1 ANNEX B

1.1 Text of Annex B

ANNEX B

TRANSPARENCY OF SANITARY AND PHYTOSANITARY REGULATIONS

Publication of regulations

1. Members shall ensure that all sanitary and phytosanitary regulations which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.

(*footnote original*)[5] Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

2. Except in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

Enquiry points

3. Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:

(a) any sanitary or phytosanitary regulations adopted or proposed within its territory;

(b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;

(c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;

(d) the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this Agreement, and the texts of such agreements and arrangements.

4. Members shall ensure that where copies of documents are requested by interested Members, they are supplied at the same price (if any), apart from the cost of delivery, as to the nationals[6] of the Member concerned.

(*footnote original*)[6] When "nationals" are referred to in this Agreement, the term shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

Notification procedures

5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:

(a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;

(b) notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;

(c) provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;

(d) without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.

6. However, where urgent problems of health protection arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 5 of this Annex as it finds necessary, provided that the Member:

(a) immediately notifies other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);

(b) provides, upon request, copies of the regulation to other Members;

(c) allows other Members to make comments in writing, discusses these comments upon request, and takes the comments and the results of the discussions into account.

7. Notifications to the Secretariat shall be in English, French or Spanish.

> 8. Developed country Members shall, if requested by other Members, provide copies of the documents or, in case of voluminous documents, summaries of the documents covered by a specific notification in English, French or Spanish.
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> 9. The Secretariat shall promptly circulate copies of the notification to all Members and interested international organizations and draw the attention of developing country Members to any notifications relating to products of particular interest to them.
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> 10. Members shall designate a single central government authority as responsible for the implementation, on the national level, of the provisions concerning notification procedures according to paragraphs 5, 6, 7 and 8 of this Annex.
>
> *General reservations*
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> 11. Nothing in this Agreement shall be construed as requiring:
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> (a) the provision of particulars or copies of drafts or the publication of texts other than in the language of the Member except as stated in paragraph 8 of this Annex; or
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> (b) Members to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.

1.2 General

1. In *India – Agricultural Products*, the Panel explored the relationship between Annex B(2), Annex B(5) and Annex B(6) to determine the order of analysis of claims made under these provisions. The Panel found it useful to first examine whether "urgent problems of health protection" within the meaning of Annex B(6) existed and exempted India from the conditions set forth in Annex B(5).[1]

1.3 Annex B(1): publication requirements

1.3.1 Footnote to Annex B(1)

2. In *Japan – Agricultural Products II*, with reference to the footnote to Annex B(1), the Appellate Body held that the list of instruments contained therein was not exhaustive in nature and referred to the object and purpose of Annex B(1):

> "We consider that the list of instruments contained in the footnote to paragraph 1 of Annex B is, as is indicated by the words 'such as', not exhaustive in nature. The scope of application of the publication requirement is not limited to 'laws, decrees or ordinances', but also includes, in our opinion, other instruments which are applicable generally and are similar in character to the instruments explicitly referred to in the illustrative list of the footnote to paragraph 1 of Annex B.
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> The object and purpose of paragraph 1 of Annex B is 'to enable interested Members to become acquainted with' the sanitary and phytosanitary regulations adopted or maintained by other Members and thus to enhance transparency regarding these measures. In our opinion, the scope of application of the publication requirement of paragraph 1 of Annex B should be interpreted in the light of the object and purpose of this provision.
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> We note that it is undisputed that the varietal testing requirement is applicable generally. Furthermore, we consider in the light of the actual impact of the varietal testing requirement on exporting countries, as discussed by the Panel in paragraphs 8.112 and 8.113 of the Panel Report, that this instrument is of a character

[1] Panel Report, *India – Agricultural Products*, paras. 7.744-7.748.

> similar to laws, decrees and ordinances, the instruments explicitly referred to in the footnote to paragraph 1 of Annex B."[2]

1.3.2 Scope of application of publishing requirements

3. In *Japan – Agricultural Products II*, the Panel set the conditions of application of the publishing requirements under Annex B:

> "[I]n our view, for a measure to be subject to the publication requirement in Annex B, three conditions apply: (1) the measure '[has] been adopted'; (2) the measure is a 'phytosanitary regulation', namely a phytosanitary measure such as a law, decree or ordinance, which is (3) 'applicable generally'."[3]

4. The Panel, in *Japan – Agricultural Products*, in the context of verifying whether the requirement at issue could be considered as an SPS measure albeit its non-mandatory nature, considered that such a requirement could still be an SPS measure in light of the conditions under Annex A of the *SPS Agreement*:

> "Even though the varietal testing requirement is not mandatory – in that exporting countries can demonstrate quarantine efficiency by other means – in our view, it does constitute a 'phytosanitary regulation' subject to the publication requirement in Annex B. The footnote to paragraph 1 of Annex B refers in general terms to 'phytosanitary measures such as laws, decrees or ordinances'. Nowhere does the wording of this paragraph require such measures to be mandatory or legally enforceable. Moreover, Paragraph 1 of Annex A to the *SPS Agreement* makes clear that 'phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures'. It does not, in turn, require that such measures be mandatory or legally enforceable. The interpretation that measures need not be mandatory to be subject to WTO disciplines is confirmed by the context of the relevant SPS provisions, a context which includes provisions of other WTO agreements and the way these provisions define 'measure', 'requirement' or 'restriction', as interpreted in GATT and WTO jurisprudence. This context indicates that a non-mandatory government measure is also subject to WTO provisions in the event compliance with this measure is necessary to obtain an advantage from the government or, in other words, if sufficient incentives or disincentives exist for that measure to be abided by."[4]

5. In *EC – Approval and Marketing of Biotech Products*, the Panel examined whether the publishing requirements in Annex B(1) applied not only to SPS measures, but to a generally applicable measure concerning the administration or operation of an SPS measure. The Panel concluded that Annex B(1) applies only to SPS regulations, which are a sub-category of SPS measures. Therefore, the Panel determined that the publishing requirements did not apply to actions that were not SPS measures. On this basis and given its ruling that the EC general moratorium on approving applications was not an SPS measure, the Panel found that the provisions of Annex B(1) did not apply to the moratorium:

> "Annex B(1) applies to 'sanitary and phytosanitary regulations' (hereafter 'SPS regulations') which have been 'adopted'. An explanatory footnote to Annex B(1) indicates that the term 'SPS regulations' should be understood as meaning '[s]anitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally'. That SPS regulations are 'SPS measures' is confirmed by Article 7 which states that Members must notify changes in their 'SPS measures' and provide information on their 'SPS measures' 'in accordance with the provisions of Annex B'. It can be inferred from this that the 'SPS regulations' at issue in Annex B(1) are a sub-category of 'SPS measures'. Regarding the meaning of the term 'SPS measures', we recall Article 1 of the SPS Agreement.
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> …

[2] Appellate Body Report, *Japan – Agricultural Products II*, paras. 105-107.
[3] Panel Report, *Japan – Agricultural Products II*, para. 8.109.
[4] Panel Report, *Japan – Agricultural Products II*, para. 8.111.

> Annex B(1) read in conjunction with the accompanying footnote provides that a generally applicable 'SPS measure' which has been adopted must be published promptly. We recall that according to Annex A(1) the term 'SPS measures' includes 'requirements and procedures'. It can be deduced from this that a generally applicable measure imposing a substantive SPS requirement or establishing an SPS procedure is to be published, since such a measure would itself be an 'SPS measure'. In contrast, neither Annex B(1) nor its accompanying footnote suggests that a generally applicable measure concerning the administration, or operation, of an SPS measure – such as a measure providing for a particular operation of an SPS approval procedure – is, also, to be published."[5]

6. The Appellate Body in *Korea – Radionuclides* disagreed with the Panel's findings that a publication of an SPS regulation under Annex B(1) must always include specific principles and methods of SPS regulations, as nothing in Annex B(5) or Annex B(6) contains reference to the "specific principles" or "methods" of SPS regulations. Hence, the Appellate Body failed to see how "the Panel found contextual support in Annex B(5) or Annex B(6)" for this proposition.[6] The Appellate Body stated in this regard:

> "[W]e consider that the publication of an adopted SPS regulation must contain sufficient information, including the product scope and the requirements of the SPS regulation, so as to enable Members to become acquainted with it. In this respect, we agree with the Panel to the extent the Panel's reference to 'conditions' means the requirements of the adopted SPS regulation. We modify, however, the Panel's finding, in paragraph 7.464 of the Panel Report, to the extent it considered that Annex B(1) requires, in all cases, that the publication of an SPS regulation include the 'specific principles and methods' applicable to the products. We instead find that whether a publication of an adopted SPS regulation under Annex B(1) needs to include the 'specific principles and methods' applicable to the products may only be determined with reference to the specific circumstances of each case, such as the nature of the SPS regulation at issue, the products covered, and the nature of the SPS risks involved."[7]

1.3.3 Publication versus information

7. In *Japan – Agricultural Products II*, the Panel established that publication requirements are not exhausted by the mere information of the relevant entities and that, once adopted, an SPS measure, provided that it meets all three conditions for a measure to be subject to the publication requirement in paragraph 1 of Annex B, needs to be "published promptly in such a manner as to enable interested Members to become acquainted with them":

> "Japan acknowledges that it has not published the varietal testing requirement. The fact that Japan distributed the guidelines to foreign plant quarantine authorities does not mitigate the lack of publication. In our view, distribution to a limited number of addressees and MAFF's general availability to answer any queries, does not equal prompt publication which enables interested Members to become acquainted with the varietal testing requirement. The publication by MAFF of the protocols relating to approved products does not ensure publication of the varietal testing requirement itself. It only informs Members of products which have met this requirement. Moreover, we do not consider that the highly technical nature of the varietal testing requirement can excuse Japan from publishing it."[8]

[5] Panel Report, *EC – Approval and Marketing of Biotech Products*, paras. 7.1455 and 7.1458.
[6] Appellate Body Report, *Korea – Radionuclides*, para. 5.153.
[7] Appellate Body Report, *Korea – Radionuclides*, para. 5.154.
[8] Panel Report, *Japan – Agricultural Products II*, para. 8.115.

1.4 Annex B(2): a reasonable interval between publication and entry into force

8. In *India – Agricultural Products*, the Panel noted that the entry into force of a measure on the day of its publication "did not allow any interval at all" and found the measure to be inconsistent with Annex B(2).[9]

1.5 Annex B(3): enquiry points

1.5.1 General

9. The Panel in *Australia – Salmon* found that there was no obligation under the SPS Agreement for a Member to positively identify its chosen appropriate level of protection. In the context of this finding, the Panel held that paragraph 3 of Annex B did not impose a "substantive obligation on Members to identify or quantify their appropriate level of protection", but rather merely a "mainly procedural obligation to provide 'answers to all reasonable questions from all interested Members'".[10] The Appellate Body reversed the Panel's finding and held that there was such an obligation – albeit implicit – in Annex B(3).[11]

10. In *Korea – Radionuclides*, the Panel found that "compliance with Annex B(3), and thus Article 7, is achieved not only through the formality of creating an enquiry point, but also through the actual provision of information and answers to reasonable questions."[12] At the same time, the Panel noted that:

> "[C]orrespondence with an enquiry point is an iterative process, and an enquiry point must not be held to the standard of perfection. Therefore, the incompleteness of a single answer or failure to provide a particular document as part of a response to a request will not necessarily give rise to an inconsistency. However, failure to respond at all would result in an inconsistency with the obligation in Annex B(3)."[13]

11. The Appellate Body in *Korea – Radionuclides* found that the Panel had not sufficiently examined all the relevant factors required to determine whether or not Korea had acted inconsistently with Annex B(3). The Appellate Body emphasized that:

> "[W]hether and the extent to which a particular enquiry point answers all reasonable questions and provides relevant documents are not irrelevant for the assessment under Annex B(3). Rather, it informs an assessment of whether 'one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents' within the meaning of Annex B(3). In our view, this assessment requires an examination of all the relevant factors, including the total number of questions received by the enquiry point and the proportion of and the extent to which questions were answered, the nature and scope of the information sought and received, and whether the enquiry point repeatedly failed to respond. Thus, we agree with the Panel that compliance with Annex B(3) is not a mere formality of establishing an enquiry point. We disagree, however, with the Panel that a single failure of an enquiry point to respond to a request would result in an inconsistency with the obligation under Annex B(3)."[14]

1.5.2 Paragraph 3(d)

12. In relation to the reinforcement of the transparency obligation of the agreements on equivalence between Members, see the Section on Article 7 of the SPS Agreement.

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[9] Panel Report, *India – Agricultural Products*, paras. 7.757-7.758.
[10] Panel Report, *Australia – Salmon*, para. 7.15.
[11] Appellate Body Report, *Australia – Salmon*, para. 205.
[12] Panel Report, *Korea – Radionuclides*, para. 7.510.
[13] Panel Report, *Korea – Radionuclides*, para. 7.507.
[14] Appellate Body Report, *Korea – Radionuclides*, para. 5.211.

1.6 Annex B(5): conditions for notification requirements

13. The Panel in *Japan – Apples*, in determining whether any changes in Members' SPS measures constitute changes that must be notified under Article 7, found that the most important factor to be taken into consideration is "whether the change affects the conditions of market access for the product concerned, that is, would the exported product still be permitted to enter [the market (Japan in this case)] if they complied with the prescription contained in the previous regulations"[15] under the chapeau of Annex B(5). The Panel was of the view that even if this situation did not occur, the Panel must still consider whether the change could be considered to potentially have a significant effect on the trade of other Members:

> "It is not disputed that the present situation is one where 'an international standard, guideline or recommendation does not exist … or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation'. Therefore, we must determine whether the changes identified above constitute changes which are required to be notified under Article 7 because, inter alia, they 'may have a significant effect on trade of other Members' in the context of the chapeau to Paragraph 5 of Annex B.
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> We consider that the most important factor in this regard is whether the change affects the conditions of market access for the product concerned, that is, would the exported product (apple fruit from the United States in this case) still be permitted to enter Japan if they complied with the prescription contained in the previous regulations.[16] If this is not the case, then we must consider whether the change could be considered to potentially have a significant effect on trade of other Members. In this regard, it would be relevant to consider whether the change has resulted in any increase in production, packaging and sales costs, such as more onerous treatment requirements or more time-consuming administrative formalities."[17]

14. Still in this regard, the Panel in *Japan – Apples* held that it was barred from addressing legal claims falling outside its terms of reference. To succeed in a claim under Article 7 and Annex B of the SPS Agreement, the party making the allegation of the change that was not notified must establish a prima facie case by specifying in what respect any changes in SPS regulations departed from previous ones:

> "We recall that, in *EC – Hormones*, the Appellate Body noted that
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> > '… Panels are inhibited from addressing legal claims falling outside their terms of reference. However, nothing in the DSU limits the faculty of a Panel freely to use arguments submitted by any of the parties – or to develop its own legal reasoning – to support its own findings and conclusions on the matter under its consideration.'
>
> However, the Appellate Body clarified in *Korea – Dairy* that '[B]oth 'claims' and 'arguments' are distinct from the 'evidence' which the complainant or respondent presents to support its assertions of facts and arguments'. We note in this regard that the party making an allegation must provide sufficient evidence in support of this allegation, and that a Panel should not entertain a claim for which a prima facie case has not been made. In the present case, the United States has effectively argued that Japan had substantially changed its fire blight measures since the entry into force of the SPS Agreement. However, the United States limited its argumentation to mention that new regulations had been implemented and to attach translations of the regulations to its first written submission. It did not specify in what respect these new regulations departed from the previous ones.

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[15] (*footnote original*) This approach is in line with the discussion of the concept of "significant effect on trade of other Members" in the notification procedures adopted and revised by the SPS Committee G/SPS/7/Rev.2, para. 7).

[16] This approach is in line with the discussion of the concept of "significant effect on trade of other Members" in the notification procedures adopted and revised by the SPS Committee G/SPS/7/Rev.2, para. 7).

[17] Panel Report, *Japan – Apples*, paras. 8.313-8.314.

> Indeed, either the United States knows in which respect the 1997 texts differ from the ones they replace – in which case it could and should have mentioned it in its submissions – or it does not, in which case it cannot be deemed to have established a prima facie case. In either situation, for the Panel to examine the regulations at issue to identify differences would be equivalent to 'making a case' for the United States, something we are not allowed to do. For these reasons we conclude that the United States did not establish a prima facie case in relation to the violation of Article 7 and Annex B of the SPS Agreement."[18]

15. In determining whether an SPS regulation had a significant effect on the trade of other WTO Members, the Panel in *India – Agricultural Products* referred to its findings that the challenged measures affected international trade, made in the context of determining whether they constituted SPS measures within the meaning of Annex A(1) of the SPS Agreement.[19] The Panel further found that "an outright prohibition on the importation of [products] constitutes the most restrictive measure a Member could take with respect to trade."[20] The Panel concluded on this basis that the measures had a "significant" effect on trade.[21]

16. The Panel then moved on to examine whether a relevant international standard did not exist or the proposed measure was not substantially the same as the content of an international standard, guideline or recommendation. The Panel found in that regard that "for the content of an SPS regulation to be 'substantially the same' as the content of an international standard, the former must be at least 'based on' the latter according to Article 3.1 of the SPS Agreement."[22] The Panel referred to its earlier findings that India's measures were not based on the relevant international standard, to conclude that it was not substantially the same as that standard.[23]

1.6.1 Annex B(5)(b): notification requirement

17. In *India – Agricultural Products*, the Panel held that to meet the requirement in Annex B(5)(b) a Member has to notify a proposed regulation, as opposed to a regulation that is already in force:

> "Annex B(5)(b) concerns the notification of a 'proposed' regulation and thus notification must occur at least before that regulation enters into force, so that amendments can still be introduced and comments taken into account. We note that the SPS Committee's Transparency Procedures support our understanding that the notification obligation in Annex B(5)(b) concerns proposed regulations, as it recommends that the notification takes place once a draft of the complete text of a regulation is available."[24]

1.7 Annex B(6): urgent problems of health protection

18. In *India – Agricultural Products*, the Panel considered relevant for assessing whether India's measures were addressing "urgent problems of health protection" the fact that India had made several notifications of similar avian-influenza-related measures four years prior to the notification of the measure in October 2011. The Panel also noted that India had notified the measure to the WTO Secretariat on 7 October 2011 and "well after [the measure] entered into force on 19 July 2011."[25] The Panel concluded that because India's measures did address health problems that were urgent and did not meet the condition of the chapeau of Annex B(6), the Panel did not need to look into their compatibility with any of the three specific conditions spelled out in subparagraphs (a) through (c) of Annex B(6).[26]

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[18] Panel Report, *Japan – Apples*, paras. 8.316-8-318.
[19] Panel Report, *India – Agricultural Products*, para. 7.773.
[20] Panel Report, *India – Agricultural Products*, para. 7.773.
[21] Panel Report, *India – Agricultural Products*, para. 7.773.
[22] Panel Report, *India – Agricultural Products*, para. 7.780.
[23] Panel Report, *India – Agricultural Products*, paras. 7.781-7.782.
[24] Panel Report, *India – Agricultural Products*, para. 7.788.
[25] Panel Report, *India – Agricultural Products*, para. 7.763.
[26] Panel Report, *India – Agricultural Products*, para. 7.764.

1.8 Relationship with other provisions of the SPS Agreement

1.8.1 Article 7

19. The Panel in *EC – Approval and Marketing of Biotech Products* referred to the text of Article 7 as a confirmation of its understanding that the term "SPS regulations", as used in Annex B, meant SPS measures:

> "Annex B(1) applies to 'sanitary and phytosanitary regulations' (hereafter 'SPS regulations') which have been 'adopted'. An explanatory footnote to Annex B(1) indicates that the term 'SPS regulations' should be understood as meaning 'sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally'. That SPS regulations are 'SPS measures' is confirmed by Article 7 which states that Members must notify changes in their 'SPS measures' and provide information on their 'SPS measures' 'in accordance with the provisions of Annex B'. It can be inferred from this that the 'SPS regulations at issue in Annex B(1) are a sub-category of 'SPS measures'."[27]

20. In *EC- Approval and Marketing of Biotech Products*, the Panel established that, in a case where the demanding party seeks to establish an inconsistency with Article 7 on the basis of an alleged inconsistency with Annex B(1), if the measure in question is not found inconsistent with Annex B it would similarly be devoid of inconsistency with Article 7 even on the assumption that Article 7 would be applicable to the case at hand:

> "[W]e have found that the provisions of Annex B(1) are not applicable to the product-specific measures challenged by the United States, these measures cannot be inconsistent with these provisions. … [T]here can then logically be no inconsistency with Article 7 either, even assuming that Article 7 is applicable to these measures."[28]

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Current as of: June 2022

[27] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1455.
[28] Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1777.