Provisional measures under Article 5.7 of the WTO's Agreement on Sanitary and Phytosanitary Measures: Some Criticisms of the Jurisprudence so far

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Provisional measures under Article 5.7 of the WTO's Agreement on Sanitary and Phytosanitary Measures: Some Criticisms of the Jurisprudence so far

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Abstract: The purpose of this article is to identify two potential difficulties in the application of Article 5.7 which appear to follow from certain statements made by Panels and the Appellate Body in the jurisprudence under that Article so far. The first relates to the situation in which a WTO Member legitimately takes provisional measures under Article 5.7, but refuses to conduct further research as required by that Article. In such circumstances, it is argued, the relevant violation is the failure to conduct further research, not the taking of provisional measures – and the solution must therefore be to require such further research, rather than to invalidate the provisional measures themselves. The second relates to questions of evolving science, and the extent to which Article 5.7 can and ought to remain available as a safe harbour to Members even once a risk assessment has been carried out. It is argued that in some circumstances it should: where substantive inadequacies and limitations of the earlier risk assessment become apparent to policy-makers, where new evidence comes to light, and where a previously unconsidered risk is identified. Under the current jurisprudence, it is not clear that Article 5.7 remains appropriately available in all such circumstances.

INTRODUCTION

Our first decade of experience with the *Agreement on the Application of Sanitary and Phytosanitary Measures* ('*SPS Agreement*') has brought only six cases in which the provisions of this agreement were central to the dispute.[1] These six cases have,

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[1] *EC – Measures Concerning Meat and Meat Products ('EC – Hormones')*, WT/DS26 and WT/DS48; *Australia – Measures Affecting Importation of Salmon ('Australia – Salmon')*, WT/DS18; *Japan – Measures Affecting Agricultural Products* ('*Japan – Varietals*'), WT/DS76; *Japan – Measures Affecting the Importation of Apples ('Japan – Apples')*, WT/DS245, *EC – Measures Affecting the Approval and Marketing of Biotech Products ('EC – Biotech')*, WT/DS291, 292 and 293, and *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute*

however, been among the most closely watched and carefully critiqued of all WTO jurisprudence so far, and have given rise to important debates about the interpretation and application of many disciplines contained in the SPS Agreement. This brief article singles out two very specific issues which in my view have received insufficient attention in this literature. Both relate to interpretation of Article 5.7 of the SPS Agreement, and in both cases, my concern is that certain implications of the present jurisprudence may, if uncorrected, lead to difficulties in the future for governments wishing to design effective, WTO-compliant food safety regimes. First, where provisional measures are adopted under Article 5.7, there is the question of the consequences of a failure to comply with the additional obligations contained in the paragraph to 'obtain … additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time'. Although the situation is not entirely clear, the present jurisprudence suggests that such a failure renders the protective measures themselves WTO non-compliant, a result which in my view is both wrong in principle and contrary to the clear wording of the text. This argument is elaborated in Part 1. Second, there is the question whether Article 5.7 as currently interpreted adequately addresses the problems posed by the evolution of scientific knowledge. I suggest that, while Article 5.7 is in principle able to cope well with evolving science, there are some specific issues in the current jurisprudence that need clarification. This issue is covered in Part 2.

THE CONSEQUENCES OF FAILURE TO COMPLY WITH ARTICLE 5.7, SECOND SENTENCE

Article 2.2 of the *SPS Agreement* sets out an obligation to ensure that sanitary and phytosanitary measures are, amongst other things, 'based on scientific principles and … not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.' This general principle finds specific application in Articles 5.1 and 5.2[2], which require WTO Members to ensure that SPS measures 'are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plan life or health'[3], and in such an assessment, to 'take into account available scientific evidence'.[4] Perhaps the most important exemption[5] to these obligations is contained in paragraph 7 of Article 5, which reads as follows:

('Hormones Suspension'), WT/DS321/R with *US – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS320/R. (I have counted the final two as one, given the substantial similarity of the reports.

[2] *EC – Measures Concerning Meat and Meat Products,* Appellate Body Report, WT/DS26/AB/R, paragraph 180.

[3] *Agreement on Sanitary and Phytosanitary Measures*, Article 5.1.

[4] *Agreement on Sanitary and Phytosanitary Measures*, Article 5.2.

[5] By referring to the provision here as an 'exemption', I am following the careful wording of the Appellate Body in *Japan – Measures Affecting Agricultural Products*, Appellate Body Report,

> 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. *In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.* (Italics added)

Thus, while SPS measures must normally be based on scientific principles and must not be maintained without sufficient scientific evidence, Members may nevertheless adopt provisional measures where scientific evidence is insufficient, and where there is at least some evidence of potential risk. Importantly, however, such provisional measures must be reviewed within a reasonable period of time and must be accompanied by efforts to obtain additional necessary information.

The issue addressed in this section can be stated briefly: what are, and what should be, the consequences of a failure to comply with the obligations contained in the second sentence of Article 5.7, which I will call the 'research and review obligations'? In order to examine this question most clearly, it is easiest if I take a hypothetical SPS measure for which the conditions set out in the first sentence of Article 5.7 are satisfied – I will assume, in other words, that existing scientific evidence is 'insufficient' in the relevant sense, and that the measure is adopted 'on the basis of available pertinent information'. In such circumstances, what should follow from a failure by that Member to 'seek to obtain the additional information necessary' and/or to 'review the … measure … within a reasonable period of time'?

THE CURRENT STATE OF THE LAW: 'FOUR CUMULATIVE REQUIREMENTS'

The first case in which Article 5.7 was the subject of substantive argument and interpretation was *Japan – Measures Affecting Agricultural Products ('Japan – Varietals')*.[6] That case concerned Japanese measures to prevent the introduction of a pest, known as 'codling moth', through the importation of apples, cherries, peaches (including nectarines), walnuts, apricots, pears, plums and quince.[7] Japan had prohibited the importation of these products, but this prohibition could be lifted if the exporting country proposed an alternative quarantine treatment which provided the same level of protection to Japan as the import prohibition. Such quarantine treatments did exist, and for each of the products in question it

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WT/DS76/AB/R, paragraph 80, and in light of the extensive discussion relevant to this point in *EC – Biotech*, Panel Report, WT/DS291/R, paragraphs 7.2962-7.2983.

[6] See *Japan – Measures Affecting Agricultural Products*, Panel Report, WT/DS76/R and Appellate Body Report, WT/DS76/AB/R.

[7] For an interesting history of the dispute, see generally J.P. Whitlock, 'Japan-Measures Affecting Agricultural Products: Lessons for Future SPS and Agricultural Trade Disputes' (2002) 33(4) *Law and Policy in International Business* 741.

typically involved a combination of fumigation and cold storage. Once an exporting country had proposed a quarantine treatment in respect of a particular product category, the lifting of the prohibition occurred in two main stages. The first stage involved a set of test leading to an initial lifting of the prohibition in respect of a representative variety of the product (say, a Granny Smith apple). Thereafter, further tests and procedures were required for each additional variety of apple, before that variety could be imported into Japan. It was this second requirement – the 'varietal testing requirement' – which was challenged in these proceedings. It was claimed, in essence, that once one variety was demonstrated to be safe, there was no reason to think others would be any different.

While the dispute concerned a number of different provisions of the SPS agreement, it is only necessary to focus for present purposes on the arguments relating to Article 5.7. While Japan argued that the varietal testing requirement complied with Article 2.2, it also argued in the alternative that this requirement was a provisional measure justified under Article 5.7.[8] The United States disagreed. For one thing, the US argued,

> this was not a situation in which there was insufficient scientific evidence, because there was no evidence supporting Japan's claim that variety mattered, and because all evidence in the case at issue, including the success of uniform treatments of different varieties exported to Japan and the absence of failures by product-based testing regimes in other countries, indicated that varietal differences did not affect treatment efficacy.[9]

The United States further contended that Japan had not complied with the requirements of the second sentence of Article 5.7. The measure had gone into effect 48 years prior to the Panel proceedings, and on that basis 'could hardly be called "provisional"'.[10] Furthermore, there was no indication that Japan had undertaken an active process to seek further necessary information within a reasonable period of time.

The Panel began by noting that Article 5.7 lays down four requirements.[11] The first sentence, it observed, makes clear that provisional measures are available only where 'relevant scientific information is insufficient', and where the measure is adopted 'on the basis of available pertinent information'. The second sentence sets out two further obligations: to 'seek to obtain the additional information necessary for a more objective assessment of risk'; and to 'review the … phytosanitary measure accordingly within a reasonable period of time'. Thus, the Panel noted, even assuming that the conditions set out in the first sentence were met, Japan was still under an obligation to comply with the research and review

[8] n 6 above, paragraph 4.187-188.
[9] *ibid*, paragraph 4.190.
[10] *ibid*, paragraph 4.191.
[11] *ibid*, paragraphs 8.54-8.55.

obligations of the second sentence. In the opinion of the Panel, it had not done so:

> we thus find that even if the varietal testing requirement were considered as a provisional measure adopted in accordance with the first sentence of Article 5.7, Japan has not fulfilled the requirements contained in the second sentence of Article 5.7.[12] [footnote omitted.]

The Panel did not consider in any detail what the consequences ought to be of a failure to comply with the second sentence of Article 5.7. It seemed to assume that failure to comply with any of the four requirements contained in Article 5.7 would be sufficient to disapply that provision. It noted simply that Article 2.2 imposed certain obligations to be complied with 'except as provided for in paragraph 7 of Article 5' , that Japan's measures were not in 'as provided for' in Article 5.7, and that therefore Japan was in breach of its obligations under Article 2.2.[13]

Both parties challenged a number of aspects of this decision on appeal. Most relevantly in the present context, Japan argued that the safe harbour of Article 5.7 is available to Members provided only that the conditions of its first sentence are met:

> the phrase "except as provided for in paragraph 7 of Article 5 in Article 2.2", should be interpreted to refer to the first sentence of Article 5.7, so that a Member should be allowed to claim exemption from the obligation in Article 2.2 when it fulfils the requirements of the first sentence.[14]

The Appellate Body rejected this argument. It emphasised that Article 5.7 was a 'qualified exemption' from the obligation under Article 2.2, and should not be given an 'overly broad and flexible interpretation'.[15] It reiterated the Panel's view that Article 5.7 'sets out four requirements which must be met in order to adopt and maintain a provisional SPS measure'. The first two, relating to the adoption of the measure, were:

(1) that the measure be imposed in respect of a situation where 'relevant scientific information is insufficient'; and
(2) that the measure be adopted 'on the basis of available pertinent information';

The second two, relating to the maintenance of the measure, were:

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[12] *ibid*, paragraph 8.59.
[13] *ibid*, paragraph 8.61.
[14] *Japan – Measures Affecting Agricultural Products*, n 5 above, paragraph 11.
[15] *ibid*, paragraph 80.

(3) that the Member 'seek to obtain the additional information necessary for a more objective assessment of risk'; and
(4) that the Member 'review the … measure accordingly within a reasonable period of time'.[16]

These four requirements, the Appellate Body continued, 'are clearly cumulative in nature and are equally important for the purpose of determining consistency with this provision'. Thus, '[w]henever *one* of these four requirements is not met, the measure at issue is inconsistent with Article 5.7'.[17] In the view of the Appellate Body, the Panel therefore did not err when it examined the consistency of the Japanese measure solely under the second sentence of Article 5.7. (The Appellate Body also agreed with the Panel that Japan had not, in fact, complied with the research and review requirements set out in the second sentence.[18])

Later cases have confirmed and adopted these statements of the Appellate Body. For example, the Appellate Body's decision approved and repeated almost *verbatim* the interpretation of Article 5.7 set out in *Japan – Varietals*.[19] (As it happened, in that case the decision turned on a failure to comply with conditions in the first sentence of Article 5.7, not the second, but the reasoning was identical.) By and large, the Panel in *EC – Measures Affecting the Approval and Marketing of Biotech Products ('EC – Biotech')* also repeats the same view. It notes, for example, that 'the Appellate Body made clear that there are four cumulative requirements in Article 5.7 which must be met in order for a Member to adopt and maintain a provisional measure consistently with Article 5.7'.[20] Even more clearly:

> if a challenged SPS measure was adopted and is maintained consistently with the four cumulative requirements of Article 5.7, the situation is "as provided for in paragraph 7 of Article 5" (Article 2.2), and the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence 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 situation is not "as provided for in paragraph 7 of Article 5" (Article 2.2), and the relevant obligation in Article 2.2 is applicable to the challenged measure … [21]

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[16] *ibid*, paragraph 89.
[17] *ibid.*
[18] *ibid*, paragraphs 89-91.
[19] *Japan – Measures Affecting the Importation of Apples,* Appellate Body Report, WT/DS245/AB/R, paragraph 176. Interestingly, the only salient different between the two was the fact that the distinction between the first two and the last two requirements – as relating to the *adoption* and *maintenance* of the measure respectively – was lost. Cf *EC – Measures Affecting the Approval and Marketing of Biotech Products*, Panel Report, WT/DS291/R, paragraph 7.3250.
[20] *EC – Measures Affecting the Approval and Marketing of Biotech Products ibid*, paragraph 7.2973. See also paragraphs 7.2929, 7.3218-7.3219.
[21] *ibid*, paragraph 7.2974.

Thus, the Panel states, 'Article 2.2 would be applicable in a situation where a measure meets some, but not all, of the requirements of Article 5.7'.[22]

I say that 'by and large' the Panel in *EC – Biotech* followed the Appellate Body's approach in *Japan – Varietals* because it did make two additions or elaborations, which may ultimately have some significance. First of all, where the Appellate Body in *Japan – Varietals* dealt exclusively with the relationship between Articles 2.2 and 5.7, the *EC – Biotech* Panel applied precisely the same reasoning to the relationship between Articles 5.1 and 5.7:

> We have already stated the main implications … in our discussion of the relationship between Article 2.2 and Article 5.7. Nonetheless, for clarity, it is useful to do so again given that we are concerned here with the relationship between Article 5.1 and Article 5.7. Thus, in terms of applicability of Article 5.1 … if a challenged SPS measure was adopted and is maintained consistently with 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 … [23]

Secondly, the Panel elaborated on the Appellate Body's earlier characterisation of Article 5.7 as a 'qualified exemption'.[24] It found that Article 5.7 is not an *exception* to other obligations contained in the *SPS Agreement*, but rather a free-standing *right* (to take provisional measures).[25] Thus, Article 5.7 is not a 'carve-out' of Article 2.2/5.1, but rather the two provisions have mutually exclusive domains of operation. I will return to this point below, but for now the significance is that, after *EC – Biotech*, it seems that the 'research and review' obligations are properly characterised as conditions which must be fulfilled for the right to take provisional measures to lawfully continue. If these conditions are not satisfied, Article 5.7 does not apply, and the measure falls to be examined under Article 5.1. Under the current approach, therefore, the necessary consequence of a Member's failure to comply with the research and review obligations contained in the second sentence seems to be that it has no right to maintain the provisional measure in question.

AN ALTERNATIVE APPROACH: A RIGHT WITH SECONDARY OBLIGATIONS

The alternative approach, which in my view is preferable, is easy to explain. On this view, the first sentence contains a right to 'provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information'. This right

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[22] *ibid*, paragraph 7.2975.
[23] *ibid*, paragraph 7.2998.
[24] See n 5 above.
[25] See *EC – Measures Affecting the Approval and Marketing of Biotech Products* n 19 above, paragraphs 7.2962ff, especially paragraphs 7.2969 and 7.2997.

exists in all cases where relevant scientific evidence is 'insufficient'. Once a country exercises this right, it incurs a juridically independent obligation, spelled out in the second sentence, to seek additional information and to review the measure within a reasonable period of time. What is different about this approach lies in the consequence of failure to comply with the 'research and review' obligations: here, the provisional measures themselves are not rendered illegal by the failure to comply with the research and review obligations. (Of course, this failure is itself still a breach, and subject to the usual sanctioning mechanisms available under the dispute settlement mechanism). Juridically, the difference between the two lies in the characterisation of the nature of the 'research and review' obligations: instead of seeing these obligations as *conditions* attaching to the right to take provisional measures (so that failure to comply makes the right disappear), they are here seen as *supplementary obligations* which are triggered by the exercise of that right (so that failure to comply has no effect on the existence of the underlying right).[26]

There are in my view at least four reasons why this approach is preferable. *First*, at a purely textual level, it appears to conform most closely to the precise words of Article 5.7. If the drafters of the *SPS Agreement* had wished to make the right to take provisional measures conditional on fulfilment of the research and review obligations, they need only have written that 'a Member may provisionally adopt measures *provided that* it seeks to obtain additional information and reviews the measure within a reasonable period of time'. They did not. The first sentence of Article 5.7 reads: 'In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures …'

As the Panel in *EC – Biotech* noted, this sentence 'follows a classic 'if-then' logic'[27]: *if* scientific evidence is insufficient, *then* a Member may provisionally adopt SPS measures. However, this kind of logic is notably absent from the second sentence of Article 5.7: 'In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time …' Everything about this sentence – the use of the separating phrase 'in such circumstances', the contrast between the permissive 'may' and the obligatory 'shall', the very fact that it is a new sentence – suggests that it sets out independent obligations, not additional conditions. There is an obvious division of labour between the first and second sentences: the first sets out the basic right to take provisional measures and the circumstances in which that right arises, while the second sets out further obligations triggered by the adoption of provisional measures under the first sentence. In short, there is no explicit support in the text

[26] In fact, something very close to this argument was made by the EC in *ibid*, paragraph 7.2955: 'Moreover, the European Communities considers that if the Panel nonetheless were to determine that the safeguard measures did not meet one of the requirements of Article 5.7, *e.g.*, because there was sufficient scientific evidence, the Panel would need to conclude that the provisional measure in question is inconsistent with Article 5.7, and not that Article 2.2 or Article 5.1 becomes the relevant applicable provision'. See also paragraph 7.2975 of the same decision.

[27] *ibid*, paragraph 7.2939.

for the conclusion drawn by the Appellate Body that 'a provisional measure may not be maintained unless the Member' complies with the research and review obligations.[28] It is not surprising, therefore, that this conclusion was stated without explicit consideration of whether or not the text supports it.

Second, and perhaps more importantly, the present interpretive approach adopted by the Appellate Body has the perverse implication that, in some circumstances, Members may not take provisional measures even where such measures are clearly legitimate and justified on the basis of available pertinent evidence. This is an obvious point, but it is worth stressing: under the Appellate Body's current approach, if a country has adopted clearly justified provisional protection on the basis of real evidence, but fails for one reason or another to seek further science in time, then the protective measures themselves become unlawful – even if the objective justification for provisional protection remains as strong as ever. This is a perverse result, and one which undermines the object and purpose of Article 5.7. Article 5.7, it should be remembered, is a compromise between two objectives: on the one hand to ensure that Members maintain their right to take protective SPS measures on a temporary basis where there is objective cause for concern but where there is as yet inadequate science to make a proper risk assessment; and on the other hand to discipline the use of such provisional measures to ensure that their use does not in practice undermine other obligations contained in the agreement. The current approach profoundly undermines one side of this compromise in the hypothetical case under consideration. The alternative approach I am proposing, on the contrary, stays true to both sides of the basic compromise which underlies Article 5.7: while Members are permitted to maintain their provisional measures in such circumstances, international supervision through the WTO ensures that they promptly and effectively seek further information and review the provision in light of it.

This argument works at the level of principle: there is something objectionable in principle about a situation in which the right to take protective measures can become legally unavailable, even where a clearly legitimate reason exists for such measures. But there is even greater cause for concern to the extent that the current interpretative approach actually requires the *withdrawal* of protective measures as a consequence of failure to comply with the research and review obligations. Admittedly, this may be uncommon: Members are under an obligation only to bring themselves into compliance with the agreement, and withdrawal of the provisional measure will not always be the only way of doing so.[29] But the possibility certainly exists. It is not clear, for example, that conducting the appropriate further research *after* a violation has been found is sufficient to bring a Member into compliance (the obligation, recall, is to conduct research 'within a reasonable period of time'). It is fair to say that present jurisprudence is far from clear on this point, and that the alternative approach sketched above has

[28] *Japan – Measures Affecting Agricultural Products* n 5 above, paragraph 89.
[29] See generally Articles 19:1 and 21:1 of the Dispute Settlement Understanding.

the benefit of clarity on this point. Furthermore, there may conceivably be situations in which further research is prohibitively costly or technically unfeasible for some Members. And even where the only problem is the time that further research takes, there is the question of whether withdrawal of the measure is required in the interim period.[30]

Third, the alternative approach is preferable because it provides better quality guidance to WTO Members as to how to comply with their WTO commitments. In *Australia – Measures Affecting Importation of Salmon ('Australia – Salmon')*, the Appellate Body observed that Panels ought generally to make sufficient findings 'to enable the DSB to make sufficiently precise recommendations and rulings so as to allow for prompt compliance by a Member with those recommendations and rulings'.[31] The current approach to the interpretation of Article 5.7, however, can easily lead to a Member being given insufficient guidance to ensure compliance. Since a finding of non-compliance with any one of the four requirements in Article 5.7 is at present sufficient to making a finding of non-compliance with that provision, the violating Member often has no guidance as to whether compliance with this one requirement is sufficient to validate the relevant measure. For example, in the *Japan – Varietals* dispute discussed above, the Panel found that Japan had not complied with its research and review obligations, but did not need to determine whether or not the requirement of 'insufficient scientific evidence' had been satisfied. Thus the decision left genuine uncertainty for Japan: would compliance with the research and review obligations ensure that their measures was WTO-compliant? Or would it still be vulnerable to attack on the basis that sufficient scientific evidence existed to perform a risk assessment? The alternative approach, on the other hand, remedies this defect. Since, on this approach, the research and review obligations are free-standing, and only triggered once provisional measures are adopted under the first sentence, a finding on compliance with the first sentence is a logically prior step. The result is that Members are left with a clear indication whether or not provisional measures are in principle available to it.

Fourth, the present approach involves a serious logical flaw. To illustrate this point, recall the hypothetical case in which insufficient scientific evidence exists to perform a risk assessment, a government therefore provisionally imposes a restrictive measure, but fails to seek additional information within a reasonable period of time. On the current approach, this failure to seek additional information disapplies Article 5.7, such that Article 5.1 applies, and the government is under an obligation to perform a risk assessment.[32] But this is an impossibility, as there is *ex hypothesi* insufficient evidence to do so. Article 5.1

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[30] This last problem may conceivably be remedied through effective use of the 21.3(c) procedure.
[31] *Australia – Measures Affecting Importation of Salmon*, Appellate Body Report, WT/DS18/AB/R, paragraph 223.
[32] This is abundantly clear from a number of passages in *EC – Measures Affecting the Approval and Marketing of Biotech Products* n 19 above, paragraphs 7.2974-7.2975 and 7.32217, to offer only two examples.

logically can *never* (without absurdity) apply in a situation where there is insufficient scientific evidence to perform a risk assessment.

There are actually a number of occasions in the *EC – Biotech* decision in which the Panel seems to recognise this logical difficulty.[33] To take one example: in paragraph 7.2939, after considering the first sentence of Article 5.7, the Panel notes that 'it is clear that Article 5.7 is applicable … in every case where scientific evidence is insufficient'.[34] For support for that proposition, it refers to an earlier statement of the Appellate Body, to the effect that 'the application of Article 5.7 is triggered … by the insufficiency of scientific evidence'.[35] However, in apparent recognition of the seeming inconsistency between this statement and its later arguments (that failure to conform with any of the 'four cumulative requirements' disapplies Article 5.7), the Panel adds a footnote:

> When we refer to the "applicability of Article 5.7", we address the issue of whether or not the right conferred by the first sentence of Article 5.7 is, in principle, available to a Member. In a specific case, a Member must, of course, satisfy the various requirements set forth in Article 5.7 if it wishes to benefit from the right conferred by Article 5.7.[36]

Thus the Panel seeks to resolve this apparent inconsistency by drawing a distinction between the 'in principle availability' of the right to take provisional measures, and question whether a Member may 'benefit from this right' in particular circumstances.

In my view, this distinction is confusing and ultimately unnecessary, given that the alternative approach set out above resolves this difficulty without such complications. A better distinction – actually drawn by the Panel only a few paragraphs later, though in a different context – between the *applicability* of article 5.7 and *consistency* with it, makes more sense, and seems at least potentially to open the way for the approach I am advocating.[37]

Are there compelling reasons to reject this alternative approach, despite its apparent advantages? One benefit of the current approach is that a requirement to withdraw provisional measures would provide a greater incentive to comply with the research and review obligations in the second sentence. In *Japan – Varietals*, for example, the United States argued before the Appellate Body that under an approach similar to the one advocated here, Article 5.7 would be 'drained of

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[33] In addition to the cases cited in the text below, see also the examples in *ibid*, paragraphs 7.2995 and 7.2983, where the Panel explicitly acknowledges that Article 5.7 and not Article 5.1 *must* logically apply in all cases of insufficient scientific uncertainty, regardless of compliance with the other requirements under Article 5.7 However, in these paragraphs, the Panel uses this to support its argument that Article 5.7 is a qualified right, not an exemption, and does not follow through on its implications for other aspects of its reasoning.

[34] *ibid*, paragraph 7.2939.

[35] *ibid*, paragraph 7.2931, quoting *Japan – Measures Affecting the Importation of Apples* n 19 above, paragraph 184.

[36] *EC – Measures Affecting the Approval and Marketing of Biotech Products* n 19 above, footnote 1807.

[37] *ibid*, paragraph 7.2942.

content', as it would in effect allow Members to maintain provisional measures indefinitely.[38] But this concern is overstated: the need to show that there is insufficient evidence to perform a risk assessment, and that the measure in dispute was based on available pertinent information, are both important safeguards against abuse of the provision. Furthermore, it is misplaced: if there are concerns about the enforceability of the research and review obligations, the answer to these concerns must be to improve precisely supervisory mechanisms, rather than the more extreme position of making provisional measures absolutely unavailable in the case of a failure to comply. It may be that making these obligations truly operable and effective may require some innovation and experimentation with post-judgment dispute resolution processes, to enable ongoing and effective supervision of efforts to obtain further knowledge and revise measures in light of them.

ARTICLE 5.7 AND THE CHALLENGES OF EVOLVING SCIENTIFIC KNOWLEDGE

Let me now turn to the second of the two issues that I wish to address in this article, concerning what might be called the 'expiry' of Article 5.7. I have already set out above the prevailing view that Articles 5.1 and 5.7 have mutually exclusive domains of application, and in particular that Article 5.1 applies once the relevant scientific evidence is no longer 'insufficient'.[39] The Appellate Body in *Japan – Measures Affecting the Importation of Apples ('Japan – Apples')* expressed its view that the term 'insufficient' means insufficient to perform an adequate assessment of risk, whether in quantitative or qualitative terms.[40] And the Panel in *EC – Biotech* has made clear that once a risk assessment is actually performed, then that will at the very least raise a presumption that scientific evidence is sufficient in the relevant sense.[41] The result appears to be that once a risk assessment is performed, the right to take provisional measures under Article 5.7 expires. This has struck some commentators as inappropriate. Scientific knowledge, it is observed, does not stay still – rather, the state of our knowledge continues to evolve, to be revised and revisited, and nature continues to throw surprises at us. Governments, the argument continues, ought still to have the ability to take provisional measures in response to such surprises (and in response to evolving knowledge more generally) whether or not a prior risk assessment has been performed.

In this section, I examine whether this concern is justified. To the extent that it is, I suggest ways in which Articles 5.1 and 5.7 could be reinterpreted or clarified

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[38] *Japan – Measures Affecting Agricultural Products* n 5 above, paragraph 25.
[39] See text to n 21 above.
[40] *Japan – Measures Affecting the Importation of Apples* n 19 above, paragraph 179.
[41] For example, *EC – Measures Affecting the Approval and Marketing of Biotech Products* n 19 above, paragraph 7.3260.

to resolve any problems. For clarity, I distinguish between three different situations in which a government may wish to take provisional measures even after the completion of a favourable risk assessment.

NEW EVIDENCE RELATING TO AN ALREADY-IDENTIFIED RISK

The simplest case occurs when substantive new evidence comes to light that casts doubt on the reliability of evidence which formed the basis of the earlier favourable risk assessment. An example would be, say, if new trials found evidence of the development of antibiotic resistance in species interacting with genetically-modified crops. This new evidence need not be direct, nor need it necessarily be more persuasive than earlier evidence: the case I am concerned with here involves merely some new empirical evidence which suggests that an earlier positive risk assessment could be wrong. (This is different from a new study which reassesses pre-existing evidence in new or different ways, a case I deal with below.)

In most cases, I think we can be reasonably confident that a WTO Member would be entitled to take protective measures in response to this new evidence. It is of course totally clear that in such circumstances the Member could perform another risk assessment on the basis of the new evidence and (assuming of course that the new assessment warrants it) take new measures based on it.[42] From some comments of the Panel in *EC – Biotech*, it may even be that this new risk assessment need only be in the nature of a 'review assessment' – that is, a speedier, shorter and less cumbersome process than a full risk assessment.[43] This leaves at least two issues. The first is whether a government is entitled to take provisional protective measures in the period between the publication of the new evidence and the performance of the new risk assessment. Regardless of the legal position here, this is unlikely to be a major one in practice. The operation of the WTO dispute settlement system is such that the period of months in which a Member is in technical violation of the agreements can easily be accommodated on a pragmatic basis. The second issue concerns the situation in which the new evidence is of a kind which suggests the need for significant further research, and which therefore makes the existing body of evidence 'insufficient' to perform an adequate risk assessment. Such a situation raises the question whether a body of evidence which was once sufficient for the purposes of Article 5.7 can subsequently become 'insufficient'.

Happily, this question was addressed in the most recent decision of the Panel in *Canada – Hormones Suspension*.[44] In that case, the Panel makes it quite clear, first of all, that 'scientific evidence which was previously deemed sufficient could

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[42] This is what occurred, of course, in both *Australia – Measures Affecting Importation of Salmon*, WT/DS18 and *Japan – Measures Affecting the Importation of Apples,* WT/DS245.

[43] eg, *EC – Measures Affecting the Approval and Marketing of Biotech Products* n 19 above, paragraph 7.3260, including n2081.

[44] *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute*, Panel Report, WT/DS321/R. I will refer throughout to this decision, though the parallel decision with the US as respondent is in substantially similar terms.

subsequently become insufficient'.[45] It also went to specify the following test: 'there must be a *critical mass* of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence …' [46] I have some specific concerns about the way in which this test was applied in that case, which I set out below. But as a general point, this test seems to establish a very high threshold: it will have to be a very significant piece of new evidence indeed to call into question 'the fundamental precepts' of previous knowledge. One can easily imagine the existence of new evidence which casts some doubt on the reliability of previous risk assessments but which does not call the fundamental precepts of prior knowledge into question. The implications of this are troubling. For example, what it means is that wherever an international standard exists – and indeed, wherever a risk assessment has been carried out – there is in effect a new and very significant obstacle to the application of Article 5.7. And since, as the Panel itself has noted, the procedural steps of a risk assessment can *always* be carried out in some form,[47] this raises the spectre of a serious evisceration of the safe harbour provided by Article 5.7. Furthermore, this test can lead to practical difficulties for governments in the context of WTO litigation. In that case, the Panel found the EC to be in violation of Article 5.1 in part because the existing evidence was not sufficient to draw causal inferences of risk[48] – only to determine, during the analysis under Article 5.7, that the EC had not done enough to show that relevant scientific evidence was insufficient to perform an adequate risk assessment.

In my view, the response to these concerns ought to be twofold. First, a different test ought to be applied from the one set out by the Panel in *Canada – Hormones Suspension*. It ought not be necessary for the new evidence to 'call into question the fundamental precepts' of prior knowledge. Rather, it should be sufficient if the new evidence is enough to give a regulator good reason to doubt the reliability or conclusiveness of the evidence on which the prior risk assessment was based. But second, the effective presumption that scientific evidence is 'sufficient' where a risk assessment has been carried out, must be made more open to challenge. The Appellate Body has made it clear that relevant scientific evidence will be 'insufficient' when 'does not allow … the performance of an adequate assessment of risks'.[49] In *Canada – Hormones Suspension*, the Panel suggested that an 'adequate' assessment of risk is one which analyses the risk 'fully'[50] and which represents an 'objective evaluation'[51] of the risk. It ought to be possible, then, both as a matter of law and as a matter of principle, for a responding party to argue that a prior risk assessment was 'inadequate' and that therefore existing scientific

[45] *ibid*, paragraphs 7.597-7.599.
[46] *ibid*, paragraph 7.626.
[47] *ibid*, paragraph 7.606.
[48] *ibid*, paragraph 7.505 and surrounding.
[49] *Japan – Measures Affecting the Importation of Apples* n 19 above, paragraph 179.
[50] *n 44 above*, paragraph 7.606.
[51] *ibid.*

evidence is (and always was) 'insufficient' for the purposes of Article 5.7. This is different from – and additional to – the argument that new evidence has turned a body of evidence from sufficient to insufficient. Furthermore, a decision on the adequacy or not of a risk assessment must in principle always be taken in light of the needs and preferences of the regulating Member – a risk assessment is adequate, after all, only for particular purposes and in a particular content. Unfortunately, the Panel's continued rejection of the claim that the sufficiency of existing evidence ought to be considered in light of a Member's level of protection,[52] comes dangerously close to precluding this line of argumentation.

A NEWLY-IDENTIFIED RISK

Governments may also wish to take new provisional protective measures in response to new information disclosing a new kind of risk which has not previously been considered by earlier risk assessments. For example, new concerns might arise about the long-term implications of gene modification technology for biodiversity and ecosystem health, after a risk assessment has been carried out solely in respect of (say) the toxicity or allergenic effects of GMOs. Alternatively, information may come to light suggesting a new and previously unconsidered pathway for the potential gene transfer from modified crops to other species. Again, the government can of course perform a new risk assessment and impose new measures on the basis of it, but it is a slightly more difficult question whether it can invoke article 5.7 in the interim period, and impose provisional safeguard measures.

In principle, I see no reason why a government ought not to be able to do so. If little or no reliable evidence exists with respect to a particular specific risk posed by a product, then the mere fact that a risk assessment has been carried out with respect to *other* risks posed by that product surely should not preclude the application of Article 5.7. It must be true that scientific evidence can be 'sufficient' in respect of some risks related to a product, but 'insufficient' for others.

Current jurisprudence raises two potential difficulties with this view. First, the Appellate Body in *Japan – Apples* appears (at first glance) to have considered and rejected a similar argument. Japan had argued that in determining whether or not scientific evidence is sufficient, a Panel should look at the quantity and quality of evidence which specifically addresses the particular problem or risk at issue.[53] The Appellate Body responded that 'the question is not … whether there is sufficient evidence related to a specific aspect of a phytosanitary problem, or a specific risk'. This may seem to suggest that the 'sufficiency' of scientific evidence is not to be understood and interpreted in relation to the particular risk at issue. In truth, however, this statement goes to a different issue. The Appellate Body went on to say: 'The question is whether the relevant evidence, be it 'general' or 'specific' … is

[52] See, eg, *ibid*, paragraph 7.588 and surrounding.
[53] *Japan – Measures Affecting the Importation of Apples* n 19 above, paragraph 178.

sufficient to permit the evaluation of the likelihood of entry, establishment or spread of, in this case, fire blight in Japan.'[54] As this sentence makes clear, the Appellate Body was simply making the point that evidence of a general nature may still assist in the assessment of a specific risk. It was not suggesting that the sufficiency of scientific evidence could or should be evaluated without reference to a specific risk.[55]

The second potential difficulty arises from the decision in *EC – Biotech*, and is most easily explained using an example. One of that challenged member state safeguard measures in that case was Greece's measure with respect to 'topas oilseed rape'.[56] Greece had given a number of reasons for adopting this safeguard measure, and one of them was that the original (SCP) risk assessment failed to consider that:

> some of the wild plant varieties at issue are collected and consumed in Greece as food. Greece points out in this regard that if out-crossing were to confer on these wild plant varieties the herbicide resistance trait, the consequences of the consumption of these varieties would be unpredictable. Greece observes that these consequences have not been considered in the original risk assessment prior to the approval of Topas oilseed rape.[57]

The EC argued, on behalf of Greece, that 'having regard to the specific concerns of Greece's legislators … [they] were entitled to conclude that relevant scientific evidence was insufficient for their purposes.'[58] Put in other words, the claim here was that the original risk assessment had failed to consider some risks related to topas oilseed rape which were peculiar to the Greek context, and that therefore that risk assessment should not be taken as evidence that sufficient scientific evidence existed to perform an assessment of those risks.

In response to this argument, the Panel did *not* perform the analysis which might have been expected – namely, to determine whether or not the community-level risk assessment had addressed the specific risks which concerned Greece, and (if it didn't) to determine whether or not existing scientific evidence was sufficient to adequately assess those risks. Instead, it inferred that relevant scientific evidence was sufficient from the response of the SCP to Greece's concerns. The Panel simply noted that the SCP had reconsidered its original risk assessment in light of Greece's concerns, and 'concluded that the information provided by Greece did not constitute new scientific information which would change the original risk assessment'.[59] The Panel therefore went on:

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[54] *ibid*, paragraph 179.
[55] *ibid*. This conclusion is buttressed by the statement, earlier in that paragraph, that 'this evaluation must be carried out, not in the abstract, but in the light of a particular inquiry.'
[56] See generally, *EC – Measures Affecting the Approval and Marketing of Biotech Products* n 19 above, paragraphs 7.3161ff. and 7.3330ff.
[57] *ibid*, at paragraph 7.3168.
[58] *ibid*, at paragraph 7.3336.
[59] *ibid*, at paragraph 7.3340.

> In light of this, we agree … that the SCP's 1999 review assessment of Topas oilseed rape, and the SCP's original risk assessment of Topas oilseed rape (which, as noted, was confirmed by the SCP's review assessment), serve to demonstrate that … the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 …[60]

Strictly speaking, this inference is not justified. The question for the Panel was different from that which confronted the SCP. The SCP determined only that Greece's information did not constitute 'new scientific information which would change the original risk assessment'. The Panel, on the other hand, was required to determine whether Greece's information disclosed a specific risk which had not been (and could not have been) covered in the risk assessment – a judgement not about the character or persuasiveness of Greece's new information, but rather about the existence of a gap in the original risk assessment. The Panel should not have made this determination without a close analysis of the content of both the initial and the review assessment performed by the SCP – whether or not the risk assessment purported to be a general one covering all conceivable risks. Because it failed to perform this close analysis, the result was that the existence of a risk assessment covering *some* risks was treated in practice as if it proved that 'sufficient' evidence existed to assess *all* risks related to the product.

In my view, however, this is primarily a deficiency in the way that the Panel applied its own reasoning rather than a problem with its interpretation of the law itself, and therefore does not stand in the way of the approach identified above. If the Panel in *EC – Biotech* had followed its own reasoning more rigorously, it could have analysed the content of the relevant risk assessments more closely to determine whether or not they covered the particular risk that Greece had raised. The failure of the Panel to perform this analysis may have as much to do with procedural questions as anything else: a careful reading of the Panel's decision reveals that the performance of a risk assessment only raises a *presumption* that the relevant scientific evidence is sufficient.[61] The decision may have been different if further evidence had been submitted, or if the case had been argued differently.[62] Ultimately, it is a matter of fact whether or not that assessment actually addressed the particular risk at issue, and whether or not there is sufficient scientific evidence to do so.

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[60] *ibid*, at paragraph 7.3341.

[61] *ibid*: 'We consider, therefore, that the United States and Canada have established a presumption that Greece's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient.'

[62] The argument that the original risk assessment did not examine certain risks was raised in relation to Article 5.1 (*EC – Measures Affecting the Approval and Marketing of Biotech Products* n 19 above, paragraph 7.3168). It was not, at least as disclosed in the Panel report, raised again in relation to the interpretation of 'insufficient' in Article 5.7.

NEW AWARENESS OF THE LIMITATIONS OF EARLIER RISK ASSESSMENTS

The third case is the most difficult. Very often, our knowledge of the risks associated with particular products or organisms evolves in an incremental fashion, as risk assessments are subject to criticism, scrutiny and re-evaluation. Assessments may, for example, be criticised for their incomplete coverage, overly robust assumptions, methodological flaws, or (more radically) for inherent limitations in the techniques of risk assessment process themselves.[63] As a result of such criticisms, policy-makers may lose confidence in these assessments, and wish to take protective measures in light not of new evidence, or of newly-identified risks, but of new or increased awareness of the limitations and flaws of existing risk assessments. Assuming for present purposes that this is legitimate, to what extent are they able to do so under current WTO jurisprudence, before going through the entire process of another risk assessment?

In some cases, of course, a risk assessment will contain an explicit acknowledgement of its own limitations: it may set out both orthodox and minority scientific opinions, it may acknowledge alternative ways of reading relevant evidence, or it may explicitly identify remaining uncertainties and other factors which reduce the level of confidence of the assessment. In such cases, the Appellate Body has made it perfectly clear that a government may rely on these elements in a risk assessment to justify protective measures, and that such reliance will satisfy the requirements of Article 5.1.[64] But what of the case in which the risk assessment does not acknowledge remaining uncertainties or its own limitations, perhaps because those limitations only become apparent arise through careful scrutiny once the assessment has been carried out? What if the risk assessment comes to be seen as flawed, because it was carried out on the basis of unjustified assumptions, or because it came to its conclusions on the basis of what comes to be perceived as inadequate evidence? What of the situation in which a decision-maker wishes to take protective measures on the basis of that special *irreducible* kind of uncertainty that arises from the process of scientific risk assessment itself? The question is whether protective measures are permitted in such situations is a more difficult one.

It may be thought that Article 5.7 ought to provide a safe harbour in such cases. In other words, even where a risk assessment has been carried out, and the product has been found safe, Article 5.7 ought still to operate to justify protective measures which are based on *remaining* uncertainty, including irreducible uncertainty.[65] After all, Article 5.7 is designed to address the problem of the

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[63] For an excellent explanation on the nature and sources of 'uncertainty' in scientific risk assessment, including irreducible uncertainty, see V. Walker, 'The Siren Songs of Science: Toward a Taxonomy of Scientific Uncertainty for Decisionmakers' (1999) 23 Connecticut LR 567.

[64] See n 2 above, paragraph 194. See also *EC – Measures Affecting the Approval and Marketing of Biotech Products* n 19 above, paragraphs 7.3240, 7.3060, 7.3065.

[65] See J. Scott, 'European Regulation of GMOs and the WTO' (2003) 9 *Columbia Journal of European Law* 213, 228-29; D. Wirth, 'The Transatlantic GMO Dispute Against the European Communities: Some

insufficiency of available evidence – and the existing of flaws in, and limitations of, existing risk assessments is often evidence of 'insufficiency'.. But whatever the attractions of this approach, it seems to have been foreclosed by existing jurisprudence. For one thing, the *EC – Biotech* decision unequivocally rejects the possibility of Articles 5.1 and 5.7 applying concurrently, which precludes an argument Article 5.7 remains available even once an adequate risk assessment has been carried out.[66] For another, the Panel's decision in *Canada – Hormones Suspension* seems also to have precluded the argument that a new awareness of the limitations and flaws in earlier risk assessments can be enough make a once-sufficient body of evidence now 'insufficient'. As noted above, in that case, it was made clear that for a body of evidence to move from sufficient to insufficient, there must be new evidence, and this new evidence must call into question the 'fundamental precepts' of existing evidence. The Panel went on to say that, at least in the context of that case, this test would only be satisfied if the new evidence 'put[s] into question existing relevant evidence to the point that this evidence is no longer sufficient to support the conclusions of existing risk assessments'.[67] Thus, it was not enough for the European Communities in that case to show that there were flaws in the measurement techniques used to gather the earlier evidence, nor that there were specific gaps in the information on which the prior evidence was based, nor more generally to show good reasons to doubt the reliability or conclusiveness of prior evidence. It was clear that – at least the way that the Panel applied this test in the present case – what was required was nothing short of reliable and validated positive evidence of risk which directly contradicted earlier evidence.[68] New awareness of flaws in existing science was not enough.

There are – perhaps – still two potential arguments which a regulating Member may still make in this situation. The first is that our new awareness of the flaws in existing risk assessments shows that the existing evidence is *and always was* insufficient to perform an 'adequate' risk assessment. This argument was referred to earlier. The second is based not on Article 5.7 but rather Article 5.1, and derives from the decision of the Panel in *EC - Biotech*. In that case, of course, all of the products in question had been found to be essentially risk-free in the risk assessments performed by the lead country and the SCP, and these assessments did not refer to any remaining uncertainties or disagreements of a kind which would themselves justify protective measures.[69] But these risk assessments were subsequently subject to serious criticism and rigorous analysis by other groups, and Member states of the EC purported to justify their safeguard measures in part on the basis of these criticisms. For example, Austria criticised the risk assessment

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Preliminary Thoughts' (Boston College Law School, Faculty Paper no. 144, 2006) 28, at http://lsr.nellco.org/bc/bclsfp/papers/144.

[66] See *EC – Measures Affecting the Approval and Marketing of Biotech Products* n 19 above, paragraphs 6.174, 6.176 and compare paragraph 7.3399 with paragraph 7.3390 of the interim panel report.

[67] n 44 above, paragraph 7.626.

[68] See, eg, *ibid*, paragraph 7.696, 7.676. This is clearly what is required in practice despite what the Panel appears to say in paragraph 7.591.

[69] *ibid*, paragraph 7.3059, and the paragraphs referred to in n 74 below.

in relation to T25 maize on the basis that 'the product had not been examined under realistic conditions', and on the grounds that 'regional ecological aspects were not differentiated as far as resistance development is concerned'.[70] Germany identified specific potential consequences which had not been examined in the initial risk assessment in relation to Bt-176 maize.[71] Italy suggested that the applicable risk assessment procedures were inadequate specifically in relation to the assessments of T25 maize, MON810 maize and Bt-11 maize.[72] More radically, Austria noted certain types of risks in relation to T25 maize which are 'incalculable in principle in predictive risk assessment'.[73]

Taking into account these flaws and limitations, the EC argued, the member state safeguard measures could be said to be 'based on' the risk assessments which carried out, in the sense that they were based on a careful consideration of those assessments, and on a recognition of their limitations. The Panel disagreed, but in the following terms:

> We … have reached the conclusion that [the relevant] safeguard measure … cannot be considered to be 'based on' the risk assessments performed by the lead CA and the SCP ... This is because … :
>
> (a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the risk assessments which were conducted by the SCPE, the SCAN or the SCF with regard to [the product in question];
>
> (b) the European Communities or [the member state in question] did not explain, by reference to these risk assessments, how and why [the member state] assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;
>
> (c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such uncertainties or constraints, [the member state's] prohibition is warranted by the relevant risk assessments; and
>
> (d) there is no apparent rational relationship between the member state's safeguard measure, which imposes a prohibition, and risk assessments which found no evidence that the product in question will give rise to any adverse effects on human or animal health and the environment …
>
> Thus, in view of our conclusion that Austria's safeguard measure on Bt-176 maize cannot be considered to be 'based on' the risk assessment performed by the lead CA or the risk assessments.[74]

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[70] *ibid*, paragraph 7.3041.
[71] *ibid*, paragraph 7.3149.
[72] *ibid*, paragraph 7.3185.
[73] *ibid*, paragraph 7.3044.
[74] *ibid*, at paragraph 7.3085, relating to Austria, Bt-176 maize. For the same reasoning, almost *verbatim*, in respect of the other safeguard measures, see paragraphs 7.3066 (Austria, T25 maize), 7.3106 (Austria, MON 810 maize), 7.3127 (France, MS1/RF1 oilseed rape (EC-161), 7.3137 (France, Topas oilseed rape),

The clear implication of this passage – particularly paragraphs (b) and (c) – is that if the member states had explained how and why they assessed the risks differently, if they had identified possible uncertainties and constraints in the risk assessments in question, and/or if they had explained why in view of such constraints and uncertainties their prohibitions were warranted, then the Panel's conclusion would have been different.[75] This is in many respects a clever and subtle compromise: on the one hand permitting countries to take into account the uncertainties and constraints of the risk assessment procedure, even where the uncertainties are not explicitly acknowledge in the risk assessment itself, and on the other hand requiring such countries to explain precisely what those uncertainties are and demonstrating how they warrant the particular protective measures at issue.

Nevertheless, there are at least two potential difficulties with the Panel's approach. First, although the test they set out is reasonable in principle, the way it was applied seems overly strict. Taken together, the arguments and information provided by the member states to justify their safeguard measures *prima facie* represent a substantial and reasoned criticism of the limitations of the risk assessments initially carried out. It is true that the information provided did not itself constitute a new risk assessment. But the information did point out some genuine potential flaws in the original risk assessments, and it did set out the substance of a divergent scientific opinion which had not been included in the original risk assessments. It is hard to see why a reasonable policy-maker ought not to be able to take these elements into account. Where a government lacks confidence in a positive risk assessment, a WTO should in my opinion only require that this lack of confidence is explicit, comprehensible, minimally rational and transparent. Thus, while the Panel's reasoning is hard to fault, it needs to be applied without strict regard to formalities, in a sensitive and rigorous way, and mindful of the facts that the particulars of a 'reasoned critique' of a risk assessment will depend heavily on the nature of the critique and on all the circumstances.

Second, although the Panel raises the possibility that countries can rely on 'uncertainties' in risk assessments to justify protective measures, it is not clear precisely what is meant by that term. In particular, it is not clear whether or not it includes forms of 'irreducible' uncertainty referred to earlier, which derive from the risk assessment process itself, and which cannot ever be eliminated through further research and study. Are governments entitled, in other words, to take protective measures on the basis of the inherent limitations of risk assessment

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7.3157 (Germany, Bt-176 maize), 7.3177 (Greece – Topas oilseed rape), 7.3195 (Italy, T25 maize, MON810 maize, Bt-11 maize (EC-163)), and 7.3211 (Luxembourg, Bt-176 maize).

[75] To the extent that paragraph (b) also suggests that there is also a need for a further risk assessment, this may present difficulties. As I have noted above, the claim that an additional risk assessment can justify new and different SPS measures is uncontroversial, but the primary concern is with the interim period. The phrase 'revised or supplemental assessment', which implies a briefer version of the full risk assessment process, goes some way towards addressing this concern.

procedures, and of the fundamental inability of scientific methods and tools to reliably predict all forms of risk? Of course the question whether or not governments *ought* to be able to rely on irreducible uncertainty of this kind is a heavily contested one, but even the more modest question of the legality of such measures is difficult. It has never been squarely addressed by WTO panels or the Appellate Body, but there are at least three comments from *EC – Biotech* which suggest a lack of sympathy to the problems posed by irreducible uncertainty. For one thing, in paragraph 7.3064, the Panel notes that governments may legitimately take into account 'factors which affect scientists' level of confidence' as well as 'uncertainties' left open by a risk assessment – but then explicitly qualifies this statement by saying: 'We are not referring here to the theoretical uncertainty which inevitably remains because science can never provide absolute certainty that a product will never have adverse affects on human health or the environment.'[76] (Precisely the same sentiment is echoed in the more recent *Canada – Hormones Suspension* panel, where it notes that the existence of 'theoretical uncertainty' in not enough to make a body of evidence 'insufficient' for the purposes of Article 5.7.[77]) While it is not clear precisely what the Panel has in mind when it uses the phrase 'theoretical uncertainty' (nor the Appellate Body in the report from which the phrase is drawn), it certainly seems close to a notion of irreducible uncertainty. In another potentially problematic comment, in the lengthy passage cited above,[78] the Panel suggests that a government may need to provide a 'revised or supplemental assessment of the risks' where it lacks confidence in an earlier risk assessment. This arguably does not sit comfortably with a notion of irreducible uncertainty, for which any further supplemental risk assessment is by definition *inutile*. Finally, the way that, throughout its judgement, the Panel consistently gives short shrift to arguments that certain risks simply cannot adequately be assessed in principle, will raise some concerns for those who see irreducible uncertainty as a serious problem to be addressed.[79]

CONCLUSION

We are still in the early stages of the development of jurisprudence under the *Agreement on Sanitary and Phytosanitary Measures*, in particular as it relates to provisional measures under Article 5.7. No doubt, as the jurisprudence evolves, and as the issues identified in this article are addressed more directly by Panels and

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[76] See *EC – Measures Affecting the Approval and Marketing of Biotech Products* n 19 above, footnote 1094, referring back to the famous line from n 2 above, paragraph 186.
[77] n 44 above, paragraph 7.609.
[78] See text to n 74 above.
[79] See, in particular, the treatment of such arguments in the Panel's reasoning under Article 5.1 with respect to Austria's measures on T25 maize, Bt-176 maize and MON 810 maize, and Greece's measure on topas oilseed rape.

the Appellate Body, we will have a much clearer picture of how those bodies will respond to them. Nevertheless, the modest purpose of this article has been to identify two potential difficulties in the application of Article 5.7 which appear to follow from certain statements made by Panels and the Appellate Body so far. The first relates to the situation in which a WTO Member legitimately takes provisional measures under Article 5.7, but refuses to conduct further research as required by that article. In such circumstances, I have argued, the relevant violation is the failure to conduct further research, not the taking of provisional measures – and the solution must therefore be to require such further research, rather than to invalidate the provisional measures themselves. The second issue relates to questions of evolving science, and the extent to which Article 5.7 ought to remain available as a safe harbour to Members even once a risk assessment has been carried out. I have argued that indeed it should, where substantive inadequacies and limitations of the earlier risk assessment become apparent to policy-makers, where new evidence comes to light, and where a previously unconsidered risk is identified. Under current jurisprudence, it is not fully clear that Article 5.7 remains available in all such circumstances. Both of these arguments identify certain (modest) flexibilities which in my view can comfortably be read into the SPS Agreement itself, but which are in danger of being unnecessarily tightened by the approach that Panels and the Appellate Body have taken to the interpretation of Article 5.7.