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1 ARTICLE 5

1.1 Text of Article 5

Article 5

Procedures for Assessment of Conformity by Central Government Bodies

5.1 Members shall ensure that, in cases where a positive assurance of conformity with technical regulations or standards is required, their central government bodies apply the following provisions to products originating in the territories of other Members:

- 5.1.1 conformity assessment procedures are prepared, adopted and applied so as to grant access for suppliers of like products originating in the territories of other Members under conditions no less favourable than those accorded to suppliers of like products of national origin or originating in any other country, in a comparable situation; access entails suppliers' right to an assessment of conformity under the rules of the procedure, including, when foreseen by this procedure, the possibility to have conformity assessment activities undertaken at the site of facilities and to receive the mark of the system;
- 5.1.2 conformity assessment procedures are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. This means, *inter alia*, that conformity assessment procedures shall not be more strict or be applied more strictly than is necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create.

- 5.2 When implementing the provisions of paragraph 1, Members shall ensure that:
- 5.2.1 conformity assessment procedures are undertaken and completed as expeditiously as possible and in a no less favourable order for products originating in the territories of other Members than for like domestic products;
 - 5.2.2 the standard processing period of each conformity assessment 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 assessment 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 conformity assessment if the applicant so requests; and that, upon request, the applicant is informed of the stage of the procedure, with any delay being explained;
 - 5.2.3 information requirements are limited to what is necessary to assess conformity and determine fees;
 - 5.2.4 the confidentiality of information about products originating in the territories of other Members arising from or supplied in connection with such conformity assessment procedures is respected in the same way as for domestic products and in such a manner that legitimate commercial interests are protected;
 - 5.2.5 any fees imposed for assessing the conformity of products originating in the territories of other Members are equitable in relation to any fees chargeable for assessing the conformity of like products of national origin or originating in any other country, taking into account communication, transportation and other costs arising from differences between location of facilities of the applicant and the conformity assessment body;
 - 5.2.6 the siting of facilities used in conformity assessment procedures and the selection of samples are not such as to cause unnecessary inconvenience to applicants or their agents;
 - 5.2.7 whenever specifications of a product are changed subsequent to the determination of its conformity to the applicable technical regulations or standards, the conformity assessment procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the technical regulations or standards concerned;
 - 5.2.8 a procedure exists to review complaints concerning the operation of a conformity assessment procedure and to take corrective action when a complaint is justified.
- 5.3 Nothing in paragraphs 1 and 2 shall prevent Members from carrying out reasonable spot checks within their territories.
- 5.4 In cases where a positive assurance is required that products conform with technical regulations or standards, and relevant guides or recommendations issued by international standardizing bodies exist or their completion is imminent, Members shall ensure that central government bodies use them, or the relevant parts of them, as a basis for their conformity assessment procedures, except where, as duly explained upon request, such guides or recommendations or relevant parts are inappropriate for the Members concerned, for, *inter alia*, such reasons as: national security requirements; the prevention of deceptive

practices; protection of human health or safety, animal or plant life or health, or the environment; fundamental climatic or other geographical factors; fundamental technological or infrastructural problems.

5.5 With a view to harmonizing conformity assessment procedures on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of guides and recommendations for conformity assessment procedures.

5.6 Whenever a relevant guide or recommendation issued by an international standardizing body does not exist or the technical content of a proposed conformity assessment procedure is not in accordance with relevant guides and recommendations issued by international standardizing bodies, and if the conformity assessment procedure may have a significant effect on trade of other Members, Members shall:

- 5.6.1 publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular conformity assessment procedure;
- 5.6.2 notify other Members through the Secretariat of the products to be covered by the proposed conformity assessment procedure, together with a brief indication of its objective and rationale. Such notifications shall take place at an early appropriate stage, when amendments can still be introduced and comments taken into account;
- 5.6.3 upon request, provide to other Members particulars or copies of the proposed procedure and, whenever possible, identify the parts which in substance deviate from relevant guides or recommendations issued by international standardizing bodies;
- 5.6.4 without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.

5.7 Subject to the provisions in the lead-in to paragraph 6, where urgent problems of safety, health, environmental protection or national security arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 6 as it finds necessary, provided that the Member, upon adoption of the procedure, shall:

- 5.7.1 notify immediately other Members through the Secretariat of the particular procedure and the products covered, with a brief indication of the objective and the rationale of the procedure, including the nature of the urgent problems;
- 5.7.2 upon request, provide other Members with copies of the rules of the procedure;
- 5.7.3 without discrimination, allow other Members to present their comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.

5.8 Members shall ensure that all conformity assessment procedures which have been adopted are published promptly or otherwise made available in such a manner as to enable interested parties in other Members to become acquainted with them.

5.9 Except in those urgent circumstances referred to in paragraph 7, Members shall allow a reasonable interval between the publication of requirements concerning conformity assessment procedures and their entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products or methods of production to the requirements of the importing Member.

1.2 Article 5

1.2.1 General

1. The Appellate Body in *Russia – Railway Equipment* noted that the title of Article 5 of the TBT Agreement indicates that the provision relates to procedures for the assessment of conformity. Obligations set forth in this provision apply with respect to a Member's "central government bodies" where the Member requires "a positive assurance of conformity" with technical regulations or standards. Annex 1.3 to the TBT Agreement defines "[c]onformity assessment procedures" as "[a]ny procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled". Pursuant to the explanatory note to Annex 1.3, conformity assessment procedures "include, *inter alia*, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations".¹

1.3 Article 5.1.1

1.3.1 General

2. The Panel in *Russia – Railway Equipment* noted that Article 5.1.1 establishes obligations to provide national treatment and most-favoured nation treatment with regard to access for suppliers from other Members to covered conformity assessment procedures of importing Members.²

1.3.2 Legal test

3. The Panel in *Russia – Railway Equipment* noted that two requirements must be met for a conformity assessment procedure to be covered by Article 5.1.1: (a) it must concern procedures for the assessment of conformity by central government bodies and (b) it must concern a situation where a positive assurance of conformity with technical regulations or standards is required (i.e., a mandatory conformity assessment procedure).³

4. The Panel in *Russia – Railway Equipment* considered that an importing Member would act inconsistently with the non-discrimination obligations in Article 5.1.1 in respect of a covered conformity assessment procedure if three elements are established:

"a. The suppliers of another Member who have been granted less favourable access are suppliers of products that are *like* the products of domestic suppliers or suppliers from any other country who have been granted more favourable access;

b. the importing Member (through the preparation, adoption or application of a covered conformity assessment procedure) *grants* access for suppliers of products from another Member *under conditions less favourable* than those accorded to suppliers of domestic products or products from any other country⁴; and

c. the importing Member grants access under conditions less favourable for suppliers of like products *in a comparable situation*."⁵

1.3.3 "Like products"

5. According to the Panel in *Russia – Railway Equipment*, the same criteria that are applied for determining whether products are "like" in the context of Article 2.1 of the TBT Agreement are applicable in the context of Article 5.1.1.⁶

¹ Appellate Body Report, *Russia – Railway Equipment*, para. 5.210.

² Panel Report, *Russia – Railway Equipment*, para. 7.248.

³ Panel Report, *Russia – Railway Equipment*, para. 7.249.

⁴ (*footnote original*) We recall that pursuant to the text of Article 5.1.1 of the TBT Agreement the relevant treatment concerns "conditions" of access granted to suppliers from Members.

⁵ Panel Report, *Russia – Railway Equipment*, para. 7.251.

⁶ Panel Report, *Russia – Railway Equipment*, para. 7.254.

1.3.4 "grant access ... under conditions no less favourable"

6. The Panel in *Russia – Railway Equipment* observed that the meaning of the term "access" in the first sentence of Article 5.1.1 is clarified by the second sentence. Accordingly, the "access" to be examined in an Article 5.1.1 analysis relates to the conditions under which suppliers have been given the right to have the conformity of their products assessed under the relevant rules of the conformity assessment procedure. Such analysis also includes assessing whether suppliers have been given the possibility to have the conformity of their products assessed under the rules of the relevant conformity assessment procedures, and whether suppliers are able to exercise that right or possibility.⁷

7. The Panel in *Russia – Railway Equipment* explained that the phrase "conditions less favourable" indicates that there is a need to compare the conditions of access granted to suppliers of products from the complaining Member, on the one hand, and suppliers of like domestic products, or like products from any other country, on the other hand. If such comparison reveals a difference in the access conditions granted to the suppliers of the complaining Member, the issue arises whether that difference amounts to granting access under "less favourable" conditions.⁸ According to the Panel:

"Article 5.1.1 does not concern the manner in which a Member treats imported products from another Member. Rather, Article 5.1.1 focuses on suppliers and their conditions of access to a conformity assessment procedure. In our view, this is an important difference. However, similar to the situation in the context of less favourable treatment regarding imported products, it is clear to us that a mere difference in access conditions granted to suppliers of the complaining Member and other suppliers is not necessarily sufficient to conclude that access was granted under conditions less favourable. In our view, differential access conditions are relevant under Article 5.1.1 if they modify the conditions of competition, or competitive opportunities, among relevant suppliers of like products to the detriment of suppliers of the complaining Member. We note in this regard that suppliers of like products compete for prompt and unconditional access to the importing Member's market and that Article 5.1 applies in cases where the importing Member requires a positive assurance of conformity with technical regulations or standards before the product can be placed on the importing Member's market."⁹

8. The Panel in *Russia – Railway Equipment* recalled that Ukraine was challenging the application of the conformity assessment procedure, and not its preparation or adoption. The Panel observed that in the context of a claim against the application of a conformity assessment procedure:

"[L]ess favourable conditions would in our view exist where the importing Member denies or limits the right or possibility of a supplier of another Member to have conformity assessment activities undertaken under the rules of the applicable conformity assessment procedure, either in respect of the entire conformity assessment procedure or any of its relevant parts, but does not deny or limit the right or possibility of access of another supplier of a like product from the importing Member or any other country.¹⁰ Where the importing Member limits the right or possibility of two suppliers of like products to have conformity assessment activities undertaken, but in different ways, it would need to be examined further whether the difference confers a competitive

⁷ Panel Report, *Russia – Railway Equipment*, para. 7.257. See also Appellate Body Report, *Russia – Railway Equipment*, para. 5.123.

⁸ Panel Report, *Russia – Railway Equipment*, para. 7.258.

⁹ Panel Report, *Russia – Railway Equipment*, para. 7.260. See also Appellate Body Report, *Russia – Railway Equipment*, para. 5.123.

¹⁰ (footnote original) As Ukraine has not put forward an "as such" challenge, we do not need to address in this dispute whether in the case of a challenge to a conformity assessment procedure as such it would be necessary to undertake an analysis of the access granted for suppliers of the group of like products originating in the territory of the complaining Member compared to the access granted for suppliers of the group of like products originating in the territory of the importing Member or any other countries. See Appellate Body Report, *US – Tuna II (Mexico) (Article 21.5 – Mexico)*, para. 7.281, which involved a challenge under Articles I:1 and III:4 of the GATT 1994 to the amended United States tuna measure as such.

advantage to one or other supplier. If that were the case, the disadvantaged supplier would have been granted access under conditions less favourable."¹¹

9. The Panel in *Russia – Railway Equipment* examined whether, based on the interpretation of Article 2.1 developed by the Appellate Body, before reaching a conclusion on whether the importing Member grants access under less favourable conditions, a panel must examine whether the identified difference in the conditions of access to a conformity assessment procedure stems from a legitimate regulatory distinction. The Panel underscored the textual differences between Article 2.1 and Article 5.1.1, particularly the qualification of the most-favoured nation and national treatment obligations in Article 5.1.1 by the phrase "in a comparable situation".¹² The Panel noted that:

"[I]t is not necessary to determine whether any differential conditions of access stem from a legitimate regulatory distinction, before reaching a conclusion on whether the differential access conditions amount to granting access under 'less favourable' conditions. However, as indicated in the text of Article 5.1.1, even where the conclusion is that less favourable access conditions have been granted, it would still be necessary to go on to determine whether less favourable access was granted in a comparable situation."¹³

1.3.5 "in a comparable situation"

10. According to the Panel, the phrase "in a comparable situation" in Article 5.1.1 warrants a comparison of differential conditions of access with a view to determining whether the less favourable conditions of access are being granted despite the situation being comparable.¹⁴ The Panel then discussed the need to identify relevant factors that render a situation comparable or not:

"The relevant context, as is clear from the second sentence of Article 5.1.1, is that of assessing conformity under the rules of the procedure and conducting conformity assessment activities. We also consider that Articles 5.1.2 and 5.2.7 of the TBT Agreement provide useful context in this regard. They indicate that conformity assessment procedures must not be applied more strictly than necessary to give 'the importing Member adequate confidence that products conform with the applicable technical regulations or standards' (Article 5.1.2) and that they serve to 'determine whether adequate confidence exists that the product ... meets the [applicable] technical regulations or standards concerned' (Article 5.2.7). This is confirmed by the definition of conformity assessment procedures in Annex 1.3 to the TBT Agreement. A conformity assessment procedure is 'any procedure used directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled'. Accordingly, aspects of a situation that have a bearing on, for instance, the ability of the importing Member to undertake such activities under the rules of the procedure with adequate confidence would, in principle, seem to be relevant. In our view, the relevant aspects of a situation would include aspects specific to the suppliers who are claimed to have been granted access under less favourable conditions or to the location of the suppliers' facilities. In all events, whether a situation is comparable must be assessed on a case-by-case basis and in the light of the relevant rules of the conformity assessment procedure and other evidence on record."¹⁵

11. The Appellate Body in *Russia – Railway Equipment* observed that the assessment of whether access is granted under conditions no less favourable "in a comparable situation" within the meaning of Article 5.1.1 should focus on factors with a bearing on the conditions for granting access to conformity assessment in that specific case and the ability of the regulating Member to ensure compliance with the requirements in the underlying technical regulation or standard. The Appellate Body stated:

"[S]uch an assessment may involve the analysis of various factors, including the rules of the conformity assessment procedure; whether its preparation, adoption, or

¹¹ Panel Report, *Russia – Railway Equipment*, para. 7.261.

¹² Panel Report, *Russia – Railway Equipment*, paras. 7.269-7.273.

¹³ Panel Report, *Russia – Railway Equipment*, para. 7.274.

¹⁴ Panel Report, *Russia – Railway Equipment*, para. 7.282.

¹⁵ Panel Report, *Russia – Railway Equipment*, para. 7.283.

application is challenged; the nature of the products at issue; and the situation in a particular country or supplier. Nevertheless, the relevant factors for determining the existence of a 'comparable situation' should ultimately relate to the Member's ability to make a positive assurance of conformity with respect to the specific suppliers of like products at issue, such that if no comparable situation existed for these suppliers, the obligation to grant non-discriminatory access to conformity assessment would not apply to them. In all instances, this analysis has to be made on a case-by-case basis in light of the measure at issue and the particular circumstances of the case."¹⁶

12. The Appellate Body noted that the Panel had outlined a number of factors that may be relevant in determining the existence of a "comparable situation", and in particular recognized the relevance of factors specific to the suppliers at issue. The Appellate Body agreed with the Panel that whether a situation is comparable must be assessed on a case-by-case basis and in light of the relevant rules of the conformity assessment procedure and other evidence on the record.¹⁷ Thus, the Appellate Body did not consider that the Panel erred in its interpretation of the phrase "in a comparable situation" in Article 5.1.1 by failing to elaborate on what has to be compared in establishing the existence of a comparable situation.¹⁸

13. In reviewing the Panel's application of Article 5.1.1 of the TBT Agreement, the Appellate Body considered that the Panel did not, in fact, focus, as it stated in its interpretation, on "aspects specific to the suppliers who are claimed to have been granted access under less favourable conditions or to the location of the suppliers' facilities" and relied instead on information on the record concerning the general security situation in Ukraine.¹⁹ The Appellate Body considered that:

"[E]vidence concerning an entire country may provide a basis for concluding that a conformity assessment procedure cannot be conducted in any part of the country, e.g. when its entire territory is affected by a natural disaster or an armed conflict that has an impact on the situation of specific suppliers. Evidence of risk for the security of governmental employees, as opposed to actual incidents relating to the security of those employees, may also be probative in this regard. However, as noted above, the language in Article 5.1.1 makes clear that comparability of the situations has to be assessed by reference to the 'suppliers', thus taking account of the fact that conditions of access to conformity assessment may vary within a country. Therefore, the existence of a 'comparable situation' must be established on the basis of evidence pertaining to the specific suppliers of like products to which the conditions for access to conformity assessment granted by the importing Member relate. In the present case, we do not see that, in making this assessment, the Panel sufficiently considered the situation of the specific suppliers at issue or the regions where the relevant suppliers were located or provided an explanation as to how the evidence on the record concerning the existence of security concerns and anti-Russian sentiment in Ukraine in general related to these regions and suppliers."²⁰

14. The Appellate Body disagreed with the Panel's conclusion that there was a need to "weigh and balance" the market access interests of suppliers of products originating in the territories of other Members against the interest of safeguarding the life and health of governmental employees. The Appellate Body explained that:

[T]he question before the Panel was whether, in light of all evidence on the record, the security situation in Ukraine as it applied to the relevant suppliers of Ukrainian railway products affected the conditions of granting access to conformity assessment to those suppliers, such that the situations relating to those suppliers and to suppliers in other countries could no longer be considered comparable.

¹⁶ Appellate Body Report, *Russia – Railway Equipment*, para. 5.128. See *ibid.* paras. 5.124-5.127.

¹⁷ Appellate Body Report, *Russia – Railway Equipment*, para. 5.135 (referring to Panel Report, *Russia – Railway Equipment* para. 7.283).

¹⁸ Appellate Body Report, *Russia – Railway Equipment*, para. 5.136.

¹⁹ Appellate Body Report, *Russia – Railway Equipment*, para. 5.140 (referring to Panel Report, *Russia – Railway Equipment*, para. 7.283).

²⁰ Appellate Body Report, *Russia – Railway Equipment*, para. 5.141.

... [I]n assessing the existence of a 'comparable situation', the Panel apparently 'balanced' the evidence on the record concerning the objective existence of security concerns and anti-Russian sentiment generally in Ukraine, on the one hand, and the perception of the importing Member as to the existence of such concerns and sentiment, on the other. As noted, however, such weighing and balancing has no basis in the language of Article 5.1.1 of the TBT Agreement."²¹

15. The Appellate Body considered that the Panel's error in applying the correct legal framework for examining the existence of a "comparable situation" is also reflected in the Panel's reliance on evidence that was either of a general nature and did not relate to the existence of security concerns and anti-Russian sentiment in the specific regions where the relevant suppliers were located or reflected the situation in regions other than those of the suppliers. The Appellate Body also observed that some of the evidence relied on by the Panel explicitly referred to regions different from the ones where the relevant suppliers were located.²² The Appellate Body stated:

"[T]he Panel specifically observed that officials from Belarus, the European Union, India, Kazakhstan, and Pakistan travelled to Ukraine 'despite the above-noted evidence of unrest, rallies and protests in various parts of Ukraine, and despite the armed conflict in eastern Ukraine'. The Panel thus recognized that the security situation in Ukraine posed danger for the life and health of only Russian governmental employees, to the extent that evidence on the record demonstrated the existence of anti-Russian sentiment. In these circumstances, it was of particular importance for the Panel to analyse the comparability of situations with respect to the specific suppliers of Ukrainian railway products at issue, in order to be in a position to answer the question whether the security situation in certain regions of Ukraine, coupled with the existence of anti-Russian sentiment in those same regions and over the period between 2014 and 2016, resulted in the absence of a 'comparable situation' with respect to suppliers located in those regions and for purposes of conducting on-site inspections by Russian FBO employees over the relevant period."²³

16. The Appellate Body considered that, under Article 5.1.1, the assessment of whether access is granted under conditions no less favourable "in a comparable situation" should focus on factors having a bearing on the conditions for granting access to conformity assessment to suppliers of like products and the ability of the regulating Member to ensure compliance with the requirements in the underlying technical regulation or standard. Thus, factors relevant to the inquiry of whether a "comparable situation" exists have to affect the specific suppliers to which the conditions for access to conformity assessment granted by the importing Member relate.²⁴

17. In the light of these considerations, the Appellate Body ultimately reversed the Panel's findings concerning the Panel's application of Article 5.1.1 of the TBT Agreement.²⁵ The Appellate Body declined to complete the legal analysis because, *inter alia*:

"[W]e are not in a position to assess whether the security situation in Ukraine affected the conditions of granting access to conformity assessment for the specific suppliers at issue over the relevant period, such that it was no longer comparable to the situation applicable to other countries and suppliers of like products."²⁶

1.4 Article 5.1.2

1.4.1 General

18. The Panel in *EC – Seal Products* made several findings on Article 5.1.2 that were declared "moot and of no legal effect" by the Appellate Body in consequence of reversing the Panel's finding

²¹ Appellate Body Report, *Russia – Railway Equipment*, paras. 5.145-5.146.

²² Appellate Body Report, *Russia – Railway Equipment*, para. 5.148. See also *ibid.* para. 5.147.

²³ Appellate Body Report, *Russia – Railway Equipment*, para. 5.148.

²⁴ Appellate Body Report, *Russia – Railway Equipment*, para. 5.153. See also *ibid.* paras. 5.143 and 5.154.

²⁵ Appellate Body Report, *Russia – Railway Equipment*, paras. 5.155 and 5.156.

²⁶ Appellate Body Report, *Russia – Railway Equipment*, para. 5.151.

that the measure at issue was a technical regulation.²⁷ In the context of making these findings, the Panel examined the first and second sentences of Article 5.1.2, having concluded that certain aspects of the measure at issue constituted a conformity assessment procedure (CAP).²⁸

19. The Panel considered that "the text and structure of Article 5.1.2 indicate that the provision consists of general obligations, set out in the first sentence, and an example of the general obligations, set out in the second sentence".²⁹ More specifically, according to the Panel:

"[T]he general obligations under the first sentence are not to prepare, adopt, or apply conformity assessment procedures with a view to or with the effect of creating unnecessary obstacles to international trade. The second sentence explains the meaning of the general obligations by prescribing a situation where a certain CAP may be found in violation of the obligation under the first sentence.³⁰ Therefore, a violation of the obligations set out in the first sentence could be established by demonstrating, for instance, that a given CAP has the effect of creating unnecessary obstacles to international trade or by showing a breach of the specific requirement in the second sentence."³¹

20. The Panel in *Russia- Railway Equipment* observed that for a conformity assessment procedure to fall within the scope of Article 5.1.2, it must concern (a) procedures for the assessment of conformity by central government bodies, and (b) a situation where a positive assurance of conformity with technical regulations or standards is required (i.e., a mandatory conformity assessment procedure).³²

1.4.2 First sentence

21. The Panel in *Russia – Railway Equipment* observed that due to the relationship between the first and the second sentences of Article 5.1.2, a complaining party may establish an inconsistency with the first sentence either by demonstrating that the conformity assessment procedure is applied with a view to or with the effect of creating an unnecessary restriction to international trade or through the specific means illustrated in the second sentence.³³

22. The Appellate Body in *Russia – Railway Equipment* noted that the first sentences of Articles 2.2 and 5.1.2 contain an obligation for WTO Members not to "prepare[], adopt[] or appl[y]" technical regulations or conformity assessment procedures respectively "with a view to or with the effect of creating unnecessary obstacles to international trade".³⁴

23. In resolving the question of whether the first sentence of Article 5.1.2 permits a CAP that requires third-party accreditation and conformity assessment without creating or designating a default body independent of third-party approval, the Panel in *EC – Seal Products* first noted:

"[T]he text of Article 5.1.2 contains no precise indication of permitted and prohibited types of CAP. Thus, the text provides no direct prescription as to the permissibility of third-party accreditation, nor does it indicate whether such accreditation would require creation or designation of a default and/or back-up body."³⁵

24. The Panel further observed:

²⁷ Panel Reports, *EC – Seal Products*, paras. 7.511-7.547; and Appellate Body Reports, *EC – Seal Products*, para. 6.1.

²⁸ Panel Reports, *EC – Seal Products*, para. 7.510.

²⁹ Panel Reports, *EC – Seal Products*, para. 7.512.

³⁰ (*footnote original*) The term "inter alia" in the second sentence signifies that it is only one example of the requirements stemming from the general obligation set out in the first sentence.

³¹ Panel Reports, *EC – Seal Products*, para. 7.513. See also Panel Report, *Russia – Railway Equipment*, paras. 7.402 and 7.413.

³² Panel Report, *Russia – Railway Equipment*, para. 7.403.

³³ Panel Report, *Russia – Railway Equipment*, para. 7.413.

³⁴ Appellate Body Report, *Russia – Railway Equipment*, para. 5.185.

³⁵ Panel Reports, *EC – Seal Products*, para. 7.522.

"[T]he context provided in other provisions of the TBT Agreement supports the view that there is some flexibility as to permissible CAP regimes, particularly with respect to the possibility of third-party accreditation. For example, the definition of a CAP in Annex 1 of the TBT Agreement encompasses, in addition to inspection and verification procedures, procedures for 'registration, accreditation and approval as well as their combinations'. We note that this explicit provision for accreditation does not contain any limitation as to the type of entity to be accredited. Moreover, the use of the term 'inter alia' and the stipulation 'as well as their combinations' suggest wide versatility in the types of regime that may be considered a CAP under the TBT Agreement. We also note that Article 6 of the TBT Agreement provides for Members' *recognition* of conformity assessment from other Members 'provided they are satisfied that those procedures offer an assurance of conformity ... equivalent to their own procedures'. To this end, it is explicitly contemplated that the system for recognizing conformity assessment from other Members may entail 'limitation of the acceptance of conformity assessment results to those produced by designated bodies in the exporting Member'."³⁶

25. The Panel thus considered that:

"Article 5.1.2 permits a system of third-party accreditation as part of a CAP. Accordingly, we do not consider that the third-party accreditation system under the EU Seal Regime (the CAP) violates Article 5.1.2. Nor do we find from the relevant text and context of Article 5.1.2 an obligation on the part of a responding Member to create or designate a default body pending accreditation or recognition of third-party entities to perform a CAP."³⁷

26. With respect to the question of whether a CAP must be capable of allowing trade in conforming products to occur from the date of entry into force of a given measure, in the context of the first sentence of Article 5.1.2, the Panel found:

"[T]he measure in question was established such that the CAP was not capable of allowing trade in conforming products to occur on the date of its entry into force. In light of this, we conclude that the CAP had the effect of creating unnecessary obstacles to international trade inconsistently with the first sentence of Article 5.1.2."³⁸

1.4.3 Second sentence

27. According to the Panel in *EC – Seal Products*:

"Given the similarities in its text and structure to the second sentence of Article 2.2 of the TBT Agreement, the Panel considers, and the parties do not dispute, that the requirement under the second sentence of Article 5.1.2 calls for a relational analysis similar to that applied in Article 2.2, namely a weighing and balancing of a measure's trade-restrictiveness, degree of its contribution to an objective, and possible less trade-restrictive alternative measures. In the context of a claim under Article 5.1.2, however, the analysis relates to the fulfilment of only one objective: giving positive assurance that the relevant requirements of the technical regulation are fulfilled."³⁹

28. The Panel in *Russia – Railway Equipment* noted similarities and differences between the second sentence of Article 5.1.2 and Article 2.2 of the TBT Agreement. Regarding the similarities, the Panel noted that both provisions concern the notion of "necessity". To that extent, the Panel considered useful, when interpreting the second sentence of Article 5.1.2, to refer to the holistic weighing and balancing of certain factors set out by the Appellate Body in respect of Article 2.2.⁴⁰

³⁶ Panel Reports, *EC – Seal Products*, para. 7.523.

³⁷ Panel Reports, *EC – Seal Products*, para. 7.524.

³⁸ Panel Reports, *EC – Seal Products*, para. 7.528.

³⁹ Panel Reports, *EC – Seal Products*, para. 7.539.

⁴⁰ Panel Report, *Russia – Railway Equipment*, paras. 7.418-7.419.

29. Regarding the differences, the Panel first noted that the only relevant objective for an examination under the second sentence of Article 5.1.2 is that of giving the importing Member adequate confidence of conformity.⁴¹ In this regard, the Panel noted that:

"[T]he reference to 'adequate' confidence acts as a limit on the type or level of confidence that an importing Member may seek to achieve through its conformity assessment procedures or their application. The immediate context indicates that what is 'adequate' confidence depends on 'the risks [that] nonconformity would create'. Thus, more confidence might be required, for instance, in situations where the likelihood of the risks materializing is higher or where the risks to be controlled concern very important legitimate objectives. Moreover, more confidence could be achieved depending on the applicable conformity assessment procedures. However, a type or level of confidence that is more than 'adequate', taking account of the risks that may result from non-conformity with the underlying technical regulations or standards, could not be enforced consistently with the second sentence of Article 5.1.2."⁴²

30. The Panel noted another difference between the second sentence of Article 2.2 and that of Article 5.1.2, namely, that the former uses the concept of "trade-restrictiveness", whereas the latter uses the concept of "strictness" or "strict application". The Panel observed that:

"[A] conformity assessment procedure that is more trade-restrictive than necessary, or is applied in a more trade-restrictive manner than is necessary, would constitute a conformity assessment procedure that is more strict than necessary, or a conformity assessment procedure that is applied more strictly than necessary. This is so because the first sentence of Article 5.1.2 prohibits Members from 'creating unnecessary obstacles to international trade' and the second sentence indicates that '[t]his means' that a conformity assessment procedure must not be more strict, or be applied more strictly, than necessary. However, there may be other ways (not involving the restriction of trade per se) in which a conformity assessment procedure could be more strict, or could be applied more strictly, than necessary and could thus fall foul of the second sentence of Article 5.1.2."⁴³

31. The Appellate Body in *Russia – Railway Equipment* further elaborated on the textual similarities and differences between Article 2.2 and Article 5.1.2 of the TBT Agreement. The Appellate Body noted:

"Specifically, the first sentences of Articles 2.2 and 5.1.2 contain an obligation for WTO Members not to 'prepare[], adopt[] or appl[ly]' technical regulations or conformity assessment procedures respectively "with a view to or with the effect of creating unnecessary obstacles to international trade". At the same time, there are relevant differences in the texts of these provisions. For instance, while the second sentence of Article 2.2 refers to 'trade-restrictive', the second sentence of Article 5.1.2 refers to 'more strict' or 'applied more strictly'. Moreover, the function of conformity assessment procedures expressed in the second sentence of Article 5.1.2 is to give 'adequate confidence' that products conform with the applicable technical regulation or standard. By contrast, the third sentence of Article 2.2 refers to a list of indicative legitimate objectives that technical regulations could fulfil. As we see it, both Articles 2.2 and 5.1.2 set out obligations for WTO Members not to create unnecessary obstacles to international trade with regard to technical regulations and conformity assessment procedures, respectively, and identify certain factors to be considered in a necessity analysis. In particular, the factors relevant to the analysis under Article 2.2 include the legitimate objective of the technical regulation, its trade restrictiveness, and the risks non-fulfilment of the objective would create. Under Article 5.1.2, relevant factors include the function of the conformity assessment procedure, its strictness, and the risks non-conformity with the underlying technical regulation or standard would create."⁴⁴

⁴¹ Panel Report, *Russia – Railway Equipment*, para. 7.420.

⁴² Panel Report, *Russia – Railway Equipment*, para. 7.421.

⁴³ Panel Report, *Russia – Railway Equipment*, para. 7.422.

⁴⁴ Appellate Body Report, *Russia – Railway Equipment*, para. 5.185.

32. Based on its interpretation of Article 5.1.2, the Panel in *Russia – Railway Equipment* noted that it examined whether Russia had applied its conformity assessment procedure in accordance with the second sentence of Article 5.1.2, by undertaking a holistic weighing and balancing of the following factors:

"First, we will examine the contribution of Russia's application of its conformity assessment procedure to the objective of giving Russia adequate confidence that Ukrainian railway products conform with the relevant technical regulations.⁴⁵ Second, we will examine the strictness of the manner in which Russia applies its conformity assessment procedure, which includes its trade restrictiveness. Third, we will examine the nature and gravity of the risks that non-conformity would create. After having examined those elements, we will compare the manner of applying the procedure chosen by Russia against the alternative manners of applying Russia's conformity assessment procedure suggested by Ukraine, except if the manner of applying the procedure chosen by Russia does not contribute to giving Russia adequate confidence of conformity. We will determine for the identified alternative manners of applying Russia's procedure whether they (a) are less strict; (b) provide an equivalent contribution to giving Russia adequate confidence of conformity; and (c) are reasonably available to Russia."⁴⁶

33. The Appellate Body agreed with the Panel's interpretation of Article 5.1.2 of the TBT Agreement as stated above.⁴⁷

34. Regarding whether alternative manners of applying a conformity assessment procedure are reasonably available to the responding Member, in the specific context of a challenge concerning exclusively the "application" of the conformity assessment procedure, the Panel in *Russia – Railway Equipment* noted that:

"Regarding the reasonable availability of an alternative manner of applying Russia's procedure, we consider that this element would be satisfied if the alternative option is not merely theoretical in nature, the importing Member is capable of utilizing it, and it does not impose an undue burden on the importing Member, such as prohibitive costs. In the specific context of a challenge concerning exclusively the "application" of a conformity assessment procedure (and not the procedure as such), it is clear to us that the competent body has to operate within the constraints of the domestic law in force at the time and cannot apply the conformity assessment procedure in a manner that the domestic law does not authorize.⁴⁸ We therefore consider that an alternative manner of applying a conformity assessment procedure that is not permissible under the applicable domestic law should not be considered reasonably available to the importing Member."⁴⁹⁵⁰

⁴⁵ (*footnote original*) The parties have in a number of instances referred to the contribution that Russia's manner of applying its conformity assessment procedure makes to the objective of achieving "positive assurance of conformity" of railway products with the applicable technical regulations. We note that in accordance with Article 5.1 and 5.2, Article 5.1.2 applies to conformity assessment procedures that require "a positive assurance of conformity" with technical regulations or standards, i.e. to mandatory conformity assessment procedures. However, Article 5.1.2, second sentence, refers to "giv[ing] the importing Member adequate confidence that products conform with the applicable technical regulations or standards". Therefore, what needs to be examined under Article 5.1.2 is the contribution that a challenged manner of applying a conformity assessment procedure makes to the objective of giving the importing Member adequate confidence that products conform with the applicable technical regulations or standards.

⁴⁶ Panel Report, *Russia – Railway Equipment*, para. 7.423.

⁴⁷ Appellate Body Report, *Russia – Railway Equipment*, para. 5.186 (referring to Appellate Body Reports, *US – COOL (Article 21.5 – Canada and Mexico)*, para. 5.211).

⁴⁸ (*footnote original*) In this context, we note that the domestic law in force at the time includes the rules governing the conformity assessment procedure as well as any other general or specific applicable rules that govern the competent body.

⁴⁹ (*footnote original*) We note that any concern on the part of a complaining party about certain alternative manners of applying a conformity assessment procedure not being permissible under the applicable domestic law of the responding party could be pursued by the complaining party through a claim that a conformity assessment procedure as such is inconsistent with Article 5.1.2.

⁵⁰ Panel Report, *Russia – Railway Equipment*, para. 7.424.

35. The Appellate Body considered that, since the burden of proof under Article 5.1.2 of the TBT Agreement is on the complainant to establish the elements of a breach of a positive obligation, the allocation of the burden of proof for complainants and respondents under this provision should be guided by similar considerations to the burden of proof under Article 2.2 of the TBT Agreement. The Appellate Body then engaged in a discussion similar to that of the Panel above:

"[W]hile under Article XX of the GATT 1994 a respondent must establish that the alternative measure identified by the complainant is ultimately *not* reasonably available to the respondent, under Article 2.2 of the TBT Agreement a complainant must make a *prima facie* case that its proposed alternative measure *is* reasonably available. In any event, the fact that alternative measures serve as 'conceptual tool[s]' in the assessment of the trade restrictiveness of a measure also informs the nature and amount of evidence required. In particular, such alternative measures are of a hypothetical nature for purposes of a necessity analysis, because they do not (yet) exist, or at least not in the particular form proposed by the complainant. Thus, complainants cannot be expected to provide complete and exhaustive descriptions of the alternative measures they propose. Taking into account that the specific details of implementation may depend on the capacity and particular circumstances of the implementing Member in question, it would appear incongruous to expect a complainant to provide detailed information on how a proposed alternative would be implemented by the respondent in practice, and precise and comprehensive estimates of the cost that such implementation would entail. Therefore, once a complainant has established *prima facie* that a proposed alternative is reasonably available, it would then be for the respondent to adduce specific evidence as to why the implementation of this alternative would be actually impracticable, for instance because it is associated with prohibitive costs or substantial technical difficulties."⁵¹

36. The Panel in *Russia – Railway Equipment* discussed the burden of proof when a complaining party seeks to establish an inconsistency with the second sentence of Article 5.1.2, by raising an alternative manner of applying a conformity assessment procedure. The Panel observed that a complaining party in that situation:

"[N]eeds to first identify any alternative manner of applying a conformity assessment procedure that in its view is less strict. In addition, the complaining party needs to make a *prima facie* case that this alternative manner of application is (a) less strict, (b) makes an equivalent contribution to the objective of providing the importing Member adequate confidence of conformity, and (c) is reasonably available to the importing Member.

If the complaining party satisfies that burden, the responding party then needs to rebut the complaining party's arguments and evidence, for example by showing that the alternative proposed manner of application is not less strict, does not make an equivalent contribution to providing adequate confidence of conformity, or is not reasonably available to the responding party."⁵²

37. With respect to the allocation of the burden of proof under Article 5.1.2, the Appellate Body in *Russia – Railway Equipment* noted that, under the second sentence, the complainant must present evidence and arguments sufficient to establish that the challenged conformity assessment procedure is more strict or applied more strictly than necessary to give the importing Member adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create. The Appellate Body then outlined the legal test to be applied in considering an alternative measure as described by the Panel in paragraph 36 above.⁵³

38. The Appellate Body noted, in the context of Article 2.2 of the TBT Agreement, that the nature and degree of evidence required to establish a *prima facie* case of "reasonable availability" of proposed alternative measures should be informed by the fact that "alternative measures are of a hypothetical nature" and "do not yet exist in the Member in question, or at least not in the particular

⁵¹ Appellate Body Report, *Russia – Railway Equipment*, paras. 5.189. See also *ibid.* paras. 5.195, and 5.206.

⁵² Panel Report, *Russia – Railway Equipment*, paras. 7.433-7.434.

⁵³ Appellate Body Report, *Russia – Railway Equipment*, para. 5.188.

form proposed by the complainant".⁵⁴ The Appellate Body took the view that a similar burden of proof applies with regard to the assessment of alternative measures under Article 5.1.2.⁵⁵

39. For the Appellate Body, the purpose of the relational analysis under Article 5.1.2 is therefore to compare the measure at issue and an alternative measure, or their respective applications, in terms of strictness and the degree of contribution to the achievement of the objective to give adequate confidence of conformity. The Appellate Body stated:

"Such comparison cannot be carried out with an alternative measure that is merely theoretical in nature, because, for instance, the implementing Member is not capable of taking it, or because it imposes an undue burden on that Member. At the same time, the comparison of the challenged measure with a hypothetical alternative measure remains at a conceptual level. Thus, the fact that a measure with the same or similar content as the proposed alternative already exists in the legislative framework of the respondent Member does not change the function of the alternative measure as a 'conceptual tool' in the necessity analysis. Therefore, as part of making a *prima facie* case, the complainant should provide sufficient indication that the proposed alternative would be reasonably available to the implementing Member, for instance by showing that the costs of the proposed alternatives would not be *a priori* prohibitive, and that potential technical difficulties associated with their implementation would not be of such a substantial nature that they would render the proposed alternatives merely theoretical in nature. The burden would then shift to the respondent to submit evidence substantiating that the proposed alternative measures were indeed merely theoretical in nature, or entailed an undue burden, for instance, because they involved prohibitively high costs or would entail substantial technical difficulties."⁵⁶

40. After formulating its interpretation of Article 5.1.2 of the TBT Agreement, the Appellate Body in *Russia – Railway Equipment* assessed whether the Panel had failed to make an objective assessment of Article 11 of the DSU in its allocation of the burden of proof when examining the alternative measures proposed by Ukraine. The Appellate Body ultimately found that the Panel erred in its allocation of the burden of proof under Article 5.1.2 of the TBT Agreement.⁵⁷ The Appellate Body stated:

"[F]or purposes of establishing reasonable availability, the Panel had to assess whether the alternative, as described by Ukraine, was not merely theoretical in nature and *a priori* did not entail any undue burden for Russia. The Panel should have then turned to examine whether Russia had submitted evidence rebutting Ukraine's *prima facie* case by adducing specific evidence and arguments as to why, in the circumstances of this case, the alternative measure was not in fact reasonably available. The Panel, however, did not address the question whether the description of the measure provided by Ukraine was sufficient to demonstrate *prima facie* that Russia would not be incapable of taking such an alternative measure. Indeed, the Panel should have considered the implications of the fact that the proposed measure already existed as a possible alternative to on-site inspections in Russia's legislation and the extent to which this fact in itself demonstrated that the measure was *prima facie* reasonably available, as opposed to merely theoretical. Instead, the Panel reasoned that, because information on the absence of non-conformities and consumer complaints was in principle available to Ukraine, it was for Ukraine to submit evidence relating to the application of these conditions to the products covered by the suspensions at issue. ...

... [W]e do not see that, for purposes of establishing the reasonable availability of the alternative measure consisting in the conduct of off-site inspections, it was necessary for Ukraine to provide information about the compliance with the two requirements of [the measure at issue], namely, the absence of non-conformities and consumer complaints, with respect to the railway products covered by the suspensions at issue.

⁵⁴ Appellate Body Report, *Russia – Railway Equipment*, para. 5.196 (quoting Appellate Body Reports, *US – COOL (Article 21.5 – Canada and Mexico)*, para. 5.328).

⁵⁵ Appellate Body Report, *Russia – Railway Equipment*, para. 5.196.

⁵⁶ Appellate Body Report, *Russia – Railway Equipment*, para. 5.197 (referring to Appellate Body Reports, *US – COOL (Article 21.5 – Canada and Mexico)*, para. 5.339). See also *ibid.* para. 5.206.

⁵⁷ Appellate Body Report, *Russia – Railway Equipment*, para. 5.201.

However, the majority of the Panel's findings that Ukraine failed to demonstrate the availability of off-site inspections ... for the railway products covered by instructions 1 to 14 are based on *the absence of evidence* on record regarding non-conformities and consumer complaints concerning these products. This was so even in those cases where it remained unclear whether evidence on inconsistencies related to the products at issue or where evidence showed no non-conformities in the most recent inspection control but there was no evidence of consumer complaints with respect to the same products. Therefore, the burden of proof that the Panel placed on Ukraine went beyond what Ukraine was required to establish in making a *prima facie* case that a hypothetical measure ... would have been reasonably available to Russia in the circumstances of the case."⁵⁸

1.5 Article 5.2.1

41. In the context of a finding declared "moot and of no legal effect" by the Appellate Body, the Panel in *EC – Seal Products* examined whether the CAP at issue was "undertaken and completed as expeditiously as possible" under Article 5.2.1.⁵⁹ The Panel first examined the relationship between Articles 5.1 and 5.2 and noted:

"The chapeau of Article 5.2 directly references Article 5.1 and clarifies the relationship between the obligations in the sub-paragraphs of the two provisions. Specifically, Article 5.2 provides that '[w]hen *implementing* the provisions of' Article 5.1, Members must adhere to the specific obligations laid out in the sub-paragraphs of Article 5.2 with respect to the implementation of the CAP."⁶⁰

42. With respect to the precise point in time when the obligation to "undertake and complete" a CAP is triggered during the implementation process of a CAP, the Panel considered:

"In our view, the chapeau of Article 5.2 dictates that the detailed obligations of the sub-paragraphs are confined to the *implementation* of the more general obligations under Article 5.1. While Article 5.1.2 covers the entire process in which a CAP is 'prepared, adopted or applied', Article 5.2.1 applies only to the implementation stage of the process. This means that the obligations of Article 5.2 are not coterminous with those of Article 5.1, but limited to the application of a CAP."⁶¹

43. The Panel further noted that Annex C(1)(a) of the SPS Agreement contains a similar obligation to the one contained in Article 5.2.1 of the TBT Agreement and agreed with the parties that:

"[T]here are certain parallels in the terms and scope of Article 5.2.1 of the TBT Agreement and Annex C(1)(a) of the SPS Agreement. Both provisions pertain to procedures adopted to ensure fulfilment of specific requirements contained in a measure falling under the TBT Agreement or the SPS Agreement, respectively."⁶²⁶³

44. Based upon the relevant text and context of Article 5.2.1, and "consistent with the interpretive guidance of the same phrase in the SPS Agreement"⁶⁴, the Panel considered that

⁵⁸ Appellate Body Report, *Russia – Railway Equipment*, paras. 5.199-5.200.

⁵⁹ Panel Reports, *EC – Seal Products*, paras. 7.548-7.580; and Appellate Body Reports, *EC – Seal Products*, para. 6.1.

⁶⁰ Panel Reports, *EC – Seal Products*, para. 7.556.

⁶¹ Panel Reports, *EC – Seal Products*, para. 7.559.

⁶² (*footnote original*) There is also overlap in the indicative terms provided in the explanatory notes for "conformity assessment procedures" under the TBT Agreement and "control, inspection and approval procedures" under the SPS Agreement. In particular, these terms and their explanatory notes coincide with respect to "sampling", "testing", and "inspection", and the inclusion of "*inter alia*" to indicate the non-exhaustive nature of the list.

⁶³ Panel Reports, *EC – Seal Products*, para. 7.561.

⁶⁴ Panel Reports, *EC – Seal Products*, para. 7.562 (quoting Panel Report, *EC – Approval and Marketing of Biotech Products*, para. 7.1494).

"undertaken and completed" in Article 5.2.1 applies to the implementation of a CAP from the moment when an application for recognition has been received and through the completion of the process.⁶⁵

45. With respect to the meaning of the word "expeditiously" in Article 5.2.1, the Panel considered as follows:

"Further, we observe that the adverb 'expeditiously' indicates that the obligation relates to the speed and/or timing of the performance of a CAP. At the same time, the term 'expeditiously' is qualified by the phrase 'as possible'. We take this qualification to be based on the fundamental purpose of any CAP to secure 'a positive assurance of conformity with technical regulations', and recognition that doing so may necessarily entail some time to determine that relevant requirements are fulfilled.

In this connection, we also take note of the interpretation by the panel in *EC – Approval and Marketing of Biotech Products* of the phrase 'without undue delay' to mean that approval procedures were required to be undertaken and completed 'with no unjustifiable loss of time'. The panel similarly accounted for the function of approval procedures to check and ensure fulfilment of SPS requirements, and reasoned on this basis that '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'.

We agree with the approach of the panel in *EC – Approval and Marketing of Biotech Products*. While the duty of expeditious conformity assessment prescribed in Article 5.2.1 must be carried out so as not to create an unnecessary obstacle to trade, such duty of the regulating Members must be balanced against the regulating Members' need and practical ability to make an adequate conformity assessment. Therefore, in our view, Article 5.2.1 permits the time that is reasonably required to assess conformity with technical requirements."⁶⁶

1.6 Article 5.2.2

1.6.1 General

46. The Panel in *Russia – Railway Equipment* noted that pursuant to Article 5.2, the obligations set out in Article 5.2.2 apply to the type of conformity assessment procedures covered by Article 5.1, that is, conformity assessment procedures applied by central government bodies and providing for mandatory conformity assessment procedures.⁶⁷

47. In *Russia – Railway Equipment*, the Panel noted that Article 5.2.2 stipulates five distinct procedural obligations that the competent body of the central government must fulfil.⁶⁸ Ukraine raised claims against Russia's measures in respect of the competent body's obligations to: (a) promptly examine the completeness of the documentation and informing the applicant in a precise and complete manner of all deficiencies (second obligation) and (b) transmitting as soon as possible the results of the conformity assessment in a precise and complete manner to the applicant so that corrective action may be taken (third obligation).⁶⁹ The Panel thus provided an interpretation of the second and third obligations stipulated in Article 5.2.2.

1.6.2 Second obligation

48. The Panel in *Russia – Railway Equipment* noted that the second obligation in Article 5.2.2 focuses on the completeness of the documentation and thus the applicant's work. This provision assumes that the competent body may require that applicants submit documents establishing the conformity of their products. The Panel described the obligation in the second sentence as follows:

⁶⁵ Panel Reports, *EC – Seal Products*, para. 7.563.

⁶⁶ Panel Reports, *EC – Seal Products*, paras. 7.564-7.566.

⁶⁷ Panel Report, *Russia – Railway Equipment*, para. 7.553.

⁶⁸ Panel Report, *Russia – Railway Equipment*, para. 7.553.

⁶⁹ Panel Report, *Russia – Railway Equipment*, paras. 7.546 and 7.765.

"The second obligation imposes a twofold duty on the competent body that arises as soon as it has received an application. First, the competent body must examine whether the documentation is complete, that is, whether the applicant has submitted all required documents. Second, the competent body must inform the applicant of all deficiencies. As the competent body has only examined the completeness of the documentation at this stage, the 'deficiency' of an application in our view relates to a shortcoming affecting the application or incomplete documentation."⁷⁰

49. Regarding the competent body's obligation to "promptly examine[] [the application] ... and inform[] the applicant", the Panel in *Russia – Railway Equipment* observed:

"[T]he adverb 'promptly' qualifies both the verb 'examine' and the verb 'inform'. Otherwise the obligation to examine completeness promptly would be ineffective, as the competent body could delay informing the applicant of deficiencies. We note that 'promptly' means 'quickly' and 'without undue delay'. Whether the competent body has acted promptly will depend on the circumstances and must be assessed on a case-by-case basis."⁷¹

50. Regarding the competent body's obligation to inform the applicant in a "precise and complete manner" of all deficiencies of the application, the Panel in *Russia – Railway Equipment* noted:

"We consider that it must be assessed on a case-by-case basis whether the competent body has informed the applicant in a 'precise and complete manner'. We note, however, that the obligation to provide precise and complete information is unqualified. The competent body must always inform the applicant in a precise and complete manner. Even if the competent body considers that the applicant would know how to correctly complete a deficient application if it received less than precise and complete information, the competent body is still required to provide precise and complete information. The standard for assessing whether information provided is precise and complete is thus an objective one and not a subjective one that will vary from one applicant to another. This understanding also prevents disagreements between competent bodies and applicants, and it facilitates review by a review body."⁷²⁷³

1.6.3 Third obligation

51. The Panel in *Russia – Railway Equipment* noted that the third obligation focuses on the "results of the assessment" and thus the competent body's work. According to the Panel, the obligation to inform the applicant so that corrective action may be taken if necessary, refers to corrective action to be taken by the applicant. The Panel exemplified that "if for instance, the result of an inspection at the site of facilities was negative (non-conformity), the applicant would want to take the necessary steps to address the inspectors' concerns."⁷⁴

52. The Panel in *Russia – Railway Equipment* observed that the phrase "in a precise and complete manner" in the third obligation, should be interpreted in the same way as in the second obligation in Article 5.2.2, as an objective standard.⁷⁵

53. The Panel in *Russia – Railway Equipment* discussed the meaning of the phrase "the results of the assessment" in connection with the competent body's obligation to inform the applicant of such results. The Panel examined whether such obligation was limited to the final result of the conformity assessment, to independent results that are part of separate stages of a conformity assessment procedure or situations where there cannot be a substantive result. The Panel noted:

"The 'assessment' referred to is the 'conformity assessment', which is confirmed by the fourth obligation in Article 5.2.2 (which uses the term 'conformity assessment'). Article

⁷⁰ Panel Report, *Russia – Railway Equipment*, para. 7.554.

⁷¹ Panel Report, *Russia – Railway Equipment*, para. 7.555.

⁷² (footnote original) Under Article 5.2.8, Members are required to put in place a procedure for the review of complaints concerning the operation of a conformity assessment procedure.

⁷³ Panel Report, *Russia – Railway Equipment*, paras. 7.556-7.557.

⁷⁴ Panel Report, *Russia – Railway Equipment*, para. 7.558.

⁷⁵ Panel Report, *Russia – Railway Equipment*, para. 7.559.

5.1.1, second sentence, of the TBT Agreement makes clear that conformity assessment entails various 'conformity assessment activities'. Annex 1.3 of the TBT Agreement has an explanatory note that indicates that some of those include sampling, testing, inspection, evaluation, verification and assurance of conformity. These activities may be combined in a single conformity assessment procedure, and at least some of these activities may yield independent results. We understand that, in that sense, conformity assessment procedures may yield multiple results that may become available at different times of the process. We note in this connection that the third obligation requires that competent bodies transmit the results 'as soon as possible', 'so that corrective action may be taken if necessary'.

This dispute presents the issue of what counts as a 'result' that must be transmitted. We note that the dictionary defines the meaning of 'result' as, *inter alia*, 'outcome'. There can be no question that affirmative or negative substantive outcomes of an assessment (conformity or non-conformity) are 'results' that must be transmitted. Situations may arise, however, as in this dispute, where a relevant assessment activity that in principle would yield an independent substantive result cannot be undertaken or completed. This may be, for instance, because of circumstances that make it impossible to carry out the relevant assessment activity or a need for additional information (which may arise even where the documentation accompanying an application was complete). In such situations, there is no substantive 'yes' (conformity) or 'no' (non-conformity) result. However, the attempted or incomplete assessment has still yielded an outcome, which is that no substantive outcome is possible, at least for the time being. We consider that such an outcome is, also, a 'result' of an assessment that must be transmitted.

Were it otherwise, a competent body could delay sharing information with the applicant about an outcome even in situations where the competent body cannot proceed with the assessment and where the applicant could take corrective action. This would be at odds with the purpose of the third obligation, which is, *inter alia*, to enable applicants to initiate corrective action promptly."⁷⁶

1.6.4 Relationship between the second and third obligations

54. The Panel in *Russia – Railway Equipment* explained that while the second obligation in Article 5.2.2 focuses on the applicant's work (completeness of the application), the third obligation focuses on the competent body's work (results of the assessment). Regarding the relationship between those two obligations, the Panel noted that:

"In the ordinary course of events – and the sequence in which the two obligations appear in Article 5.2.2 reflects this – the competent body will first satisfy itself that an application is complete, and if it is, it will then proceed with the conformity assessment and transmit the results of its assessment to the applicant as soon as possible.

However, nothing in Article 5.2.2 indicates that the third obligation comes into being only once the competent body has finished its examination of the completeness of the documentation submitted by the applicant. The third obligation states, without qualification, that the competent body must transmit as soon as possible the results of its assessment so that corrective action may be taken. Consequently, the competent body must inform the applicant as soon as possible after any results become available, even if this is before the competent body has been able to finish its examination of the completeness of the documentation. As we have said above, the results to be transmitted would also include 'no substantive outcome' results."⁷⁷

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⁷⁶ Panel Report, *Russia – Railway Equipment*, paras. 7.561-7.562.

⁷⁷ Panel Report, *Russia – Railway Equipment*, paras. 7.563-7.564.