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## **1 ANNEX C**

### **1.1 Text of Annex C**

#### **ANNEX C**

##### CONTROL, INSPECTION AND APPROVAL PROCEDURES<sup>7</sup>

*(footnote original)*<sup>7</sup> Control, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification.

1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:

- (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;
- (b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;
- (c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs;
- (d) the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favourable than for domestic products and in such a manner that legitimate commercial interests are protected;
- (e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary;
- (f) any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service;
- (g) the same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents;
- (h) whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned; and
- (i) a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified.

Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.

2. Where a sanitary or phytosanitary measure specifies control at the level of production, the Member in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.

3. Nothing in this Agreement shall prevent Members from carrying out reasonable inspection within their own territories.

## **1.2 Annex C(1)**

### **1.2.1 General**

1. In *Australia – Apples*, the Panel addressed the question of whether Annex C(1)(a) of the SPS Agreement can be interpreted as applying to the development of SPS measures:

"[T]he text of Annex C(1)(a) relates to 'procedures to *check and ensure* the fulfilment of SPS measures', not to *develop* SPS measures. However, under the definition of Annex A(1) of the SPS Agreement, SPS measures include both substantive requirements and procedures. Therefore, the 'SPS measure' referenced in the language of Annex C(1)(a) may be a requirement to conduct an import risk assessment prior to allowing for the importation of goods that might pose sanitary or phytosanitary risks. In that case, the actual import risk assessment conducted for a specific good might constitute the procedure to check and ensure the fulfilment of this 'SPS measure'.<sup>1</sup>

### **1.2.2 Application of Annex C**

#### **1.2.2.1 Procedures**

2. The Panel in *US – Poultry (China)* found that Annex C does not specify or exclude any type of procedures from its application. Rather, the Panel considered that Annex C covered any measure that is aimed at checking and ensuring the fulfilment of SPS measures. The Panel stated:

"Considering the actual text of Annex C(1) of the *SPS Agreement*, the Panel notes that Annex C(1) does not specify, nor exclude, any types of 'procedures'. According to our reading, Annex C(1) basically requires that 'any procedure' is covered by its provisions so long as that 'procedure' is aimed at 'checking and ensuring the fulfilment of sanitary or phytosanitary measures', and is undertaken in the context of 'control, inspection, or approval'. In the Panel's view, no *a priori* exclusion is contemplated by the *SPS Agreement*.

We find equally important to note that the *SPS Agreement* does not specify or limit, the SPS measures referred to in Annex C(1). Indeed, Annex C(1) of the *SPS Agreement* merely provides that any procedure to check and ensure the fulfilment of SPS measures is subject to the provisions of items (a) through (i).<sup>2</sup>

3. The Panel in *US – Poultry (China)* also determined that the application of Annex C (and other SPS provisions) is not dictated by the title or the characterization given to that measure by the Member maintaining it. The Panel noted:

"The 'approval procedures' encompassed by Annex C of the *SPS Agreement* may cover a broad array of procedures, as the drafters of the *SPS Agreement* did not limit the scope of these 'procedures' to any specific type of 'approval procedures'. Bearing that

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<sup>1</sup> Panel Report, *Australia – Apples*, para. 7.1463.

<sup>2</sup> Panel Report, *US – Poultry (China)*, paras. 7.363-7.364.

in mind, the Panel considers that the application of specific provisions of the *SPS Agreement*, such as Annex C(1), is by no means restricted to the title or the characterization of an SPS measure given to that measure by the WTO Member maintaining it. To put it differently, it is not because the United States named its requirements as 'FSIS equivalence determination process' and characterizes it as a purely 'equivalence' process, that the only provisions applicable to the measure are those of Article 4 of the *SPS Agreement*.<sup>3</sup>

4. The Appellate Body in *Australia – Apples* addressed the issue of what measure may violate the obligation in Annex C(1) and Article 8 noting that, while procedures are the direct target of the obligation in these two provisions, this would not necessarily exclude other types of measures from being subject to the obligation. The Appellate Body found:

"[T]he obligation in Annex C(1)(a) requires Members to commence, and to complete specific *procedures* without undue delay. Thus, procedures are the direct target of the relevant obligation and those procedures may themselves be the measure in violation of that obligation. Yet, it does not follow that other types of measures are precluded, *a priori*, from being an appropriate target of a claim of inconsistency with Annex C(1)(a) and Article 8. In our view, the obligation to ensure that relevant procedures are undertaken and completed without undue delay may be infringed through measures other than the control, inspection and approval procedures themselves, such as actions that prohibit, prevent or impede undertaking and completing such procedures 'without undue delay', or omissions in the form of a failure to act 'without undue delay'. Such measures, even when they are not, themselves, procedures, could equally give rise to a violation of Annex C(1)(a) and Article 8."<sup>4</sup>

5. In *US – Animals*, the Panel referred to past panels' findings that procedures within the meaning of Article 8 and Annex C cover a broad variety of measures, and rejected the proposition that the covered procedures should be limited to those addressing products, excluding, as a result, determinations of the disease status of certain geographical regions from the scope of Article 8 and Annex C.<sup>5</sup>

6. The Panel in *US – Animals* also dealt with the interpretation of the requirement that procedures falling within the scope of Article 8 and Annex C check and ensure the fulfilment of sanitary and phytosanitary measures. The Panel found in that respect that "Article 8 and Annex C cover any procedure to make certain that a measure applied to achieve one of the objectives in Annex A(1) is fully implemented."<sup>6</sup>

7. In light of the past panels' findings that Article 8 and Annex C cover a broad range of measures, the Panel in *Russia – Pigs (EU)* found no basis in the language of these provisions for limiting their scope of application only to procedures that address products, excluding thus those ones that deal with, for example, the process of consideration or determination of the disease status of a particular geographic region.<sup>7</sup>

8. In *Korea – Radionuclides*, the Panel rejected the respondent's interpretation of the term "procedures" as necessarily prescribing a "specific course of action". The Panel found that "[b]oth the language and the context of [Article 8 and Annex C] instruct a broader understanding of the term 'procedure' as performance of an action or course of actions, which do not have to be specific or dictate a particular result."<sup>8</sup>

#### **1.2.2.2 "to check and ensure the fulfilment of sanitary or phytosanitary measures"**

9. In *Korea – Radionuclides*, the Panel confronted the question whether a procedure, which checks and ensures the fulfilment of a substantive SPS requirement contained in the same measure is covered by the obligation in Article 8 and Annex C(1). This question arose in the

<sup>3</sup> Panel Report, *US – Poultry (China)*, para. 7.372.

<sup>4</sup> Appellate Body Report, *Australia - Apples*, para. 438.

<sup>5</sup> Panel Report, *US – Animals*, para. 7.69.

<sup>6</sup> Panel Report, *US – Animals*, para. 7.73.

<sup>7</sup> Panel Report, *Russia – Pigs (EU)*, para. 7.515.

<sup>8</sup> Panel Report, *Korea – Radionuclides*, para. 7.371.

context of the respondent's argument that a substantive SPS measure has to be distinct from the procedure that seeks to enforce it. The Panel found that the SPS Agreement does not preclude combining substantive SPS requirements and procedures to enforce them in a single measure. In the Panel's view, "[to] adopt such an interpretation would allow Members to easily evade review of their procedural requirements under Article 8 and Annex C simply by stipulating control, inspection and approval procedures together with substantive SPS requirements in the same instrument."<sup>9</sup> The Panel concluded that "for a procedure to fall within the scope of Article 8 and Annex C, there has to be a link between the procedure and an SPS measure that the Member seeks to check and ensure the fulfilment of."<sup>10</sup>

### 1.2.2.3 Temporal scope

10. According to the Appellate Body in *Australia – Apples*, the text of Annex C(1) suggests that the measures covered by Article 8 and Annex C(1) must exist prior to the operation, undertaking or completion of the relevant procedures. The Appellate Body stated:

"[A]rticle 8 refers to the '*operation of control, inspection and approval procedures*', and subparagraph (a) of Annex C(1) requires relevant procedures to be *undertaken and completed* without undue delay. Since the procedures referred to in Annex C(1) are those that check and ensure fulfilment of SPS measures, this suggests that such measures exist *prior* to the operation, undertaking or completion of, the relevant procedures, as the latter seek to check and ensure fulfilment with the former."<sup>11</sup>

11. In *Indonesia – Chicken*, the Panel confronted the question whether a procedure within the meaning of Annex C can be considered to have commenced, even though the information provided by the exporting Member in response to the importing Member's request was incomplete. In light of the Members' obligations pursuant to Annex C(1)(a) and C(1)(b), the Panel rejected the idea that "an SPS approval procedure starts only when *all* the relevant information is submitted", but rather with a submission of an application of approval.<sup>12</sup>

### 1.2.3 Annex C(1)(a) first clause

#### 1.2.3.1 Rationale of the provision

##### 1.2.3.1.1 Principle of good faith

12. In *EC – Approval and Marketing of Biotech Products*, the Panel found that Annex C(1)(a) first clause was essentially a good faith obligation requiring Members to proceed with their approval procedures as promptly as possible, taking account of the need to check and ensure the fulfilment of their relevant SPS requirements:

"[I]t is pertinent to call attention to the introductory paragraph of Annex C(1). It indicates that approval procedures serve to 'check and ensure the fulfilment of [SPS] measures'. We consider that if approval procedures serve to check and ensure the fulfilment of SPS requirements, then Members applying such procedures must in principle be allowed to take the time that is reasonably needed to determine with adequate confidence whether their relevant SPS requirements are fulfilled, at least if these requirements are WTO-consistent. Put another way, we view Annex C(1)(a), first clause, essentially as a good faith obligation requiring Members to proceed with their approval procedures as promptly as possible, taking account of the need to check and ensure the fulfilment of their relevant SPS requirements. Consequently, delays which are justified in their entirety by the need to check and ensure the fulfilment of a Member's WTO-consistent SPS requirements should not, in our view, be considered 'undue'.<sup>13</sup>

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<sup>9</sup> Panel Report, *Korea – Radionuclides*, para. 7.377.

<sup>10</sup> Panel Report, *Korea – Radionuclides*, para. 7.378.

<sup>11</sup> Appellate Body Report, *Australia – Apples*, para. 436.

<sup>12</sup> Panel Report, *Indonesia – Chicken*, para. 7.522.

<sup>13</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1498.

### 1.2.3.1.2 Prompt enforcement of SPS provisions

13. In *EC – Approval and Marketing of Biotech Products*, the Panel ruled that the purpose of Annex C (1)(a) is to ensure the enforcement of the SPS Agreement. The Panel considered that by providing for a prompt settlement of approval procedures, this article serves, in line with the preamble of the SPS Agreement, the overall purpose of urging Members to apply rapidly and conclusively the requirements of the Agreement:

"[I]f the time taken by a Member to complete an approval procedure, or a particular stage thereof, exceeds the time that is reasonably needed to check and ensure the fulfilment of its relevant SPS requirements, for instance because the Member concerned did not proceed as expeditiously as could be expected of it in the circumstances, the delay caused in this way would, in our view, be 'undue'. This interpretation of Annex C(1)(a) is supported by the object and purpose of the *SPS Agreement*. The fourth preambular paragraph of the *SPS Agreement* states that one particular object and purpose of the *SPS Agreement* is 'the establishment of a multilateral framework of rules and disciplines to guide the [...] enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade'. Annex C(1)(a), first clause, establishes disciplines concerning the 'enforcement' of SPS measures, namely, approval procedures. If Annex C(1)(a), first clause, were interpreted to mean that Members need not undertake and complete their approval procedures as soon as possible under the circumstances, we think the object and purpose of minimizing negative trade effects of approval procedures could not be achieved."<sup>14</sup>

### 1.2.3.2 "undertake and complete"

14. In *EC – Approval and Marketing of Biotech Products*, the Panel held that the phrase "undertake and complete" covers all stages of approval procedures and should be taken to mean that, once an application has been received, approval procedures must be started and then carried out from beginning to end:

"The verb 'undertake' makes clear that Members are required to begin, or start, approval procedures after receiving an application for approval. The verb 'complete', on the other hand, indicates that approval procedures are not only to be undertaken, but are also to be finished, or concluded. Thus, in our view, the phrase 'undertake and complete' covers all stages of approval procedures and should be taken as meaning that, once an application has been received, approval procedures must be started and then carried out from beginning to end."<sup>15</sup>

15. The Panel in *Australia – Apples* held that it is perfectly plausible that an unduly delayed specific approval process is found inconsistent with Annex C(1)(a) (and consequently Article 8) of the SPS Agreement, even if that process does not lead to the adoption of substantive SPS requirements. The Panel noted that there could be situations where an approval process simply takes too long for the complainant, especially if the complainant is prevented from exporting the goods in question during that period. In such circumstances, the Panel found that it would be inappropriate if the complainant were prevented from initiating a WTO dispute merely because the lengthy approval process did not lead to substantive SPS requirements. A different interpretation would empty out the procedural requirement contained in the first clause of Annex C(1)(a) of the SPS Agreement.<sup>16</sup>

16. In *US – Animals*, the Panel found that the obligation to undertake and complete procedures without undue delays "includes not only no undue delay in the commencement of the procedure and its completion, but also in the intervening process that leads from commencement to completion".<sup>17</sup>

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<sup>14</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1499.

<sup>15</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1494. See also Panel Report, *US – Poultry (China)*, para. 7.353.

<sup>16</sup> Panel Report, *Australia – Apples*, para. 7.1472.

<sup>17</sup> Panel Report, *US – Animals*, para. 7.112.

### 1.2.3.3 "without undue delay"

#### 1.2.3.3.1 Definition

17. In *EC – Approval and Marketing of Biotech Products*, the Panel, in interpreting the phrase without undue delay, connected it to the preceding words and considered that it addresses both the verbs "undertake" and "complete", where it comes that the requirement to proceed rapidly relates to these two actions equally:

"There is one additional aspect of Annex C(1)(a), first clause, which it is appropriate to address before examining the merits of the claims before us. The phrase 'without undue delay' follows the phrase 'undertake and complete'. We consider that the phrase 'without undue delay' relates, not just to the immediately preceding verb 'complete', but to both elements of the phrase 'undertake and complete'. In other words, we consider that Annex C(1)(a), first clause, should be read as requiring that Members must 'undertake' approval procedures 'without undue delay' and, subsequently, 'complete' them 'without undue delay'. Were it otherwise, a Member could easily circumvent the requirement to complete approval procedures without undue delay by causing undue delay in the undertaking of approval procedures."<sup>18</sup>

18. Having ruled that the phrase "without undue delay" concerns both the verbs "undertake" and "complete" in the preceding clause, the Panel in *EC – Approval and Marketing of Biotech Products*, contemplated the liabilities which might come from a failure to observe this provision. The Panel emphasized the overall need to act rapidly in the completion of the whole approval process regardless of the time that might have been saved in some previous procedural steps:

"The view that the phrase 'without undue delay' relates to both elements of the phrase 'undertake and complete' implies that if a Member causes undue delay at any stage in an approval procedure, this would constitute a breach of the provisions of Annex C(1)(a), first clause. In our view, there would be a breach of Annex C(1)(a) even if the Member concerned completed one or more previous stages of the approval procedure sooner than could be expected. If, contrary to our view, a Member could balance undue delay in the completion of a particular procedural stage against a period of time 'saved' at an earlier stage in the approval procedure, the implication would be that in some cases a Member could temporarily delay the completion of an approval procedure even though there is no need to do so. We consider that such an interpretation of Annex C(1)(a), first clause, would not be supported by the object and purpose of the *SPS Agreement*. In particular, we consider that interpreting Annex C(1)(a), first clause, as permitting a Member temporarily to delay the completion of an approval procedure even when there is no need for a delay would not be consistent with the previously mentioned object and purpose of minimizing negative trade effects of approval procedures."<sup>19</sup>

19. In the specific context of compliance proceedings, the Panel in *Indonesia – Chicken (Article 21.5 – Brazil)* emphasised the continuous nature of the obligation in Annex C(1)(a) to conclude that "once a breach has occurred, the violation is not 'cured' by proceeding without undue delay thereafter."<sup>20</sup> According to the Panel, "since there must not be 'undue delay' all the way to completion of the procedure, if it occurs, it necessarily affects that completion and, therefore the violation cannot be undone."<sup>21</sup>

20. The Panel in *EC – Approval and Marketing of Biotech Products* found that the phrase "without undue delay" as used in Annex C(1)(a) means "without an unjustified loss of time":

"It is clear from the text of Annex C(1)(a), first clause, that not every delay in the undertaking or completion of approval procedures which is caused by a Member is contrary to the provisions of Annex C(1)(a), first clause. Only 'undue' delay is. Regarding the meaning of the phrase 'undue delay', we consider that of the dictionary

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<sup>18</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1501.

<sup>19</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1502.

<sup>20</sup> Panel Report, *Indonesia – Chicken (Article 21.5 – Indonesia)*, para. 7.51.

<sup>21</sup> Panel Report, *Indonesia – Chicken (Article 21.5 – Indonesia)*, para. 7.51.

meanings of the term 'delay' which have been identified by the United States, there is one which fits naturally with the provisions of Annex C(1)(a), first clause, namely, '(a period of) time lost by inaction or inability to proceed'. So far as concerns the term 'undue', of the dictionary meanings referred to by the United States we find two to be particularly relevant in the specific context of Annex C(1)(a), first clause – '[g]oing beyond what is warranted [...]' and 'unjustifiable'. We note that the United States, Canada and the European Communities have all identified 'unjustifiable' as a relevant meaning of 'undue'. This view is supported also by the French version of Annex C(1)(a), first clause, which refers to 'retard injustifié'. Thus, based on the ordinary meaning of the phrase 'without undue delay', we consider that Annex C(1)(a), first clause, requires that approval procedures be undertaken and completed with no unjustifiable loss of time."<sup>22</sup>

21. The Appellate Body in *Australia – Apples* referred to the dictionary meanings of the words "undue" and "delay" in establishing the meaning of the phrase "without undue delay". The Appellate Body stated:

"Annex C(1)(a) contains an obligation that relevant procedures be undertaken and completed 'without undue delay'. In this regard, the ordinary meaning of the word 'delay' relates to '(a period of) time lost by inaction or inability to proceed'. The term 'undue' means something 'that ought not to be or to be done, inappropriate, unsuitable, improper, unrightful, unjustifiable', or 'going beyond what is warranted or natural; excessive, disproportionate'. Thus, Annex C(1)(a) requires Members to ensure that relevant procedures are undertaken and completed with appropriate dispatch, that is, they do not involve periods of time that are unwarranted, or otherwise excessive, disproportionate or unjustifiable."<sup>23</sup>

22. In *US – Animals*, the Panel held that the requirements listed in Annex C(1)(b), in particular the requirement for the competent authorities to promptly examine the completeness of documentation and to inform the applicant in precise and complete manner of all deficiencies, provided context for the interpretation of Annex C(1)(a), first sentence.<sup>24</sup> The Panel concluded on that basis that:

"[T]hese requirements support an understanding that the normal course of a procedure requires competent authorities to actively engage with the applicant Member on the substance of its application. Thus, inaction or inability to proceed on the substance of the application would constitute something outside the normal course of the procedure and should be considered a delay within the meaning of Article 8 and Annex C(1)(a)."<sup>25</sup>

23. The Panel held that an analysis of a claim under Article 8 and Annex C(1)(a) requires two steps: "First, the complainant must establish that there has been a delay. Second, the complainant must establish that the delay was undue."<sup>26</sup>

24. In a similar vein, the Panel in *Indonesia – Chicken* declined to consider whether a delay is attributable to the exporting or importing Member, as this question, according to the Panel, pertained to the examination whether the delay is undue.<sup>27</sup>

#### **1.2.3.3.2 Determination of "undue delay"**

25. The Panel in *EC – Approval and Marketing of Biotech Products* found that an "undue delay" is determined not by the length of the delay, but by whether the delay was justified. The Panel concluded that such determinations must be made on a case-by-case basis:

<sup>22</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1495.

<sup>23</sup> Appellate Body Report, *Australia – Apples*, para. 437.

<sup>24</sup> Panel Report, *US – Animals*, para. 7.113.

<sup>25</sup> Panel Report, *US – Animals*, para. 7.113.

<sup>26</sup> Panel Report, *US – Animals*, para. 7.115.

<sup>27</sup> Panel Report, *Indonesia – Chicken*, para. 7.523.



"[I]n our view, Annex C(1)(a), first clause, requires that there not be any unjustifiable loss of time. Thus, what matters is whether there is a legitimate reason, or justification, for a given delay, not the length of a delay as such. Accordingly, if a Member causes a relatively short, but unjustifiable delay, we do not consider that the mere fact that the delay is relatively short would, or should, preclude a Panel from finding that it is 'undue'. Similarly, we do not consider that a demonstration that a particular approval procedure has been delayed by, say, two years would always and necessarily be sufficient to establish that the relevant procedure has been 'unduly' delayed. Having said this, we note that a lengthy delay for which no adequate explanation is provided might in some circumstances permit the inference that the delay is 'undue'

...

In our view, a determination of whether a particular approval procedure has been undertaken and/or completed 'without undue delay' must be made on a case-by-case basis, taking account of relevant facts and circumstances. We therefore consider that it would be neither possible nor useful to attempt to define the reasons which would render a given delay 'undue', and those which would not render it 'undue'.<sup>28</sup>

26. In *EC – Approval and Marketing of Biotech Products*, the Panel rejected the view that a delay could be considered undue if caused by a measure which is not supported by scientific evidence. The Panel listed several examples of delays originating from governmental interventions, not supported by scientific evidence but nevertheless not "undue" within the meaning of Annex C:

"We would agree that delays caused by measures which are not based on scientific evidence may in some cases be considered 'undue'.<sup>29</sup> However, we do not agree that such delays must in all cases be considered 'undue'. A delay in undertaking and completing an approval procedure may be caused by a temporary government shutdown in the wake of a natural disaster or civil unrest. Likewise, if a Member is confronting an unforeseeable and sharp increase in the number of products submitted for approval, this could cause a short delay in the processing of some or all pending applications, due to the need for that Member to reallocate existing resources, or to obtain additional resources, to deal with the new situation. In both examples provided, the delay would be caused by government action, or inaction, which is not supported by scientific evidence. Yet, in our view, there is a convincing argument to be made that the delay would be needed for the Member to be able to check and ensure the fulfilment of relevant SPS requirements. Therefore, we consider that, in both cases, the delay in undertaking and completing approval procedures could properly be viewed as not 'undue' and hence not inconsistent with Annex C(1)(a), first clause."<sup>30</sup>

27. In *Australia – Apples*, the Appellate Body concluded that "[w]hether a relevant procedure has been unduly delayed is therefore not an assessment that can be done in the abstract, but one which requires a case-by-case analysis as to the reasons for the alleged failure to act with appropriate dispatch, and whether such reasons are justifiable."<sup>31</sup>

28. In *Russia – Pigs (EU)*, the Panel referred to the Appellate Body's finding that a variety of measures can infringe the obligation in Annex C(1)(a), first clause and held that, by making "unnecessary requests for information, which go far beyond what would be required to make a substantive assessment of the situation subject to the procedure at issue, a Member would be acting in a manner that impedes undertaking and completing the respective procedures" and, as a

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<sup>28</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.1496-7.1497. See also Appellate Body Report, *Australia – Apples*, para. 441.

<sup>29</sup> (footnote original) This could be the case, for example, if a delay is caused by a request for additional information which has nothing to do with the issue of whether the relevant product meets the SPS requirements concerned.

<sup>30</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1500. See also para. 37 below.

<sup>31</sup> Appellate Body Report, *Australia – Apples*, para. 437.

result, would also violate the obligation to undertake and complete a procedure without undue delay.<sup>32</sup>

29. The Panel in *Indonesia – Chicken* held that a Member is not justified in delaying the completion of an SPS approval procedure, "because non-SPS-related information, which the Member requires the applicant to submit, is outstanding from an application."<sup>33</sup>

30. In the context of compliance proceedings specifically, the Panel in *Indonesia – Chicken (Article 21.5 – Brazil)* rejected Indonesia's argument that the delay was not undue because Brazil's application for an approval – the same that had been the subject of the original panel's ruling – had to wait for its turn. The Panel opined that:

"[A] responding Member already found to have acted inconsistently with Annex C(1)(a) cannot pursue a 'business-as-usual' approach, but must prioritize to ensure that the approval procedure advances without further delays. Additional delays, even if they might otherwise have been 'normal' are unjustifiable in this context and are, therefore, undue."<sup>34</sup>

### **1.2.3.3.3 Applying precaution while avoiding "undue delay"**

#### **1.2.3.3.3.1 Requirements of prudence and precaution**

31. In *EC – Approval and Marketing of Biotech Products*, the Panel agreed with the European Communities' argument that precaution and prudence need to be observed in the adoption and implementation of GMO-related legislation. However, the Panel set out the standard of review that it would apply in order to assess whether the measures duly entail delays or if the Members overly and purposely extended the allowable timeframe when drafting their SPS requirements:

"As an initial matter, we note that, in our view, Annex C(1)(a), first clause, does not preclude the application of a prudent and precautionary approach to identifying, assessing and managing risks to human health and the environment arising from GMOs and GMO-derived products. As we have said, we consider that Annex C(1)(a), first clause, allows a Member to take the time that is reasonably needed to determine with adequate confidence whether its relevant SPS requirements are fulfilled. Consistent with this, we consider that a Member which finds it appropriate to follow a prudent and precautionary approach in assessing and approving applications concerning GMOs and GMO-derived products, might, for instance, be justified in requesting further information or clarification of an applicant in a situation where another Member considers that the information available is sufficient to carry out its assessment and reach a decision on an application. Whether a particular request is a reflection of genuine caution and prudence or whether it is a pretext to delay the completion of an approval procedure would need to be determined in the light of all relevant facts and circumstances."<sup>35</sup>

32. The Panel in *EC – Approval and Marketing of Biotech Products* found that although Members are permitted to take actions with precaution and prudence, they must do so within reasonable time limits, otherwise Annex C(1)(a) would lose meaning:

"[W]e perceive no inherent tension between the obligation set out in Annex C(1)(a), first clause, to complete approval procedures without undue delay and the application of a prudent and precautionary approach to assessing and approving GMOs or GMO-derived products. Nevertheless, it is clear that application of a prudent and precautionary approach is, and must be, subject to reasonable limits, lest the precautionary approach swallow the discipline imposed by Annex C(1)(a), first clause. Indeed, if a Member could endlessly defer substantive decisions on the grounds of a perceived need for caution and prudence in the assessment of applications, Annex C(1)(a), first clause, would be devoid of any meaning or effect. In applying the

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<sup>32</sup> Panel Report, *Russia – Pigs (EU)*, para. 7.583.

<sup>33</sup> Panel Report, *Indonesia – Chicken*, para. 7.531.

<sup>34</sup> Panel Report, *Indonesia – Chicken (Article 21.5 – Brazil)*, para. 7.87.

<sup>35</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1522.

provisions of Annex C(1)(a), first clause, it is therefore important always to bear in mind that Annex C(1)(a), first clause, implies as a core obligation the obligation to come to a decision on an application."<sup>36</sup>

#### **1.2.3.3.3.2 Delays supported by evolving science and precautionary approach**

33. Having addressed the status of the precautionary principle in international law, the Panel in *EC – Approval and Marketing of Biotech Products* discussed the impact of the principle on the delay noted in the implementation of SPS measures. In this context the Panel examined whether evolving science and the consequent application by the European Communities of a prudent and precautionary approach would provide a justification for delays which may have occurred due to the European Communities' general suspension of final approvals between June 1999 and August 2003. Drawing from its observation that no tension exists between the precautionary approach and the requirement of avoiding undue delays, the Panel placed emphasis on the provisions of Article 5.7 and ruled out the European Communities' reliance on the precautionary principle to postpone the adoption of SPS requirements:

"The European Communities argues that in the case of applications concerning GMOs and GMO-derived products it is difficult to come to a decision, in view of evolving science and a body of available scientific information and data that is still limited. Even if we were to accept this as an accurate description of the situation as it prevailed between June 1999 and August 2003, we consider that in the light of the provisions of Annex C(1)(a), first clause, this situation in and of itself would not warrant delays in the completion of approval procedures.

We note in this regard that if relevant scientific evidence were insufficient to perform a risk assessment as defined in Annex A(1) of the *SPS Agreement* and as required by Article 5.1 of the *SPS Agreement*, pursuant to Article 5.7 of the *SPS Agreement*, a Member may provisionally adopt an SPS measure on the basis of available pertinent information. Contrariwise, in situations where relevant scientific evidence is sufficient to perform a risk assessment, a Member must base its SPS measure on a risk assessment. Of course, the mere fact that relevant scientific evidence is sufficient to perform a risk assessment does not mean that the result and conclusion of the risk assessment are free from uncertainties (e.g., uncertainties linked to certain assumptions made in the course of the performance of a risk assessment). Indeed, we consider that such uncertainties may be legitimately taken into account by a Member when determining the SPS measure, if any, to be taken. In view of these uncertainties, a given risk assessment may well support a range of possible measures. Within this range, a Member is at liberty to choose the one which provides the best protection of human health and/or the environment, taking account of its appropriate level of protection, provided that the measure chosen is reasonably supported by the risk assessment and not inconsistent with other applicable provisions of the *SPS Agreement*, such as Article 5.6."<sup>37</sup>

#### **1.2.3.3.4 Distinction between undue delay and a refusal to take SPS action**

34. Although the Panel in *EC – Approval and Marketing of Biotech Product* declined to settle on a definitive meaning of what constitutes "undue delay", it did determine that Members cannot justify refusing to take substantive SPS decisions because of evolving science, scientific complexity, uncertainty, and/or limited available scientific information or data:

"[E]volving science, scientific complexity and uncertainty, and limited available scientific information or data are not, in and of themselves, grounds for delaying substantive approval decisions, and that the SPS Agreement does not envisage that Members in such cases defer making substantive SPS decisions. Indeed, even in cases where relevant scientific evidence does not permit the performance of a risk assessment, the SPS Agreement envisages that Members take substantive SPS decisions. Certainly, such factors as evolving science and limited availability of scientific evidence affect the confidence which Members can have in the results of

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<sup>36</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1523.

<sup>37</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.1524-7.1525.

their assessments. But they do not inherently affect a Member's ability to reach substantive decisions on an application, particularly since a Member may take account of such factors in reaching substantive decisions."<sup>38</sup>

35. In *EC – Approval and Marketing of Biotech Products*, the Panel acknowledged that, in cases where scientific discoveries are likely to occur in a given field, delays could allow decisions which take into account latest evidence or fill the existing gaps in the scientific justification of the measure. However, the Panel took the view that the SPS Agreement, in Articles 5.1 and 5.7, offers the possibility to grant time-limited approvals or refuse approvals at any stage of scientific knowledge, without occasioning undue delays:

"It is quite possible that in the situation described by the European Communities where science evolves and there is limited available scientific evidence, a deferral of substantive decisions might allow for better decisions at a later point in time, provided that appropriate analyses and research are undertaken. However, we do not consider that Annex C(1)(a), first clause, can or should be interpreted to allow Members to go into a sort of holding pattern while they or other entities undertake research with a view to obtaining additional scientific information and data. As we have stated earlier, the core obligation implied by Annex C(1)(a), first clause, is for Members to come to a substantive decision. This view is entirely consistent, and fits well with the aforementioned provisions of Article 5.1 and Article 5.7. It is important to note in this regard that the *SPS Agreement* nowhere states that substantive decisions on applications need to give a straight yes or no answer to applicants. Members may in principle grant time-limited approvals or approvals subject to other appropriate conditions. Alternatively, they may in principle decide to reject an application subject to the possibility of a review of that decision if and when relevant circumstances change. Relevant circumstances could include the state of scientific knowledge. Thus, there is no reason to consider that our interpretation of Annex C(1)(a), first clause, would prejudice Members' ability to take differentiated, proportionate action to protect human health and/or the environment from potential risks arising from GMOs or GMO-derived products."<sup>39</sup>

#### **1.2.3.3.5 Delay due to failures in the national legislation**

36. The Panel found that the delays challenged in *EC – Approval and Marketing of Biotech Products* were not justified by the need to check and ensure the fulfilment of the relevant SPS requirements. The Panel added that, as a practical matter, the need for regular adjustment and amendment of relevant legislation is to be expected. The Panel considered that if a Member could suspend and delay the granting of final approvals every time it updated its approval legislation, there would be long periods of time during which final approval decisions would be suspended:

"[T]he lack of EC-level legislation ensuring labelling and traceability did not affect the European Communities' ability to *check* the fulfilment of its existing SPS requirements. Finally, even if the European Communities considered that new and additional requirements relating to labelling and traceability needed to be imposed as conditions attached to approval decisions, to *ensure* the fulfilment of existing SPS requirements (e.g., the requirement to avoid long-term adverse effects on the environment), there is no reason for believing that the need for, and modalities of, such conditions could only be established in September 2003.

...

Two further considerations militate in favour of our view that the lack of legislation ensuring labelling and traceability of GMOs and GMO-derived products would not have provided an *eo ipso* justification for delays which might have occurred for this reason in the completion of approval procedures. To begin with, putting in place new legislation is by nature a time-consuming process which not infrequently takes one or more years to complete. The European Communities itself stated that completing and updating its legislation 'inevitably took quite some time to be completed in the light of

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<sup>38</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1526.

<sup>39</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1527.

the serious social and political debate on the issues linked to GMOs and GM food production'. We also note the EC statement that legislation concerning GMOs and GMO-derived products needs to keep pace with the 'constant evolution of the scientific and regulatory debate' on these products, which suggests that a need for regular adjustment and amendment of relevant legislation is to be expected. The evolution of relevant EC legislation would appear to support this statement. In these circumstances, we are concerned that if a Member could suspend and, consequently, delay the granting of final approvals essentially every time it completes and updates its approval legislation, there might be frequent and long periods of time during which final approval decisions are suspended. Incidentally, given the time required to revise legislation, a need for further revision and updating might in some cases be identified even before the previous revision has made its way through the legislative process."<sup>40</sup>

#### **1.2.3.3.6 Delays resulting from a failure to secure appropriate resources**

37. In *EC – Approval and Marketing of Biotech Products*, the Panel held that "confronting an unforeseeable and sharp increase in the number of products submitted for approval ... could cause a short delay in the processing of some or all pending applications, due to the need for that Member to reallocate existing resources, or to obtain additional resources, to deal with the new situation".<sup>41</sup> The same Panel cautioned, however, that "it is Members' responsibility to allocate sufficient resources to their competent authorities so that they are in a position to discharge the obligations they have assumed under the WTO Agreement."<sup>42</sup>

38. Echoing the panel in *EC – Approval and Marketing of Biotech Products*, the compliance Panel in *Indonesia – Chicken (Article 21.5 – Brazil)*, found that "the relatively small number of desk review officials, does not exonerate Indonesia" from the responsibility for a delay in processing application.<sup>43</sup> While the Panel did not see, as a matter of principle, a problem with outsourcing parts of the examination process to outside experts, it reiterated that "a Member has to make sure that the (outside) capacity is such that the process can be undertaken and completed without undue delay".<sup>44</sup>

#### **1.2.3.3.7 Delays as a means of avoiding risk assessment**

39. The Panel in *EC – Approval and Marketing of Biotech Products* observed that a Member may deliberately use delays as a risk management instrument: the Member would postpone the adoption of a measure which is at odds with the present legal framework, awaiting occurrence of better legislative conditions. The Panel commented that this attitude would be inconsistent with Annex C(1)(a) and the SPS provisions addressing the risk assessment regime:

"The other consideration to be noted relates to the use of procedural delay as an instrument to manage or control risks. It is useful to illustrate this using an example. For instance, if the European Communities delayed the completion of a particular approval procedure because existing legislation precluded it from imposing a traceability requirement for a GMO which would facilitate the withdrawal of the product in the event of unforeseen adverse effects on human health or the environment, the European Communities would effectively use procedural delay as a substitute for a substantive risk management measure (the traceability requirement) that would not be impossible under existing approval legislation. In our view, however, the pursuit of a risk management objective would not justify a delay in the completion of an approval procedure and hence would be inconsistent with Annex C(1)(a), first clause. If procedural delay could be used, directly or indirectly, as an instrument to manage or control risks, then Members could evade the obligations to be observed in respect of substantive SPS measures, such as Article 5.1, which requires that SPS measures be based on a risk assessment. Clearly, we cannot interpret Annex C(1)(a), first clause, in a manner which would nullify or impair the usefulness and intended effect of other provisions of the *SPS Agreement*. Indeed, as we see it, a central

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<sup>40</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.1513 and 7.1516.

<sup>41</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1500.

<sup>42</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, fn 1290.

<sup>43</sup> Panel Report, *Indonesia – Chicken (Article 21.5 – Brazil)*, para. 7.84.

<sup>44</sup> Panel Report, *Indonesia – Chicken (Article 21.5 – Brazil)*, para. 7.84.

purpose of Annex C(1)(a), first clause, is precisely to prevent a situation where Members avoid the substantive disciplines which Articles 2 and 5 of the *SPS Agreement* impose with respect to substantive SPS decisions by not reaching final substantive decisions on applications for marketing approval."<sup>45</sup>

#### **1.2.4 Annex C(1)(a) second clause**

40. The Panel in *EC – Approval and Marketing of Biotech Products* found that in order to establish an inconsistency with Annex C(1)(a) second clause, a complainant must establish that the imported products have been treated in a "less favourable manner" than domestic products with respect to the undertaking and completion of approval procedures. The complainant must also establish that the imported products which are alleged to have been treated less favourably are "like" the domestic products which are alleged to have been treated more favourably:

"In order to establish an inconsistency with Annex C(1)(a), second clause, Argentina must establish (i) that imported products have been treated in a 'less favourable manner' than domestic products in respect of the undertaking and completion of approval procedures, and (ii) that the imported products which are alleged to have been treated less favourably are 'like' the domestic products which are alleged to have been treated more favourably. If either one of these two elements is not met, that is, if imported products have not been treated 'less favourably' than the domestic products to which they are being compared, or if these domestic products are not 'like' the relevant imported products, Argentina's claim of inconsistency must fail."<sup>46</sup>

41. As Annex C(1)(a) second clause sets out a "national treatment obligation", the Panel in *EC – Approval and Marketing of Biotech Products* referred to the past panel and Appellate Body rulings on Article III:1 and III:4 of the GATT. The Panel concluded that differential treatment of like products does not by itself demonstrate less favourable treatment. Additionally, an unfavourable result for an application for placing an imported product on the market would not be sufficient to establish less favourable treatment:

"Reading Annex C(1)(a), second clause, in the light of the jurisprudence on Article III:4, we consider that in undertaking and completing its approval procedures, a Member may, in principle, differentiate between products that have been found to be like because this would not, by itself, mean that the relevant approval procedures have been undertaken or completed in less favourable manner for the group of like imported products than for the group of like domestic products. In particular, a mere showing that a Member has undertaken or completed a particular approval procedure in a manner which is unfavourable for a given imported product would not be sufficient to establish a 'less favourable manner' of undertaking or completing approval procedures if the relevant Member's conduct is explained by factors or circumstances unrelated to the foreign origin of the product."<sup>47</sup>

42. In *Korea – Radionuclides*, the Panel rejected the proposition that Article 2.3 of the SPS Agreement informs the likeness test under Annex C(1)(a), second clause. Noting textual similarities between Annex C(1)(a), second clause and Article III:4 of the GATT 1994, the Panel found that while "Article 2.3 provides context for interpretation of Annex C(1)(a)"<sup>48</sup>, similar conditions is a broad concept that can encompass specific products, specific risks, or specific territorial differences (such as the presence of a pest or disease).<sup>49</sup> The Panel concluded that "the same likeness criteria under Article III:4 of the GATT 1994 are appropriate for an analysis under Annex C(1)(a)."<sup>50</sup>

43. The Panel then moved on to assess whether likeness of products could be presumed, because Korea's measures applied only to Japanese products. The Panel found that Korea had provided arguments and evidence showing that, even though Japan was the only country targeted

<sup>45</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1517.

<sup>46</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2400.

<sup>47</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2408.

<sup>48</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2407.

<sup>49</sup> Panel Report, *Korea – Radionuclides*, para. 7.392.

<sup>50</sup> Panel Report, *Korea – Radionuclides*, para. 7.393.

by the measures, there were grounds other than origin that formed a basis for the distinction. In that regard, the Panel reviewed Korea's regulatory framework and found that it had "a varied regime that is not based only on origin, but takes into consideration the potential of contamination of food by radionuclides."<sup>51</sup> As a result, the Panel found that Japan had failed to demonstrate that origin was the sole basis for a distinction of Japanese products and that imported Japanese products and domestic products could be presumed to be like.<sup>52</sup>

44. The Appellate Body in *Korea – Radionuclides* disagreed with the Panel's consideration that likeness may be presumed for the purposes of Annex C(1)(a) where the only distinguishing factor between products is based on their origin. The Appellate Body was not convinced that the Panel could do so for the purposes of the SPS Agreement but found it unnecessary to reach a conclusion regarding the Panel's view, as a consideration of origin was not necessary for the analysis undertaken.<sup>53</sup>

### **1.2.5 Annex C(1)(b)**

#### **1.2.5.1 General**

45. In *EC – Approval and Marketing of Biotech Products*, the Panel ruled that the provisions of Annex C(1)(b) apply "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures".<sup>54</sup>

46. The Panel in *EC – Approval and Marketing of Biotech Products* remarked that Annex C(1)(b) sets out five separate, but related, obligations to be observed by Members in the operation of their approval procedures:

"(i) the publication or communication to applicants of the processing period of each procedure;

(ii) the examination of the completeness of the documentation and the communication to applicants of deficiencies;

(iii) the transmission of the results of the procedure;

(iv) the processing of applications which have deficiencies; and

(v) the provision of information about the stage of a procedure and the provision of an explanation of any delay."<sup>55</sup>

#### **1.2.5.2 First obligation in Annex C(1)(b): publication or communication of processing period**

47. In *EC – Approval and Marketing of Biotech Products*, the United States argued that as a result of its general moratorium on approvals, the European Communities did not follow the standard processing periods which are published in its applicable approval legislation. The Panel ruled that the lack of publication was not a result of the measure at issue. The Panel also considered that the anticipated processing period is to be provided to applicants upon request and in this dispute, no evidence of applicants' requests was provided:

"Even if we were to accept that what has to be published in accordance with the first obligation in Annex C(1)(b) is the 'effective' standard processing period, and that the general moratorium on approvals effectively modified the European Communities' published standard processing periods, the fact that they were unpublished would not be a consequence of the measure at issue, *i.e.*, the general moratorium. Rather, it would be a consequence of a separate and independent failure by the European

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<sup>51</sup> Panel Report, *Korea – Radionuclides*, para. 7.400.

<sup>52</sup> Panel Report, *Korea – Radionuclides*, para. 7.400.

<sup>53</sup> Appellate Body Report, *Korea – Radionuclides*, paras. 5.233–5.234.

<sup>54</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1582.

<sup>55</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1574.

Communities to publish the new standard processing periods. This is confirmed by the fact that the European Communities could apply the general moratorium on approvals and at the same time publish any new standard processing periods.

...

The United States' second argument in support of its claim under Annex C(1)(b) is that since the European Communities does not acknowledge the moratorium, the anticipated processing period is not communicated to the applicant. We note that pursuant to Annex C(1)(b) the anticipated processing period is to be communicated to the applicant "upon request". The United States has provided no evidence to show (i) that an applicant requested that the anticipated processing period be communicated to it, (ii) that the request was denied by a relevant EC entity, and (iii) that this was because of the general moratorium on approvals. Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not communicating the anticipated processing periods to applicants upon request. The European Communities could apply the general moratorium on approvals and at the same time communicate to applicants the anticipated processing periods upon request."<sup>56</sup>

#### **1.2.5.3 Second obligation in Annex C(1)(b): completeness of documentation**

48. In *EC – Approval and Marketing of Biotech Products*, the United States argued that, because of the general moratorium on approvals, the European Communities did not promptly examine the completeness of documentation and inform applicants of any deficiencies. The Panel rejected this argument observing that the US challenge was not supported by evidence. The Panel concluded that the alleged lack of completed documentation was not the result of the measure at issue:

"We note that the United States has identified no concrete evidence to support this assertion. Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not examining promptly the completeness of documentation and not informing applicants of any deficiencies. The European Communities could apply the general moratorium on approvals and at the same time examine the completeness of documentation and inform applicants of deficiencies in the documentation submitted."<sup>57</sup>

#### **1.2.5.4 Third obligation in Annex C(1)(b): transmission of results**

49. In *EC – Approval and Marketing of Biotech Products*, the United States raised the contention that under the measure at issue, the results of procedures were not promptly communicated to applicants so that corrective action could be taken. The Panel considered that the United States had failed to establish its claim under the third obligation contained in Annex C(1)(b) as it did not identify the results that were to be transmitted:

"We note that the United States has not identified any results of procedures which were not transmitted to an applicant as soon as possible and in a precise and complete manner. Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not transmitting as soon as possible, and in a precise and complete manner, the results of approval procedures. Furthermore, it should be recalled that under the general moratorium, the European Communities prevented final results from being achieved. Thus, there were no final results which could have been communicated to applicants."<sup>58</sup>

#### **1.2.5.5 Fourth obligation in Annex C(1)(b): processing of deficient applications**

50. In *EC – Approval and Marketing of Biotech Products*, the United States complained that under the general moratorium, the respondent in that dispute did not proceed as far as practicable in the approval process. The Panel disagreed with this view and commented that the complainant

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<sup>56</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.1587-7.1589.

<sup>57</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1592.

<sup>58</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1595.



did not provide evidence of the applicant making such request and had the applicant made such request, the European Communities failure to proceed with procedures would not be a result of the measure at issue:

"We note that pursuant to Annex C(1)(b) the competent body is to proceed as far as practicable with the procedure 'if the applicant so requests'. The United States has provided no evidence of an applicant making such a request and of a relevant EC entity denying that request because of the general moratorium. Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not proceeding as far as practicable with procedures if applicants so requested. The European Communities could apply the general moratorium on approvals and at the same time proceed as far as practicable with procedures upon request."<sup>59</sup>

#### **1.2.5.6 Fifth obligation in Annex C(1)(b): explanation of delay**

51. The Panel in *EC – Approval and Marketing of Biotech Products*, dismissed the United States' argument that the respondent did not comply with the fifth obligation under Annex C(1)(b). The Panel found that the United States did not submit any evidence that it had made a request for an explanation of the delay:

"The fifth obligation states that 'upon request' the applicant is to be informed of the stage of the procedure, with any delay being explained. The United States has provided no evidence of an applicant making such a request and of a relevant EC entity denying an explanation of any delay because of the general moratorium. Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not informing applicants of the stage of procedures and not explaining any delays, if applicants so requested. The European Communities could apply the general moratorium on approvals and at the same time inform applicants of the stage of procedures and explain any delays."<sup>60</sup>

#### **1.2.6 Annex C(1)(c)**

52. In *Australia – Salmon (Article 21.5 – Canada)*, Canada claimed that Australia acted inconsistently with its obligations under Annex C(1)(c). The Panel noted that only "procedures to check and ensure the fulfilment of sanitary or phytosanitary measures" fall under the scope of paragraph 1(c) of Annex C. The Panel also considered that the Australian requirements referred to by Canada were "substantive sanitary measures in their own right" and not "procedures to check and ensure the fulfilment of sanitary or phytosanitary measures". The Panel thus concluded that no violation of Annex C(1)(c) was established.<sup>61</sup>

53. In *Russia – Pigs (EU)*, the Panel found certain types of information requested by the importing Member to be "excessive" and thus not necessary for appropriate control, inspection and approval procedures.<sup>62</sup>

54. In *Korea – Radionuclides*, the Panel rejected a claim under Annex C(1)(c), because the complainant's arguments were aimed at demonstrating that the information requirements were "more trade-restrictive than required to achieve the ALOP, instead of addressing the necessity of information requirements for the operation of the procedure".<sup>63</sup>

#### **1.2.7 Annex C(1)(e)**

55. In *EC – Approval and Marketing of Biotech Products*, Argentina argued that the detailed requirements of the EC legislation and regulation did not meet the criteria that they be limited to what is reasonable and necessary. The Panel did not address these two particular requirements

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<sup>59</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1598.

<sup>60</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1601.

<sup>61</sup> Panel Report, *Australia – Salmon (Article 21.5 – Canada)*, paras. 7.154-7.157.

<sup>62</sup> Panel Report, *Russia – Pigs (EU)*, para. 7.563.

<sup>63</sup> Panel Report, *Korea – Radionuclides*, para. 7.414.

merely observing that Annex C(1)(e) focuses on the approval requirements of "individual specimens" whereas the challenged measures did not concern "individual specimens":

"We note that Annex C(1)(e) imposes limitations on any requirements for approval of 'individual specimens of a product'. The product-specific measures challenged by Argentina do not concern 'individual specimens' of biotech products. They concern specific biotech products for which marketing approval has been sought."<sup>64</sup>

56. The Panel in *Korea – Radionuclides* further clarified that "Annex C(1)(e) aims at preventing Members from using control, inspection and approval procedures with regard to specimens of imported products in a manner that would not be 'reasonable' or 'necessary'".<sup>65</sup>

### 1.2.8 Annex C(1)(g)

57. In *Korea – Radionuclides*, the Panel grappled with the question whether Annex C(1)(g) imposes on Members a positive obligation or is merely of a hortatory nature. In interpreting the provision, the Panel recalled the Appellate Body's statement in *Canada – Aircraft* that the word "should" can express either an exhortation or an obligation.<sup>66</sup> Having regard to the context of the provision, and noting that in prior cases the Appellate Body had listed subparagraph (g) among "obligations contained in Annex C(1)", the Panel concluded that Annex C(1)(g) imposes a positive obligation on the Members.<sup>67</sup>

58. As regards the second clause of Annex C(1)(g), the Panel in *Korea – Radionuclides* held that it is meant "to address the rules Members use for selecting material that is representative of a consignment of products that will subsequently be tested as part of control, inspection and approval procedures."<sup>68</sup>

### 1.2.9 Relationship with other provisions of the SPS Agreement

#### 1.2.9.1 Article 4

59. The Panel in *US – Poultry (China)* found that while the recognition of equivalence is governed by Article 4 of the SPS Agreement, the equivalence determination process of the importing Member must still comply with the obligations on "approval procedures" under Annex C(1), particularly where a Member uses equivalence recognition as the only route for access into its market. The Panel stated:

"The Panel acknowledges that nothing in the *SPS Agreement* seems to prevent a Member from using an equivalent process to determine whoever is eligible to export certain products to its market. ... Nevertheless, we are of the view that, where the recognition of equivalence (as the one granted through the FSIS equivalence determination process) is the only way that a Member may export its products to an importing Member, then the equivalence determination process of the importing Member must comply with the pertinent obligations on 'approval procedures' under Annex C(1) of the *SPS Agreement*.

...

[T]he Panel understands that to deny that an equivalence determination process, which also has the ultimate effect of approving the importation of a product from a given WTO Member as envisaged in any other 'approval procedure', is subject to Annex C(1) of the *SPS Agreement* would unfairly reward the ingenuity of some WTO Members and possibly create a dangerous safe haven for disguised protectionism.

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<sup>64</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.2494.

<sup>65</sup> Panel Report, *Korea – Radionuclides*, para. 7.419.

<sup>66</sup> Panel Report, *Korea – Radionuclides*, para. 7.428. (citing Appellate Body Report in *Canada – Aircraft*, para. 187)

<sup>67</sup> Panel Report, *Korea – Radionuclides*, paras. 7.429-7.433.

<sup>68</sup> Panel Report, *Korea – Radionuclides*, para. 7.439.

Such an understanding would result in an undesired precedent that may entice some WTO Members to circumvent the application of the *SPS Agreement*.<sup>69</sup>

### 1.2.9.2 Article 8

60. In *EC – Approval and Marketing of Biotech Products*, the Panel ruled that the provisions of Article 8 and those of Annex C need to be read together and consequently, whenever the first paragraph of Annex C (1) is violated, Article 8 is likewise affected:

"We recall that the United States and Canada seek to establish an inconsistency with Article 8 of the *SPS Agreement* on the basis of an inconsistency with Annex C(1)(a). Article 8 requires, *inter alia*, that Members observe the provisions of Annex C in the operation of their approval procedures. It follows that a failure to observe the provisions of Annex C(1)(a) implies a breach of Article 8. We have determined above that, as a result of the general *de facto* moratorium on approvals, the European Communities has failed, in at least one approval procedure conducted under Directives 90/220 and 2001/18, to observe the provisions of Annex C(1)(a), first clause. Accordingly, we conclude that in respect of the aforementioned approval procedure, the European Communities has, by implication, also acted inconsistently with the provisions of Article 8."<sup>70</sup>

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<sup>69</sup> Panel Report, *US – Poultry (China)*, paras. 7.371 and 7.374.

<sup>70</sup> Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1569. See also Panel Report, *US – Poultry (China)*, paras. 7.393-7.395; and Appellate Body Report, *Australia – Apples*, para. 434.