CAN YOU PROVIDE EVIDENCE OF INSUFFICIENT EVIDENCE? THE PRECAUTIONARY PRINCIPLE AT THE WTO

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Can you provide evidence of insufficient evidence? The precautionary principle at the WTO

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Abstract
This paper aims to demonstrate that the WTO jurisprudence on science-related trade disputes has become entangled with a specific vision of science that has prevented any possible application of the precautionary principle. This situation is due to reasons of both legal procedures specific to the WTO dispute settlement system and the substantive nature of precautionary measures. Indeed, their foundation on “insufficient scientific evidence” dramatically complicates the question of the probative value of science for the purpose of legal adjudication and creates a seemingly contradictory situation, of which the Panel on the EC-Biotech case confirmed to be a victim: that of providing legal evidence of insufficient scientific evidence. For the first time, the US-Continued Suspension case has opened a gateway to address this fundamental issue.

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1 Introduction

The precautionary principle is an established principle of international law that is explicitly included in a number of international environmental agreements (such as the Convention on Biological Diversity and the United Nations Framework Convention on Climate Change) and is referred to in more general terms in other international agreements, such as the Marrakesh Agreement of 1994 establishing the World Trade Organization.

The place of the precautionary principle in the WTO framework is highly controversial for different reasons. Although protection measures are provided for in Article XX of the GATT 1994, their adoption under the precautionary principle is problematic in that they are based on reasons of “precaution” rather than of “strict necessity”; for the former, no clear standards of proof exist because the science underlying the precautionary principle is incomplete or inconclusive. Furthermore, the precautionary principle affects each Member State’s sovereignty in setting its own level of protection in favor of human, plant and animal health, challenging the harmonization of State practices in this field. These two elements clearly show that the precautionary principle is an easy candidate for creating indirect barriers to trade.

No explicit reference to the precautionary principle is found in the WTO agreement; rather there are “gateway” provisions to it, which have been revealed through the WTO jurisprudence on science-related disputes. However, it is the opinion of the author that despite some important changes, the status of the precautionary principle remains incompatible with WTO rules. This opinion is corroborated by one fundamental fact: that those States invoking the precautionary principle in support of protection policies have never been able to demonstrate the legitimate use of it.

This paper aims to outline an epistemological framework of science at the WTO in order to determine the proper allocation of the precautionary principle. This will be done by way of comparison with its supposed opposite, the science-based principle: through a brief analysis of the SPS Agreement and the presentation of the EC-Biotech dispute between the EU and the group composed of the United States, Canada and Argentina, the precautionary principle will immediately emerge as one of the justifications for imposing restrictive measures on trade (section 2). However, despite being given the status of an autonomous right by the EC-Biotech Panel, it will emerge that its qualification, both procedurally and substantially, is that of an exception to the rule of performing a risk assessment. This precise allocation of the precautionary principle within the realm of policy as opposed to that of science creates a crucial legal problem (section 3), for which only scientific evidence is translated into legal evidence and only an “adequate” risk assessment is considered to be relevant for providing facts for the dispute. If the defensibility of a case of precaution becomes severely impaired by the fact that it entails “insufficient scientific evidence”, or even impossible when it has to counter a case of “sufficient scientific evidence”, the question arises as to whether the precautionary principle can still refer to the autonomous right of WTO Members to set their preferred level of protection as found by the EC-Biotech Panel (section 4). This issue is addressed through the analysis of another similar dispute, the US-Continued Suspensions case (section 5), which opens the gateway for important changes to the epistemology of science maintained at the WTO. The final section concludes.

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2 The relation between science and precaution at the World Trade Organization

2.1 The Sanitary and Phytosanitary Agreement

In order to shed light on the discourse on the applicability of the precautionary principle in WTO law, we will focus on the WTO Sanitary and Phytosanitary (hereinafter SPS) Agreement, since it strictly addresses the relation between the validity of scientific instructions to protect human, plant and animal health and the legitimacy of Member States (hereinafter MSs) accordingly applying restrictive measures to trade.

Article 2.2 of the SPS Agreement states that “Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.” Therefore, besides requiring that all possible less restrictive solutions be exhausted before imposing protective measures (the so-called “necessary test”), the SPS Agreement states that those actions producing higher trade-restrictive effects (than those generally expected from similar measures based on international standards) must be corroborated by scientific justification.

As specified in Article 5.1, this justification implies that a risk assessment of the product under protection be performed: “Members shall ensure that their sanitary or phytosanitary 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.”

But Article 2.2 also provides an exception to this rule, which is included in Article 5.7 and considers a situation where scientific evidence is insufficient to conclude that there is a definite risk: “In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members [...]”. Does this mean that the case in Article 5.7 is exempt from scientific justification? The WTO jurisprudence up until the EC-Biotech dispute confirms precisely this approach, validating a dramatic dichotomy between science (Article 5.1) and precaution (Article 5.7). We shall see that this situation has important consequences in terms of the legal capacity to justify precautionary measures in case of dispute (see paragraph 3).

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4 This requirement instructs the so-called “necessary test”, which was first formulated by the Panel Report on the Tuna-Dolphin case; in order to demonstrate that a trade-restrictive measure is consistent with Article XX(b) of GATT 1994, Member States must have exhausted all possible less restrictive alternatives, provided that the Panel determines whether any such alternative is “reasonably available” (United States – Restrictions on Imports of Tuna, para. 5.22, DS21/R, DS21/R, 3 September 1991, unadopted, BISD 39S/155).

5 In the Japan-Agricultural Products case (Appellate Body Report, Japan – Measures Affecting Agricultural Products. WT/DS76/AB/R, adopted 19 March 1999, DSR 1999:I, 277, at para. 102), the Appellate Body stated that it would have been wrong to convert an advantage, i.e. the presumption of legitimacy for those SPS measures based on international standards, into an obligation for Members to comply with these standards.
2.2 The EC-Biotech dispute: legal background

In the European Communities-Measures Affecting the Approval and Marketing of Biotech Products dispute (hereinafter EC-Biotech), the group composed of the United States, Canada and Argentina accused the European Union of having imposed a de facto moratorium on the commercialization of genetically modified organisms (hereinafter GMOs) since 1998, due to “undue delay” in the approval procedure. The complainants claimed that either the risk assessments on GMOs were not carried out by European Member States to legitimate safeguard measures, or the positive results of risk assessments were completely dismissed, since the approval procedure for twenty-four out of twenty-seven GMOs had never been completed. Thus, according to the complainants, the European behavior violated Article 5.1 of the SPS Agreement, which requires that SPS measures be based on scientific principles, namely on risk assessment. In the absence of such an assessment, the European delay accounted for a non-necessary (“more trade restrictive than required”, Article 5.6, SPS Agreement) and non science-based (“maintained without sufficient scientific evidence”, Article 2.2, SPS Agreement) restrictive measure to trade.

In their defense, the European Communities (hereinafter EC) argued that to the extent that safeguard measures on the importation of certain GMOs were adopted by six EC Member States, the case of (in)consistency was on the contrary to be examined under Article 5.7 of the SPS Agreement instead of Article 5.1, the former contemplating the case of scientific uncertainty and better reflecting the precautionary principle.

On 29 September 2006, the WTO Dispute Settlement Body issued its ruling on the complaints, on the one hand faulting the EC for “undue delay” in approving GMO products for a four-year period ending in 2003 (de facto, the suspension of the approval procedure produced a general moratoria inconsistent with the provisions of Article 8 and Annex C(1) of the SPS Agreement) and on the other, accusing a number of EC Member States of maintaining unjustified bans on GM products already found safe by the European scientific committees; indeed, the justification of the six European states that scientific results were not “convincing” and needed further evaluation before allowing the importation of these products was not upheld by the Panel, which found no GMO case where scientific evidence was insufficient to perform an adequate risk assessment.

2.3 The role of Article 5.7 with respect to Article 5.1 of the SPS Agreement

Despite the fact that the Panel managed to bypass substantial questions on the compatibility between European legislation on GMOs and WTO rules, and finally concluded by faulting the

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7 In this paper, biotechnology products are also referred to as Genetically Modified Organisms (GMOs), except where differently stated. GMOs are products that have been altered using recombinant DNA technologies.
8 Safeguard measures are trade-restrictive measures for the sale or use of GMOs that EC Member States may adopt on a provisional basis, even if those products have already received consent for introduction into the European market. At the time of the dispute, the safeguard was laid down in Article 16 of Council Directive 90/220/EEC of 23 April 1990, on the deliberate release into the environment of genetically modified organisms, Official Journal L 117, 08/05/1990 p. 0015 - 0027; and Article 12 of Regulation (EC) no 258/97 of the European Parliament and of the Council of 27 January 1997, concerning novel foods and novel food ingredients, Official Journal L 043, 14/02/1997 P. 0001 – 0007.
9 The six European States concerned are Austria, France, Germany, Greece, Italy, and Luxembourg.
EC only on procedural grounds (“undue delay”), some important issues of a substantial nature emerged – and even exploded – at different levels: concerning the tension between a State’s sovereign right to apply the level of protection it deems appropriate for its citizens on the one hand, and the need to harmonize State practices by means of some neutral standard – science being assumed to be the best candidate – on the other; concerning the boundary between science and non-science (or “pertinent available information” pursuant to Article 5.7); and, most of all, concerning the probative value of all pertinent information with respect to science.

To address this question, we should begin by understanding why and how the European Union invoked the precautionary principle, claiming that scientific evidence was insufficient. After all, some risk assessments had already been performed on certain GMOs and had concluded favorably on them. The complainants’ argument was specifically based on this point: since the EC’s measures accounted for a ban and since there was no reason for concern about these products, the EC’s conduct was not rationally or objectively based on risk assessment, contrary to Article 5.1.10

The European legislation on GMOs contains the so-called “safeguard clause”, which integrates the precautionary principle and allows European States to derogate from the final consent of the Commission to introduce certain GMOs into the European market by provisionally restricting their sale and usage (Article 16 of Directive 220/90/EEC). Is the European safeguard clause compatible with the SPS agreement? It is indeed, for two reasons: as determined by the Appellate Body in the EC-Hormones case, Article 3.3 of the SPS Agreement confers upon WTO Member States the right to choose their own level of protection, including a higher level of protection than that established by international standards;11 furthermore, Article 5.7 of the same Agreement considers that “in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures […]” (emphasis added). But can Articles 3.3 and 5.7 override the requirement set out in Article 5.1 to base SPS measures on risk assessment?

An extensive part of the proceedings was devoted to precisely this point. Its discussion was undertaken as a matter of legal procedure: the issue was to define whether the complainants had to provide their prima facie case on the basis of Article 5.1, as they themselves requested, or of Article 5.7, which was instead invoked by the EC. Since both are considered as justification for protection measures under Article 2.2 (see supra paragraph 2), the EC called for a parallelism: inasmuch as Article 3.3 of the SPS Agreement granted MSs the autonomous right to set their chosen standards of protection,12 it was an autonomous right – and not an exception – for each MS to take precautionary actions under Article 5.7. According to this view, Article 5.7 gave precautionary actions the same legitimacy as Article 5.1 gave to risk-based actions. In terms of legal procedure, this would have implied that the complainants present their prima facie case of inconsistency on the basis of Article 5.7.

The Panel agreed with the EC’s position and held that: “[…] characterizing Article 5.7 as a right means that if a challenged SPS measure was adopted and is maintained consistently with

10 The requirement that SPS measures be “based on” risk assessment has been interpreted in other cases by the Appellate Body to be a substantive requirement that there be a rational or objective relationship between SPS measures and risk assessment. See Appellate Body Report, EC Measures Concerning Meat and Meat Products (Hormones), para. 186. WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, DSR 1998:I, 135; and Appellate Body Report, Japan –Agricultural Products (see supra note 5), at para. 84.
11 In the EC-Hormones case (ibid. at para. 172), the Appellate Body reversed the previous Panel finding on the same case that the setting of higher standards of protection represented an exception to the general objective of the SPS Agreement to promote international standards harmonization: “[The] right of a Member to establish its own level of sanitary protection under Article 3.3 of the SPS Agreement is an autonomous right and not an ‘exception’ from a ‘general obligation’ under Article 3.1.”
12 Ibid.
the four cumulative requirements of Article 5.7, the obligation in Article 5.1 to base SPS measures on a risk assessment is not applicable to the challenged measure. Conversely, if a challenged SPS measure is not consistent with one of the four requirements of Article 5.7, the aforementioned obligation in Article 5.1 is applicable to that measure, provided there are no other elements which render Article 5.1 inapplicable\textsuperscript{13} (emphasis added).

This interpretation set an important precedent for the precautionary principle within the WTO legal framework, conferring upon it the status of an autonomous right. Concerning the EC-Biotech case, this interpretation gave sense to the EC’s invocation of the precautionary principle under Article 5.7, despite the fact that some risk assessments had already concluded favorably on certain GMOs. It therefore fell to the complainants to prove that a case of “insufficient scientific evidence” did not subsist and, once they had discharged the burden of proof, it would have fallen to the EC to provide evidence for its case of “insufficient scientific evidence”.

However, proceedings did not ultimately go this way: the EC-Biotech Panel totally dismissed its own findings and decided to revise the \textit{prima facie} case of the complainant under Article 5.1. This choice was explained as a matter of legal procedure: since the two Articles applied to exclusive situations (one of sufficient and the other of insufficient scientific evidence), if the European safeguard measures had been found consistent with Article 5.1, the Panel held, there would have been no need to assess their consistency with Article 5.7.\textsuperscript{14}

However, precisely because of this exclusivity between Articles 5.1 and 5.7, the opposite reasoning would have been equally valid: if the safeguard measures had been found consistent with Article 5.7, then there would have been no need to further analyze their consistency with Article 5.1. Therefore, what is the real difference between the two legal procedures? I shall explain that in practical terms, given the vision of mainstream science maintained by the Panel and confirmed by previous WTO jurisprudence on similar cases, the difference is null (see section 3.2); theoretically, if the vision changed, this difference could be of a substantial nature (see paragraph 5.2).

### 3 Legal and scientific standards of proof

The EC-Biotech Panel concluded that Articles 5.1 and 5.7 of the SPS Agreement applied to two exclusive situations, respectively of sufficient and insufficient scientific evidence, so that when one applies the other is excluded.\textsuperscript{15} Although the exclusivity between the two Articles implies – theoretically – equality of treatment in terms of legal procedure, the definition of Article 5.7 as “a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence”,\textsuperscript{16} which the EC-Biotech Panel upheld, nevertheless suggests that the same equality may not apply in substantial terms. Indeed, in terms of their probative value, science (corroborated by a risk assessment in the form of “sufficient scientific evidence”) certainly has an advantage over precaution (“insufficient scientific evidence”): after all, what is more “evident” than science?

\textsuperscript{13} EC-Biotech (see supra note 6), at para. 7.2997.
\textsuperscript{14} \textit{Ibid.} at para. 7.3006. This choice was explained as a matter of legal procedure: in fact, if the safeguard measures had been found consistent with Article 5.1, the Panel held, then there would have been no need to assess their consistency with Article 5.7, given their exclusivity (no Article takes precedence over the other).
\textsuperscript{15} \textit{Ibid.}
\textsuperscript{16} Japan –Agricultural Products, see supra note 5, at para. 80.
To answer this question, we should first specify precaution ("insufficient scientific evidence") with respect to science ("sufficient scientific evidence"), before identifying the consequences this distinction has on the relation between scientific evidence and legal evidence. To begin with, the wording of Article 2.2 (see paragraph 2) rephrases the essence of the two realms denoted by Articles 5.1 and 5.7 as "scientific principles" on the one hand, and "available pertinent information" on the other. We should be aware that this rephrasing deprives the notion of "insufficient scientific evidence" of its scientific and evident nature, creating a problem that is both scientific (see paragraph 3.1) and legal (see paragraph 3.2).

3.1 The relation between sufficient scientific evidence and adequate risk assessment

The wording of the SPS Agreement conveys the idea that only scientific evidence that is sufficient remains scientific, whereas scientific evidence that is insufficient loses its scientific character and becomes "available pertinent information". But what makes scientific evidence insufficient? According to the Appellate Body Report on Japan-Apples,17 which the EC-Biotech Panel upheld, "[…] ‘relevant scientific evidence’ will be ‘insufficient’ within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate risk assessment […]". In the EC-Biotech case, assessments of the risk entailed by certain GMOs were already available, therefore calling for a situation of "sufficient scientific evidence" (Article 5.1). But we know that the EC actually invoked a situation of "insufficient scientific evidence" despite the availability of those risk assessments. If the "adequate risk assessment" is the boundary between the two situations,18 the question remains: how could the EC invoke the precautionary principle? In terms of legal procedure, we already know the answer (see paragraph 2.3); but in terms of legal substance, this creates a true problem, whose origins are to be found in the epistemology of science maintained by the Panel. According to the Panel’s view, an “adequate risk assessment” is one that follow the standards contained in Annex A(4) of the SPS agreement and is able to demonstrate the existence of a risk in terms of the probability, and not just possibility,19 that an event (a cause) may induce another event (an effect).20 Going back to the definition of insufficient scientific evidence as one where “the body of available scientific evidence does not allow […] the performance of an adequate risk assessment […]” (emphasis added), the correspondence between the “adequacy” of risk assessment and the “sufficiency” of scientific evidence can be summarized through the following syllogism: risk assessment is adequate when it builds on the Annex A(4) standards; to follow Annex A(4) standards implies that scientific evidence is sufficient; therefore, an adequate risk assessment is one where scientific evidence is sufficient. The epistemological problem with respect to this interpretation is that the transitivity between the adequacy of risk assessment and the sufficiency of scientific evidence is totally incorrect:

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18 EC-Biotech (see supra note 6), at para. 7.2939.

19 As maintained by the Appellate Body on the Australia-Salmon case, the risk assessed in the court should be a probable and not a possible one, for it must be ascertainable and verifiable and must allow for an objective risk assessment. Appellate Body Report, Australia – Measures Affecting Importation of Salmon, WT/DS18/AB/R, adopted 6 November 1998, DSR 1998:VIII, 3327, at para. 123.

20 This position is confirmed by the Appellate Body report in Japan-Apples (see supra note 17), stating that the adjective “insufficient” attached to scientific evidence indicates a relational concept, as it is “adequate” for risk assessment.
risk assessment is certainly the labeling feature of “science”, but it does not provide any guarantee of producing sufficient scientific evidence. Indeed, it is a matter of ontological and epistemological correctness to distinguish between the information that is processed in a risk assessment (input) and the evidence that can result from it (output). As with any decision, the evidence is not produced by facts (the collection of sufficient data), but by the moment when knowledge is closed.\textsuperscript{21} When this does not happen, for example when a cause-effect relationship between two events cannot be established, knowledge remains open to possible and alternative conclusions, which in any case are all the product of a scientific analysis. This means that sufficient scientific evidence is not the inevitable product of processing all the information relevant and available to a subject, but is the product of interpretation. Most importantly, scientific evidence does not lose its scientific character if it is inconclusive as to the existence of a risk.

3.2 \textit{Legally locked-in scientific evidence}

The previous paragraph has shown that the legal operation of linking the sufficiency of scientific evidence, i.e. science, to the adequacy of risk assessment is not supported by a modern understanding of the epistemology of science;\textsuperscript{22} this vision applies even less to the case of GMOs, where the supporting sciences of biology and ecology are by nature anything but complete, objective and undisputed.\textsuperscript{23}

The dichotomy between science and precaution, between “sufficient scientific evidence” and “insufficient scientific evidence”, creates a serious legal problem. It is common knowledge that before a court (or a legal panel as with the WTO) the parties in dispute must provide some evidence in support of their case. Putting aside the question of the allocation of the burden of proof (indeed, there is nothing to discuss, since legal procedure prescribes that it falls to the complainant to form a \textit{prima facie} case of inconsistency between the defendant’s behavior and his obligations), the issue is to establish which obligations are relevant to prove a case of inconsistency. Indeed, determining whether Article 5.1 or Article 5.7 is the relevant provision for the dispute makes a huge difference as to the type of evidentiary burden the parties must discharge.

In case of litigation, the defendant must provide scientific explanation in support of their stricter protection policies as of Article 2.2 of the SPS Agreement. Legally speaking, this kind of justification corresponds to providing scientific evidence of some threat to human or animal health or the environment, which is meant to qualify a situation of “necessity” (Article 5.1). For cases where no evidence of risk is available, i.e. cases of insufficient scientific evidence, Article 5.7 considers another kind of justification, which is apparently “less scientific” because not supported by conclusive evidence, but only by “available pertinent information”, calling for “precaution” instead of strict necessity.

These preliminary considerations already suggest that even if the fundamental characteristic of legal evidence is to be reasonable and rational, the kind of science intended by the Panel (always sufficient, complete and objective) is more apt, if not automatically apt, to provide evidence for a case than is precaution. Indeed, the kind of rationality behind the latter is much less evident and much more difficult to disclose before a court. In brief, science, if conclusive and temporarily undisputed, creates a legal advantage for whoever wants to use it as evidence


\textsuperscript{22} For further discussion on this point, see Elisa Vecchione, \textit{Science for the environment: examining the allocation of the burden of uncertainty}, European Journal of Risk Regulation (2011).

\textsuperscript{23} Interview with Antoine Méssean, Head of Unit, INRA (France), Paris, France (16 April 2008).
for his case and, conversely, imposes a huge burden on whoever wants to provide a case to the contrary. This is the characteristic of scientific knowledge per se and these are its legal implications when used in a tribunal. The high risk of this situation is that scientific standards of proof may be automatically translated into legal standards of proof: if science is considered equivalent only to complete scientific knowledge enabling cause-effects relationships to be established in factual terms through risk assessment, then there could not be any competing legal evidence, much less any based on a case of “insufficient scientific evidence”.

This risk explicitly materialized in the EC-Biotech case, which is why, after all, there would have been practically no difference if the Panel had maintained its own findings and revised the complainant’s case on the basis of Article 5.7 instead of Article 5.1 (see paragraph 2.3). Indeed, if that had been the case, the complainants would have had to demonstrate that scientific evidence was not insufficient25 (i.e. was sufficient) and, as a second step, that evidence would have rationally called for a different (i.e. zero or less stringent) level of protection.

If we retain the vision of science emerging from WTO jurisprudence and confirmed by the EC-Biotech Panel, we can conclude without difficulty that this burden is relatively easy to discharge: not only risk assessments but also international standards, such as the Codex Alimentarius,26 were in place to demonstrate that scientific evidence was in fact sufficient. The burden of proof would have then shifted to the defendant, which would have had to prove that scientific evidence was on the contrary insufficient. This proof requires disrupting already existing international standards or already available risk assessments by providing new scientific evidence. But this very condition means that the justification for precautionary actions is highly impaired: first of all because the evidence required is extremely burdensome in scientific terms as it corresponds to a paradigm shift; second, because this condition goes back to the same requirement set out in Article 5.1, forgetting that the case of precaution should instead be provided on the basis of Article 5.7, i.e. on the basis of “insufficient scientific evidence”. However, even without falling into the trap of searching for new scientific evidence, it is clearly unlikely that already available scientific evidence (contained in international standards) will be countered by insufficient scientific evidence or “pertinent available information”.

The vicious circle of incessant searching for scientific truth is caused by the strict dichotomy maintained between sufficient science as the only science, and insufficient science as something else: less scientific, less evident. And indeed in the actual proceedings the Panel

24 The science used for informing legal trials and instructing policy decisions – which are eventually contested within legal trials – is a form of knowledge that is “frozen” contingent upon consensus of the majority of the scientific community. This means that it can be contested, but to do so involves a heavy burden on whoever wants to confute the state of the art.

25 Specifically, as per the Appellate Body’s findings in the Japan-Agricultural Products case (see supra note 5, at para. 90), compliance with Article 5.7 was to be determined upon four requirements. Measures shall be: (1) imposed in respect of a situation where “relevant scientific information is insufficient”; (2) adopted “on the basis of available pertinent information”. Members shall (3) “seek the […] measure accordingly within a reasonable period of time”; (4) review the […] measure accordingly within a reasonable period of time”. Thus, the complainants would have discharged their burden by simply demonstrating the inconsistency of EU measures with at least one of these requirements.

26 The Codex Alimentarius is one of the so-called “three sisters” organizations explicitly referred to by the SPS Agreement for providing international standards, guidelines and recommendations.
tried to evaluate, with the help of a scientific panel specially appointed for the case,\textsuperscript{27} whether the scientific studies conducted by the European States could account for new scientific evidence able to counteract previous science. As such, new scientific evidence should have been able to demonstrate the existence of a probable, not just a possible risk:\textsuperscript{28} no matter how minimal the risk found, it had to be proved as a matter of fact, in other words to be “ascertainable” in terms of a cause-effect relationship.\textsuperscript{29} But this position again dismisses the fact that a case of precaution originates from the exact opposite situation, that is the inability to prove a cause-effect relationship.

As a consequence of the dichotomy between science and precaution, a perfect and dangerous conceptual match emerges between scientific evidence and legal evidence, while an oxymoron seems to dominate the relationship between uncertainty, in the form of insufficient scientific evidence, and (legal) evidence. How is it in fact possible to provide evidence of uncertainty?

4 A question of rights: how to provide legal evidence of insufficient scientific evidence

The previous section has demonstrated that the dichotomy between science and precaution translates into a dramatic overlapping between scientific and legal standards of proof, the standard for both being that of risk assessment.

The consequence of such an approach is that precautionary measures cannot find any defense in case of dispute, simply because the legal issue of providing evidence of a case (i.e. a case of insufficient scientific evidence) is discarded as almost a contradictory operation. But if we suppose that the existence of a right (i.e. the right to set preferable levels of protection as of Article 3.3) depends on the ability of the party invoking that right to demonstrate the legitimacy of its conduct, then we might wonder whether this right subsists for the case of precautionary measures.

As in any international organization, within the WTO tension always exists between national States’ sovereignty and their international obligations. In the context of SPS measures, the WTO obligation to provide scientific justification for restrictive trade measures is a necessary coordination rule for a multilateral trade system in which each MS has in principle the right to choose its own level of protection. The risk is that SPS measures become de facto “disguised

\textsuperscript{27} A scientific panel was established to discern science, truth and certain information from everything else. However, the recourse to the scientific panel was more a procedural artifice than the expression of a true consciousness of the complexity of the science-law interface (interview with Eric Schoonejans, Legal Service for the delegation of the European Communities to the EC-Biotech dispute, Paris, France, 1 September 2008): the complexity and accuracy of this part of the report is both undeniable and useless to the purpose of legal proceedings; moreover, the five scientists appointed to the scientific panel were definitely not enough to handle commentaries on more than forty GM products.

\textsuperscript{28} For instance, for the Austrian ban on T-25 maize, the probabilities of specific risks were not reported, just the possibility of risks; and, with respect to the potential adverse effects for human and animal safety, only reservations on risk assessment procedures were advanced, which did not persuasively contend against its adequacy.

\textsuperscript{29} The EC-Biotech panel maintained the Appellate Body findings in the Australian-Salmon case (see supra note 19, at para 125) that if Article 3.3 confers upon a MS the right to set the preferred level of protection, then each MS had in principle the right to ban a product even if the risk of dangerous effects from its usage was minimal: “As stated in our Report in European Communities – Hormones, the ‘risk’ evaluated in a risk assessment must be an ascertainable risk; theoretical uncertainty is ‘not the kind of risk which, under Article 5.1, is to be assessed.’ This does not mean, however, that a Member cannot determine its own appropriate level of protection to be ‘zero risk’.”
restriction to international trade” and subside into the right to undertake unilateral action. How can a balance be struck between this right and scientific obligations? There is no WTO jurisprudence on science-related disputes clearly defining this relation. Until the EC-Biotech case, WTO jurisprudence had never defined it more than in terms of a unilateral relationship between science and policy, where science served as a pivot for national governments to fine-tune policies according to their degree of risk aversion. Indeed, the dichotomy between science and precaution makes the relationship between scientific analysis and policy decisions a unilateral one, where the former instructs the latter: once the risk is set in probabilistic terms (scientific justification), the legislator’s leeway (its autonomous right to set the level of protection) is reduced to its degree of aversion to this risk. In this sense, the legislator only has the autonomous right to be more or less risk averse, provided there is a risk (established through a cause-effect relationship) justifying its aversion. Therefore, in terms of the EC-Biotech case, it is clear that the examination of whether the EC measures were “based on” risk assessment could only be straightforwardly concluded with a negative finding once it was determined that scientific evidence was sufficient: if the risk assessments already available showed no concern regarding GMOs and if the studies provided by European States could not account for scientific ones, the EC ban became “irrational” since it was based on no “objective” relationship with the results of risk assessments.

5 The US-Continued Suspension dispute: opening the gateway for a new epistemology of science at the WTO

Despite the fact that the relationship between scientific obligations and sovereign rights was dismissed in the EC-Biotech case, the question remains as to the margin of risk aversion allowed to the legislator to set higher standards of protection than those of international organizations. Considering the ideal situation where science is conclusive and complete, we know that there would be no challenge to the legitimate setting of higher standards of protection. But once scientific evidence is provided, how high can the level of protection be? Or, put differently, if two MSs adopt two different levels of protection based on the same scientific evidence, can both be judged to be “based on” risk assessment as required by Article 5.1? What is the maximum difference allowed between their degrees of risk aversion that would keep intact their right to set their own standards of protection?

If the Panel’s view of science and precaution in the EC-Biotech case prevented any discussion on the relationship between the right to protect and the obligation to provide scientific justification, the United States-Continued Suspension of Obligations in the EC-Hormones Dispute case of 2008 (hereinafter US-Continued Suspension) made important changes to this point. By dismantling the unilateral character between scientific assessment and policy measures for protection pursuant to Article 5.1, the Appellate Body (AB) distanced itself from the mainstream view of science – i.e. complete and objective – that was initially reconfirmed by the first conclusions on the dispute made by the Panel. By reversing the most salient findings of the latter, the AB put forward the idea that on the one hand scientific conclusions

30 See supra note 10.
may be multiple and equally legitimate, and, on the other, that they may be inconclusive but still legally relevant to corroborate a case of precaution.

### 5.1 The factual background of the Hormones dispute

The dispute between the group composed of the United States and Canada, and the European Union on hormone-treated meat is long-standing. It dates back to 1996, when the US and Canada held formal consultations with the EU regarding its legislation covering the ban on six hormones for growth promoting purposes in livestock. The AB on the original Hormones case (EC-Hormones) concluded by faulting the EU for maintaining a ban inconsistent with Article 5.1 of the SPS Agreement: the EU failed to conduct a proper risk assessment that provided evidence of a specific risk from residues in meat treated with hormonal growth promoters.

Later, since the EU failed to comply with the WTO decision on the dispute and did not lift its ban, the US and Canada, pursuant to Article 22.2 of the Dispute Settlement Understanding (DSU), adopted retaliatory measures against the EU in the form of 100% ad valorem duty on selected food products from European countries. The EU responded by commissioning 17 new scientific studies to reaffirm its position that there were possible risks to human health associated with hormone-treated meat, given the available scientific data.

In 2003, in conjunction with Directive 2003/74/EC, the EU notified the Dispute Settlement Body that it had brought its previously inconsistent measures into compliance: for the case of the hormone 17 beta-oestradiol, the requirements under Article 5.1 were met by establishing a clear and definite risk, whereas for the other five hormones in question, a temporary ban was invoked under Article 5.7. By virtue of these assessments, the EU asserted that it had fulfilled its WTO obligations and asked for the immediate lifting of the sanctions imposed by Canada and the US in accordance with the provisions of Article 22.8 of the DSU. As the two countries refused to withdraw their retaliatory measures, a Panel was established in February 2005.

Despite the fact that the US-Continued Suspensions case was premised on the alleged infringement of certain provisions of the DSU, the current dispute settlement text lacks an explicit post-retaliation complaint procedure. This is why the Panel decided to base the proceedings not only on the DSU, but also on the provisions of the SPS Agreement to determine whether the EC had fully complied with the ruling in the EC-Hormones case. This decision, though highly disputable, makes the US-Continued Suspensions case particularly instructive on the evolution of WTO jurisprudence for science-related disputes.

Whereas the majority of the EC-Biotech case revolved around the relation between Articles 5.1 and 5.7 to determine whether one took precedence over the other, in the US-Continued Suspensions case, the provisions relevant to the dispute are clear, as are the proceedings of the Panel to review the compliance of European studies on 17 beta-oestradiol with Article 5.1 on the one hand, and of the other studies covering the five remaining hormones with Article 5.7 on the other.

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32 17 beta-oestradiol, progesterone, testosterone, zeranol, trenbolone and melengestrol acetate.

33 The Panel held that the US and Canada had violated the DSU by maintaining their retaliatory measures rather than initiating WTO proceedings after the European Union had notified the Dispute Settlement Body of the enactment of the Directive 2003/74/EC. The Panel’s decision was then reversed by the Appellate Body.

34 It clearly emerges from the Panel report that the EC had done its utmost to avoid such a situation, probably based on the memory of similar disputes in the past, such as EC-Hormones in 1998 and EC-Biotech in 2006, where friction was evident between the epistemology of science made by the SPS Agreement and its own doctrine on the precautionary principle.

35 Unlike the EC-Biotech case, where a dispute settlement panel was requested, in the US-Continued Suspension case the complainant (the EC) initiated compliance panel proceedings, where it was in its interest to prove (and determine the relevant provisions for its case) that the respondent failed to bring itself into compliance with WTO obligations.
Using this distinction, two different questions were addressed by the US-Continued Suspensions Panel: whether the scientific reviews on the hormone 17 beta-oestradiol could account for risk assessment as for Article 5.1; and whether, as regards the five remaining hormones temporarily banned based on precautionary considerations, “relevant scientific evidence can become insufficient within the meaning of Article 5.7 in the presence of international standards” (emphasis added). Therefore, the EC had to demonstrate that previously accepted scientific studies had become outdated either due to new scientific evidence, or to new findings raising concerns as to the validity of their conclusions. In short, the EC needed to prove that scientific evidence had evolved since the 1998 AB decision, that it had overridden previous scientific examinations, and that it rationally supported new SPS measures.

5.2 How to override scientific evidence

Conceptually, overriding previous scientific evidence consists in two phases: one of disruption, where doubts and concerns are raised for different reasons, such as the scientific approach, methodologies, disciplines included, objective of the study, and so on; and one of counter-evidence, where the scientific void is replaced by new concluding evidence, confirming the errors, the incompleteness and inconclusiveness of previous scientific studies. In the EC-Biotech case, we saw that the Panel was concerned only with new scientific evidence despite the fact that the case for the GMO ban had been built upon precautionary justifications: it bypassed the first stage and asked only for counter-evidence. But in the US-Continued Suspensions case, the two phases are kept separate for the first time according to whether the parties based their case upon Article 5.1 or 5.7. Indeed, the question emerged in clear terms as to whether the occurrence of the first stage alone, that of disruption, is sufficient to provide legal evidence for a case of insufficient scientific evidence.

5.2.1 Article 5.1 of the SPS Agreement: the appropriateness of risk assessment

In examining whether the new European studies accounted for scientific evidence, the Panel sought to determine “whether scientific evidence supported the conclusions in the Opinions provided by the EU.” The reason for putting the question of sufficient scientific evidence in those terms is that, with the favorable presumption that European analysis accounted for a risk assessment, the situation was, unlike in the EC-Biotech case, one of competing risk assessments (that of the JECFA and other “old” safety assessments, and that of the EU), that were both supposedly conclusive. Therefore, the Panel went on to determine whether the new risk assessment provided by the EU could directly challenge the old ones through scientific counter-evidence.


Ibid., at para. 7.552

The United States’ position was based on different safety assessments of national and international origin, such as those of the U.S. Food and Drug Administration, the Codex Alimentarius Commission, and the Joint Expert Committee on Food Additives (JEFCA).
The procedure consisted in a legal examination of whether the EU risk assessment was “appropriate to the circumstances” as prescribed by Article 5.1, which actually translated into testing whether the transformation of the input (scientific evidence) into an output (conclusions) occurred in the right way. In short, the Panel appointed a scientific panel to determine whether it would have been rational to achieve certain results starting from certain elements. The approach was exactly the same as in the EC-Biotech case: it was maintained that the relation between the adequacy of risk assessment and the sufficiency of scientific evidence is a matter of procedural and linear evolution from (empirical) evidence to (theoretical) probabilities. In this view, scientific controversies cannot exist or should be easily settled. In this view, it is not surprising that the same overlapping between scientific standards of evidence and legal standards of evidence had again occurred. Indeed, in its attempt to obtain objective information from scientific experts, the Panel finally translated the supposed objectivity of science from laboratories to the courtroom and concluded that the EC ban on 17 beta-oestradiol was not based on a risk assessment “appropriate to the circumstances”.

The simplicity of the Panel’s interpretation of Article 5.1 was sharply overturned by the AB, which confirmed the drawbacks of incessantly searching for an objective science that sheds light on legal argumentations and decisions. The Appellate Body commented on the Panel’s decision to consult scientific experts, saying that “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” (emphasis added). In this sense, he continued, “a panel should review whether the particular conclusions drawn by the Member assessing the risk find sufficient support in the scientific evidence relied upon (emphasis added)”.

Hence, the appropriateness of risk assessment should not be judged upon objectivity, but upon the coherence of its reasoning and the rigorousness of scientific methodologies, which refers to a legal operation rather than to legal faith in scientific advocacy. Given this interpretation, the AB overturned the Panel’s previous findings and concluded that the European study on 17 beta-oestradiol accounted for a risk assessment.

5.2.2 Article 5.7 of the SPS Agreement: how to provide legal evidence of insufficient scientific evidence

The question of whether the temporary ban imposed by the EC on five hormones was justifiable because of “insufficient scientific evidence” pursuant to Article 5.7 was, as expected, a harbinger of controversy.

We saw that the EC-Biotech dispute clearly revealed the difficulty of justifying SPS measures according to the precautionary principle. And indeed, to provide legal evidence of insufficient scientific evidence seems almost a contradictory process, all the more so when it involves disrupting previously accepted scientific knowledge. This is also true in the US-Continued Suspension case, in which numerous studies and reports from international scientific

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39 The Panel agreed with the reasoning of the Panel in Japan-Apples that "the scientific evidence which is being evaluated must support the conclusions of the [risk assessment]. Therefore, if the conclusions of the risk assessment are not sufficiently supported by the scientific evidence referred to in the [risk assessment], then there cannot be a risk assessment appropriate to the circumstances, within the meaning of Article 5.1." (Panel Report, US-Continued Suspension, at para 7.538).


41 Ibid., at para. 591
organizations responsible for food quality standards\textsuperscript{42} had raised no concerns until then about the hormones in question used as growth-promoting agents in livestock.

The core question of the proceedings was clearly set by the Panel as to what extent “relevant scientific evidence can become insufficient within the meaning of Article 5.7 in the presence of international standards” (emphasis added).\textsuperscript{43} First of all, it revised the meaning of insufficient scientific evidence, confirming previous jurisprudence that the qualification of insufficient was to be given with respect to the capability of performing risk assessment.\textsuperscript{44} Specifically, insufficient scientific evidence was to be judged retrospectively on the adequacy of risk assessment. The Panel held that a risk assessment was adequate when it was complete and had established a cause-effect relationship between an event and an outcome in terms of risk. If the risk assessment was not adequate, then scientific evidence should have been found insufficient to fully reveal “the potential for the identified adverse effects”.\textsuperscript{45}

To state that precautionary measures are justified in cases where risk assessment fails to establish a cause-effect relationship has never been so clear in previous science-related trade disputes. Moreover, this interpretation is the closest to the most common international formula of the precautionary principle: the lack of full evidence of cause-effect relationships on the one hand, and the requirement to provide some tentative scientific explanation of the possibility of a severe risk on the other, are indeed the most important tenets of the principle. Therefore, the question turned out to be whether the impossibility of concluding on the evidence of a risk raised by the European inquiries could be retained as legal proof that international scientific standards had become outdated. What would have made previous cause-effect relationships unsustainable?

In the Panel’s interpretation there should have been “a critical mass of new evidence and/or information that calls into question the fundamental precepts of previous knowledge” contained in international standards.\textsuperscript{46} But a critical mass, as later recognized by the AB, pertains to a paradigm shift in the scientific community. In other words, it is a requirement to provide something close to sufficient scientific evidence, which again confirms the presence of a locked-in situation where precautionary measures are finally justified upon grounds of scientific conclusiveness instead of scientific uncertainty.

When the EC appealed to the AB and raised this very concern, the Panel’s interpretation was overturned. In the AB’s words, “[l]imiting 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 (emphasis added).” In this sense, the Appellate Body implicitly acknowledged the existence of two phases in scientific research, one of disruption and one of counter-evidence (see supra paragraph 5.2). Even if not conclusive, the former has the potential to provide some evidence (scientific and then legal) of a threat, which means the results of previous scientific analysis are now outdated and no longer reliable.

\textsuperscript{42} See supra note 38.

\textsuperscript{43} Panel Report, US-Continued Suspension (see supra note 31), at para 7.597.

\textsuperscript{44} The Panel held the Appellate Body’s interpretation in the Japan-Apples case that “‘relevant scientific evidence’ will be ‘insufficient’ within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the SPS Agreement.” See supra note 17.

\textsuperscript{45} Panel Report, US-Continued Suspension (see supra note 31), at para 7.628.

\textsuperscript{46} Ibid., at para. 7.648.
5.3 Questions left open

The findings of the Appellate Body Report on the US-Continuous Suspension case paved the way for a new epistemology of science at the WTO. First, with respect to Article 5.1, the AB destabilized the unilateral relationship between scientific evidence and legal evidence by specifying that the scientific “objectivity” pursued in laboratories translates into the search for “coherence” in the courtroom. Therefore, it implicitly acknowledged that there is no unique rationality between processing scientific data and drawing conclusions about the process; the legitimacy of scientific interpretations is tested according to their coherence. Second, once the separation between legal and scientific standards of evidence has been determined, the AB broke the transitivity between sufficient scientific evidence and sufficient legal evidence and, conversely, between insufficient scientific evidence and insufficient legal evidence.

Without these two fundamental changes in the epistemology of science, the issue of providing (legal) evidence for a case of insufficient (scientific) evidence would have never been raised as relevant for the application of the precautionary principle within the WTO legal framework; the issue would have persisted in the form of providing sufficient scientific evidence, with no distinction between the legal and scientific nature of the two standards of proof.

Despite the fact that the AB deserves credit for setting a new precedent on the relationship between science and law, it did not conclude as to whether the EU measures were based on scientific risk assessment on the one hand (Article 5.1), and whether they were justified under conditions of insufficient scientific evidence on the other (Article 5.7). This is due to the nature of the appeals, which are supposed to re-interpret points of law contained in the Panel’s final decisions and not to re-examine existing evidence or to examine new evidence. Some fundamental questions were then raised to be left open. Should the EU have opted for a different level of protection? After having found that the European study on 17 beta-oestradiol accounted for a risk assessment, i.e. that scientific evidence was legally sufficient (Article 5.1), the AB concluded that it was not in a position to determine whether the conclusions of the scientific studies were objectively related to (“based on”) the ensuing policy measures, and recommended that the parties initiate new proceedings on the issue.\(^{47}\) Therefore, the AB left open the question of the relation between the standard of evidence and the degree of risk aversion: once science indicates the probability or the possibility of a risk, what is the maximum degree of risk aversion that would be allowed to governments to legitimately maintain their right to protect human, animal and environmental health?\(^{48}\)

Concerning the five other hormones for which the EC invoked the precautionary principle, the AB failed to determine whether the doubts raised by European studies were enough to form legal proof of insufficient scientific evidence. It followed that the question of whether the corresponding policy measures (temporary ban) were consistent with the available scientific evidence (even if insufficient) did not even reach the stage of being addressed.


\(^{48}\) It may be presumed that the issue is addressed in terms of proportionality between restrictive measures to trade and scientific evidence, whether sufficient or insufficient. The principle of proportionality, indeed, is not new in cases of scientific warnings. As it is founded on the principles of a common and integrated market, the European Union knows this principle well, and it is also included in its doctrine on the precautionary principle (COMMISSION OF THE EUROPEAN COMMUNITIES, Communication from the Commission on the precautionary principle (2000)).
6 Conclusions

This paper has tried to extrapolate some fundamental features of the WTO legal approach to science-related controversies in order to outline a specific epistemological framework. The purpose of this operation was to determine a precise allocation of the precautionary principle within the WTO legal framework in order to test whether its applicability was ever admissible.

The EC-Biotech dispute was instructive in this sense. It confirmed that the only way to bring evidence of a risk before a WTO panel is by demonstrating it in factual terms, which is equivalent not only to performing a risk assessment, but most importantly to performing an “adequate” risk assessment capable of concluding that a risk exists in the form of a cause-and-effect relationship.

Given this situation, the European defense based on the precautionary principle was annulled, for two reasons: first because providing evidence of a case of “insufficient scientific evidence” is anything but an easy legal operation, whereas providing evidence of “sufficient scientific evidence” through a risk assessment seems almost automatic; second because the (non-)evidence of “insufficient scientific evidence” should have counteracted the evidence provided by those risk assessments that had already been performed on certain GMOs.

This situation, which the paper has denounced, corresponded de facto to overlapping scientific and legal standards of proof, where the only legal evidence was that of science, or “sufficient scientific evidence”.

If this overlapping has prevented any application of the precautionary principle in the WTO legal framework, it also questioned the autonomous right of WTO Member States to set their chosen levels of protection. Indeed, if this right can only be maintained if there is hard evidence provided by conclusive scientific findings, it certainly cannot be sustained according to precautionary considerations. But even without that, and considering an ideal situation where science can always provide justification for protection measures, the question that remained open and on which WTO jurisprudence had been failing to deliver was how dissimilar two levels of protection chosen by two MSs can be, given the same science.

This question has never been addressed in WTO disputes because the relationship between the obligation to provide scientific justification and the right to choose among policy measures has never been developed more than in unilateral terms, where the only right for MSs was to fine-tune their degree of risk-aversion to the risk in question.

The open and unresolved questions that the EC-Biotech case raised re-emerged in different forms in the US-Continued Suspensions case. After the US-Continued Suspensions Panel’s decision confirmed the same approach as in the EC-Biotech dispute, the Appellate Body’s findings paved the way for a new epistemology of science at the WTO. It broke the unequivocal relationship between objective science and objective policy by denouncing the gravity of testing the adequacy of risk assessment in terms of its capability to provide one objective result. Therefore, the AB not only admitted that different legitimate interpretations of data analysis could exist, but it also sanctioned the separation between the legal and the scientific search for evidence.

This separation occurred for the case of “sufficient scientific evidence”, but it opened up the opportunity to discuss whether it was ever possible to also provide legal evidence of “insufficient scientific evidence”. It defined a case of precaution as one where new scientific evidence, even if insufficient because non-conclusive, casts doubt on previous scientific assessments so as to invalidate the correctness of their conclusions.

The AB’s findings on the US-Continued Suspensions case certainly made it possible to overcome the contested dichotomy between science and precaution, opening up a true gateway to the precautionary principle within the WTO legal framework. However, the
question remained open as to the relationship between the right for MSs to set their own appropriate standards of protection and the obligation to maintain these according to scientific principles. Indeed, once it had been determined that scientific obligations had been fulfilled to provide a case of “sufficient scientific evidence”, the AB could not conclude on whether the EU policy actions (the ban on 17 beta-oestradiol) rationally corresponded to this scientific evidence; nor, for the case of “insufficient scientific evidence” concerning the other hormones under examination, did it conclude on whether the amount of doubt cast by European studies actually invalidated previous scientific analysis on the safety of those hormones. Therefore, despite the fact that the AB on US-Continued Suspensions deserved credit for advancing a far more complex view of science that re-established the autonomy of legal proceedings concerning any case of science, whether conclusive or inconclusive, the complexity raised by the sub-case of precaution nevertheless certified the limitations of science as a neutral arbiter for dispute settlement.