific evidence to perform a risk assessment under Art. 5.7 with regard to the higher level of protection chosen by the EC, such as the risk of the hormones to minors.³⁹

³⁰ SPS Agreement, Art. 3 and Preamble, Recital 6.

³¹ SPS Agreement, Art. 3.3 and Annex A, ¶ 5 (“appropriate level of protection” is “level ... deemed appropriate by the Member establishing an [SPS measure] to protect human, animal or plant life or health within its territory”).

³² Codex Alimentarius Commission, Procedural Manual (15th ed.) at 45.

³³ *Id.*

³⁴ See, e.g., Executive Summary of Oral Statement of the United States at the First Substantive Meeting with the Panel, *EC-Biotech* ¶ 27 (June 17, 2004), available at http://www.trade-environment.org/output/theme/tewto/us_oral_statement_June04_summary.pdf; David Winickoff et al., *Adjudicating the GM Food Wars: Science, Risk and Democracy in World Trade Law*, 30 YALE J. INT’L L. 81, 84-85 (2005).

³⁵ Winickoff et al, *supra* note 34, at 94-106.

³⁶ *Id.*

³⁷ *US-Continued Suspension* ¶¶ 512, 537.

³⁸ *Id.* ¶¶ 515, 518.

³⁹ *Id.* ¶ 682.

In its decision, the Panel had sided with the U.S. and Canada, taking a strict reading of the term “risk assessment” as wholly separate from “risk management.”⁴⁰ The Panel quoted approvingly from the decision of the panel in *EC-Biotech*, which stated, “the protection goals of a legislator may have a bearing on the question of which risks a Member decides to assess ... Yet there is no apparent link between a legislator’s protection goals and the task of assessing the existence and magnitude of potential risks.”⁴¹ The Panel in *US-Continued Suspension* concluded, “the determination of whether scientific evidence is sufficient to assess the existence and magnitude of a risk must be disconnected from the intended level of protection.”⁴²

The EC argued that the Panel erred by adopting a narrow interpretation of risk assessment that “failed to take into account that risk assessment and risk management partly overlap in the SPS Agreement.”⁴³ The Appellate Body agreed. Reiterating its ruling in *EC-Hormones*, the Appellate Body stated that the failure of the SPS Agreement to use the term “risk management” did not justify the Panel’s rigid exclusion of consideration of risk management principles in a risk assessment.⁴⁴ On that basis, the Appellate Body held that that Panel erred in refusing to consider the possibility of misuse or abuse of good veterinary practices as a contributing factor in the EC’s risk assessment, which the EC claimed to justify its ban on oestradiol-17 β .⁴⁵

With regard to the EC’s argument that its higher level of protection justified the provisional bans on the other hormones under Art. 5.7, the Appellate Body reiterated its holding that the level of protection chosen by a member could affect the scope or method of the risk assessment.⁴⁶ “In such a situation, the fact that the WTO Member has chosen to set a higher level of protection may require it to perform certain research as part of its risk assessment that is different from the parameters considered and the research carried out in the risk assessment underlying the international standard.”⁴⁷ The Appellate Body emphasized, however, that SPS measures must still be based on “rigorous and scientific” risk assessments, and the chosen level of protection may not “pre-determine the outcome of its determination of the sufficiency of the relevant scientific evidence.”⁴⁸

The Appellate Body’s observation that the higher level of protection “may have some bearing on the scope or method of the risk assessment” departs sharply from the previous statements of the panels in *EC-Biotech* and *US-Continued Suspension*. Instead of treating risk assessment as an objective scientific inquiry completely unaffected by risk management considerations, the Appellate Body took the view that risk management informs the scope and methods of risk assessment.⁴⁹ This decision seems to open the door to a WTO standard of risk assessment

⁴⁰ Panel Report, *US-Continued Suspension* ¶¶ 7.609 (U.S.); ¶ 7.587 (Canada).

⁴¹ Panel Report, *US-Continued Suspension*, ¶ 7.609 (quoting Panel Report *EC-Biotech*, ¶ 7.3238).

⁴² *Id.* ¶ 7.612.

⁴³ Appellate Body Report, *US-Continued Suspension* ¶ 537.

⁴⁴ *Id.* ¶ 541-42.

⁴⁵ *Id.* ¶ 545.

⁴⁶ *Id.* ¶ 685.

⁴⁷ *Id.*

⁴⁸ *Id.* ¶ 686.

⁴⁹ See Winickoff et al., *supra* note 34.

analysis that permits member states to exercise greater choice and flexibility with regard to SPS measures, so long as those measures undergo a thorough risk assessment process.⁵⁰

B. Standard of Review Under Art. 5.1: Panels Should Determine Whether Risk Assessment Is Supported By Scientific Evidence, Not Whether Conclusion Is “Correct”

In reviewing the EC’s risk assessment, the Panel had conducted its own inquiry of several scientific experts with regard to the scientific conclusions upon which the EC’s risk assessment was based. The Panel explained that it relied on the majority scientific opinion where one existed; and, where scientific views were divergent, it relied on the view that “appeared, in our view, to be the most specific in relation to the question at issue and to be best supported by arguments and evidence.”⁵¹ The EC argued that the Panel applied an improper standard of review under Art. 5.1, seeking to determine “what the correct scientific conclusions are” rather than simply assessing whether there was a sufficient scientific basis for the EC’s conclusions in its risk assessment.⁵²

The Appellate Body agreed with the EC and clarified the applicable standard of review:

A panel reviewing the consistency of an SPS measure with Article 5.1 must determine whether that SPS measure is “based on” a risk assessment. It is the WTO Member’s task to perform the risk assessment. The panel’s task is to review that risk assessment. Where a panel goes beyond this limited mandate and acts as a risk assessor, it would be substituting its own scientific judgement for that of the risk assessor and making a *de novo* review and, consequently, would exceed its functions under Article 11 of the DSU. Therefore, the review power of a panel is not to determine whether the risk assessment undertaken by a WTO member is correct, but rather to determine whether that risk assessment is supported by coherent reasoning and respectable scientific evidence and is, in this sense, objectively justifiable.⁵³

The Appellate Body noted that a WTO member is entitled to rely on divergent or minority views, as long as those views come from a “respected and qualified source.”⁵⁴ The Appellate Body held that the Panel had overstepped its bounds in reviewing the EC’s risk assessment by seeking to ascertain and apply the majority scientific view of the risks of the hormones, rather than questioning whether reputable scientific opinion existed to support the EC’s ban on oestradiol-17β. This conclusion lends further support to the notion that the WTO is moving in the direction of permitting more individualized regulation by members, allowing for unique risk tolerance levels in that country that may differ from the prevailing international attitude. The Appellate Body appears likely to balance this move toward national individualization by requiring rigorous

⁵⁰ See Ilona Cheyne, *Precaution in International Trade in Food and Other Agricultural Products*, 4 EUR. FOOD & FEED L. REV. 47, 56-57 (2009).

⁵¹ *US-Continued Suspension* ¶ 596 (quoting Panel Report, *US-Continued Suspension* ¶ 7.420).

⁵² *US-Continued Suspension* ¶ 585.

⁵³ *Id.* ¶ 590.

⁵⁴ *Id.* ¶ 591 (citing Appellate Body Report, *EC-Hormones* ¶ 194).

scientific inquiry and reasonable proffers of “coherent reasoning and respectable scientific evidence” to support regulations based on divergent or minority scientific views.

C. “Insufficiency” Under Art. 5.7: New Scientific Evidence Need Not Reach “Critical Mass” But Merely “Cast[] Doubts” On Previous Conclusions

With regard to the provisional bans on the other five hormones under Art. 5.7, the parties agreed that, because of the evolving nature of science, it was possible that new scientific evidence could render the state of scientific knowledge insufficient to perform a risk assessment, even where previous risk assessments had been conducted.⁵⁵ In assessing the level of scientific change necessary to render the previous scientific evidence no longer sufficient to perform a risk assessment under Art. 5.7, the Panel had stated that “there must be a *critical mass* of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence so as to make relevant, previously sufficient, evidence now insufficient.”⁵⁶

The Appellate Body held that this standard was “too inflexible” because it “could be understood as requiring that the new scientific evidence lead to a paradigm shift.”⁵⁷ Instead, the Appellate Body stated,

It may be useful to think of the degree of change as a spectrum. On one extreme of this spectrum lies the incremental advance of science. Where these scientific advances are at the margins, they would not support the conclusion that previously sufficient evidence has become insufficient. At the other extreme lie the more radical scientific changes that lead to a paradigm shift. Such radical change is not frequent. Limiting the application of Article 5.7 to situations where scientific advances lead to a paradigm shift would be too inflexible an approach. WTO Members should be permitted to take a provisional measure where new evidence from a qualified and respected source puts into question the relationship between the pre-existing body of scientific evidence and the conclusions regarding the risks. We are referring to circumstances where new scientific evidence casts doubts as to whether the previously existing body of scientific evidence still permits of a sufficiently objective assessment of risk.⁵⁸

Thus, with regard to this issue as well, the Appellate Body seemed to endorse an approach that favors nation-specific assessment and management of risks, provided that nation-specific solution is not so idiosyncratic as to be unsupported by reasonable scientific evidence.

⁵⁵ *Id.* ¶¶ 699-700.

⁵⁶ Panel Report, *US-Continued Suspension* ¶ 7.648 (emphasis in original).

⁵⁷ Appellate Body Report, *US-Continued Suspension* ¶ 705.

⁵⁸ *Id.* ¶ 703.

Conclusion

The solution reached by the Appellate Body will likely result in less harmonization of SPS measures across WTO members, with the result of higher costs in international trade as countries and businesses adjust operations to comply with nation-specific SPS measures. While this outcome may impede the WTO goal of international harmonization of trade measures, it offers the countervailing advantage of preserving a sense of legitimacy of the WTO by permitting national authorities to choose SPS measures based on nation-specific situations and concerns, rather than deferring in every case to one-size-fits-all standards determined in the risk assessments performed by largely unaccountable international standards bodies. The Appellate Body's approach attempts to place limits on this national freedom by requiring that the scientific standards embodied in the SPS Agreement are observed, albeit relying more on rigorous process than on specific outcomes. With the increasing controversy regarding globalization and the role of the WTO, the benefits of increasing the perceived legitimacy of the WTO as a complement to, rather than a usurpation of, national government authority may outweigh the costs incurred as a result of lesser uniformity of SPS measures from country to country.