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1 ANNEX 1

1.1 Text of Annex 1

ANNEX 1

TERMS AND THEIR DEFINITIONS FOR THE PURPOSE OF THIS AGREEMENT

The terms presented in the sixth edition of the ISO/IEC Guide 2: 1991, General Terms and Their Definitions Concerning Standardization and Related Activities, shall, when used in this Agreement, have the same meaning as given in the definitions in the said Guide taking into account that services are excluded from the coverage of this Agreement.

For the purpose of this Agreement, however, the following definitions shall apply:

1. *Technical regulation*

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Explanatory note

The definition in ISO/IEC Guide 2 is not self-contained, but based on the so-called "building block" system.

2. *Standard*

Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Explanatory note

The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This Agreement deals only with technical regulations, standards and conformity assessment procedures related to products or processes and production methods. Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. This Agreement covers also documents that are not based on consensus.

3. *Conformity assessment procedures*

Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Explanatory note

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.

4. *International body or system*

Body or system whose membership is open to the relevant bodies of at least all Members.

5. *Regional body or system*

Body or system whose membership is open to the relevant bodies of only some of the Members.

6. *Central government body*

Central government, its ministries and departments or any body subject to the control of the central government in respect of the activity in question.

Explanatory note:

In the case of the European Communities the provisions governing central government bodies apply. However, regional bodies or conformity assessment systems may be established within the European Communities, and in such cases would be subject to the provisions of this Agreement on regional bodies or conformity assessment systems.

7. *Local government body*

Government other than a central government (e.g. states, provinces, Länder, cantons, municipalities, etc.), its ministries or departments or any body subject to the control of such a government in respect of the activity in question.

8. *Non-governmental body*

Body other than a central government body or a local government body, including a non-governmental body which has legal power to enforce a technical regulation.

1.2 General

1. The Appellate Body in *US – Tuna II (Mexico)* observed that the use of the word "however" in the introductory clause of Annex 1 "indicates that the definitions contained in Annex 1 to the

TBT Agreement prevail to the extent that they depart from the definitions set out in the ISO/IEC Guide 2: 1991."¹

1.3 Annex 1.1: "technical regulation"

1.3.1 Three-tier test

2. In *EC – Asbestos* and *EC – Sardines*, the Appellate Body established a three-tier test for determining whether a measure is a "technical regulation" under the TBT Agreement, which has been followed by panels and the Appellate Body in subsequent cases²:

"First, the document must apply to an identifiable product or group of products. The *identifiable* product or group of products need not, however, be expressly *identified* in the document. *Second*, the document must lay down one or more characteristics of the product. These product characteristics may be intrinsic, or they may be related to the product. They may be prescribed or imposed in either a positive or a negative form. *Third*, compliance with the product characteristics must be mandatory. As we stressed in *EC – Asbestos*, these three criteria are derived from the wording of the definition in Annex 1.1."³

1.3.2 "identifiable product or group of products"

3. In *EC – Asbestos*, the Appellate Body elaborated on the first element of the definition of a "technical regulation":

"A 'technical regulation' must, of course, be applicable to an *identifiable* product, or group of products. Otherwise, enforcement of the regulation will, in practical terms, be impossible. This consideration also underlies the formal obligation, in Article 2.9.2 of the *TBT Agreement*, for Members to notify other Members, through the WTO Secretariat, of 'the *products to be covered*' by a proposed 'technical regulation'. (emphasis added) Clearly, compliance with this obligation requires identification of the product coverage of a technical regulation. However, in contrast to what the Panel suggested, this does not mean that a 'technical regulation' must apply to '*given*' products which are actually *named, identified or specified* in the regulation. (emphasis added) Although the *TBT Agreement* clearly applies to 'products' generally, nothing in the text of that Agreement suggests that those products need be named or otherwise *expressly* identified in a 'technical regulation'. Moreover, there may be perfectly sound administrative reasons for formulating a 'technical regulation' in a way that does *not* expressly identify products by name, but simply makes them identifiable – for instance, through the 'characteristic' that is the subject of regulation."⁴

1.3.3 "one or more product characteristics"

1.3.3.1 General

4. In *EC – Asbestos*, the Appellate Body stated that "[t]he heart of the definition of a 'technical regulation' is that a 'document' must 'lay down' – that is, set forth, stipulate or provide – 'product *characteristics*'".⁵ The Appellate Body explained that the term "product characteristics" in Annex 1.1 of the TBT Agreement should be interpreted in accordance with its ordinary meaning:

"The word 'characteristic' has a number of synonyms that are helpful in understanding the ordinary meaning of that word, in this context. Thus, the 'characteristics' of a

¹ Appellate Body Report, *US – Tuna II*, para. 354 (referring to Appellate Body Report, *EC – Sardines*, paras. 224 and 225).

² See Panel Reports, *EC – Seal Products*, paras. 7.85-7.87; *US – COOL*, paras. 7.147-7.148; *US – Tuna II (Mexico)*, paras. 7.53-7.55; and *US – Clove Cigarettes*, paras. 7.24-7.25. See also Appellate Body Reports, *EC – Seal Products*, paras. 5.21-5.23; and *US – Tuna II (Mexico)*, para. 183.

³ Appellate Body Report, *EC – Sardines*, para. 176 (referring to Appellate Body Report, *EC – Asbestos*, paras. 66-70).

⁴ Appellate Body Report, *EC – Asbestos*, para. 70.

⁵ Appellate Body Report, *EC – Asbestos*, para. 67.

product include, in our view, any objectively definable 'features', 'qualities', 'attributes', or other 'distinguishing mark' of a product. Such 'characteristics' might relate, *inter alia*, to a product's composition, size, shape, colour, texture, hardness, tensile strength, flammability, conductivity, density, or viscosity. In the definition of a 'technical regulation' in Annex 1.1, the *TBT Agreement* itself gives certain examples of 'product characteristics' – 'terminology, symbols, packaging, marking or labelling requirements'. These examples indicate that 'product characteristics' include, not only features and qualities intrinsic to the product itself, but also related 'characteristics', such as the means of identification, the presentation and the appearance of a product."⁶

5. In *EC – Sardines*, the Appellate Body recalled the above-quoted passage, and emphasized that product characteristics include not only "features and qualities intrinsic to the product", but also those that are related to it, such as means of identification.⁷

6. The Appellate Body in *EC – Seal Products* noted that the definition of a technical regulation provides that such a regulation may prescribe "product characteristics or their related processes and production methods" and elaborated on the meaning of "their related processes and production methods" (PPMs):

"The definition of a technical regulation further provides that such a regulation may prescribe 'product characteristics or their related [PPMs]'. The use here of the disjunctive 'or' indicates that "related [PPMs]" may play an additional or alternative role vis-à-vis 'product characteristics' under Annex 1.1. The noun 'process' is ordinarily understood to refer to 'a course of action, a procedure, a series of actions or operations directed to some end, as in manufacturing'. We further note that the dictionary defines the term 'production' as '[t]he process of being manufactured commercially, esp. in large quantities', while the word 'method' is defined as 'a (defined or systematic) way of doing a thing'. The ordinary meaning of the term 'related' is '[h]aving relation; having mutual relation; connected'. A plain reading of Annex 1.1 thus suggests that a 'related' PPM is one that is 'connected' or 'has a relation' to the characteristics of a product. The word 'their', which immediately precedes the words 'related processes and production methods', refers back to 'product characteristics'. Thus, in the context of the first sentence of Annex 1.1, we understand the reference to 'or their related processes and production methods' to indicate that the subject matter of a technical regulation may consist of a process or production method that is *related* to product characteristics. In order to determine whether a measure lays down related PPMs, a panel thus will have to examine whether the processes and production methods prescribed by the measure have a sufficient nexus to the characteristics of a product in order to be considered related to those characteristics."⁸

7. In *EC – Seal Products*, the Appellate Body also provided its understanding of "applicable administrative provisions" referred to in Annex 1.1:

"Continuing with our review of the first sentence of Annex 1.1, we note the reference to 'applicable administrative provisions', which is linked to the words 'product characteristics or their related processes and production methods' by the conjunctive 'including'. The word 'provision' is relevantly defined as 'a legal or formal statement providing for some particular matter'. The adjective 'administrative', in turn, is defined as '[p]ertaining to management of affairs'. The term 'applicable' in this context indicates that the relevant 'administrative provisions' must 'refer' to or be 'relevant' to the product characteristics or their related PPMs as prescribed in the relevant document. The word 'including' suggests that, where a mandatory document laying down product characteristics or their related processes and production methods also contains 'administrative provisions' that refer to those 'product characteristics' or 'related processes and production methods', those administrative provisions are to be

⁶ Appellate Body Report, *EC – Asbestos*, para. 67.

⁷ Appellate Body Report, *EC – Sardines*, para. 189 (quoting Appellate Body Report, *EC – Asbestos*, para. 67).

⁸ Appellate Body Reports, *EC – Seal Products*, para. 5.12.

considered as an integral part of the technical regulation and are thus subject to the substantive provisions of the TBT Agreement. In the context of Annex 1.1, we understand the appositive clause 'including the applicable administrative provisions' to refer to provisions to be applied by virtue of a governmental mandate in relation to either product characteristics or their related processes and production methods."⁹

8. The Appellate Body in *EC – Seal Products* also observed that "[t]o the extent that the essential and integral aspects" of the measure "do not set out product characteristics, it follows that their related administrative provisions cannot be characterized as being applicable to product characteristics".¹⁰

9. In *Australia – Tobacco Plain Packaging*, the Panel considered in detail whether Australia's tobacco plain packaging measures "lay down product characteristics for tobacco products". In the course of its analysis, the Panel opined that requirements concerning the "appearance" and "packaging" of products could be said to "lay down product characteristics".¹¹ Further, the Panel found that the term "characteristics" is "sufficiently broad to encompass requirements relating to terminology, marking or labelling that affect the manner in which a sign, including one that is protected as a trademark, may be displayed on the relevant product".¹² Quoting the Panel in *EC – Trademarks and Geographical Indications (Australia)*, the Panel emphasized that "[t]he issue is not whether the content of the label refers to a product characteristic: the label on a product *is* a product characteristic".¹³

1.3.3.2 In a negative form

10. The measures at issue in *EC – Asbestos* and *EC – Sardines* both laid down product characteristics in a negative form, and both were found to be "technical regulations" within the meaning of Annex 1.1 of the TBT Agreement. In *EC – Asbestos*, the Appellate Body found that the measure at issue was "formulated *negatively* – products containing asbestos are prohibited", and that "in effect, the measure provides that *all* products must *not* contain asbestos fibres".¹⁴ The Appellate Body explained that:

"Product characteristics' may, in our view, be prescribed or imposed with respect to products in either a positive or a negative form. That is, the document may provide, positively, that products *must possess* certain 'characteristics', or the document may require, negatively, that products *must not possess* certain 'characteristics'".¹⁵

11. In *EC – Sardines*, the Panel found that by requiring the use of only the species *Sardina pilchardus* as preserved sardines, the measure at issue "in effect lays down product characteristics in a negative form".¹⁶ The Appellate Body agreed with the Panel's overall conclusion that the measure at issue laid down product characteristics.¹⁷

1.3.4 "mandatory"

12. In *EC – Asbestos*, the Appellate Body made the following observations about the requirement that a document lay down product characteristics with which compliance is "mandatory":

"The definition of a 'technical regulation' in Annex 1.1 of the *TBT Agreement* also states that '*compliance*' with the 'product characteristics' laid down in the 'document'

⁹ Appellate Body Reports, *EC – Seal Products*, para. 5.13.

¹⁰ Appellate Body Reports, *EC – Seal Products*, para. 5.52.

¹¹ Panel Reports, *Australia – Tobacco Plain Packaging*, paras. 7.142 and 7.145.

¹² Panel Reports, *Australia – Tobacco Plain Packaging*, para. 7.149.

¹³ Panel Reports, *Australia – Tobacco Plain Packaging*, para. 7.151 (citing Panel Report, *EC – Trademarks and Geographical Indications (Australia)*, para. 7.449).

¹⁴ Appellate Body Report, *EC – Asbestos*, para. 72.

¹⁵ Appellate Body Report, *EC – Asbestos*, para. 69.

¹⁶ Panel Report, *EC – Sardines*, para. 7.45.

¹⁷ Appellate Body Report, *EC – Sardines*, para. 193.

must be '*mandatory*'. A 'technical regulation' must, in other words, regulate the 'characteristics' of products in a binding or compulsory fashion."¹⁸

13. In *EC – Sardines*, both the Panel and the Appellate Body concluded that the measure at issue set forth product characteristics that were "mandatory". The conclusion was based on the fact that the measure at issue stated that the requirements contained therein were "binding in its entirety and directly applicable in all Member States".¹⁹

14. The Panel in *EC – Trademarks and Geographical Indications (Australia)* noted that the word "mandatory" means "obligatory in consequence of a command, compulsory".²⁰

15. In assessing whether compliance with the Vilsack letter was mandatory, the Panel in *US – COOL* observed that "[o]n its face, the Vilsack letter is clearly not mandatory". However, the Panel held that "the nature of compliance with the Vilsack letter is not a merely formalistic question":

"On its face, the Vilsack letter is clearly not mandatory. Unlike the instruments composing the COOL measure, the Vilsack letter is not a piece of legislation or regulation legally binding in US law. In outlining action by industry, the Vilsack letter uses permissive, hortatory terms such as 'might', 'should' and 'would'; it mentions the word 'voluntary' at least four times; and it notes that it contains 'suggestions for voluntary action'. It is also not followed up by a classic legal enforcement mechanism.

But the nature of compliance with the Vilsack letter is not a merely formalistic question. We agree with the complainants that this matter should not be decided purely on the basis of the language in the Vilsack letter, in particular the use of the word 'voluntary'. Adopting a formalistic interpretation of the phrase 'with which compliance is mandatory' would allow Members to escape the coverage of large portions of the TBT Agreement merely by qualifying their own measures as non-mandatory, or compliance with such measures as voluntary. This would strip Annex 1.1 and ultimately large portions of the TBT Agreement of their *effet utile*.

It would also be contrary to the clarification made by the Appellate Body with respect to the mandatory compliance criterion of a technical regulation: a regulation that has the *effect* of prescribing or imposing one or more 'characteristics' could also qualify as a technical regulation under Annex 1.1. The question therefore remains whether compliance with the Vilsack letter may be considered *de facto* mandatory; namely, whether, in the words of the Appellate Body, 'with respect to products' the Vilsack letter 'has the *effect* of prescribing or imposing one or more 'characteristics' – 'features', 'qualities', 'attributes', or other 'distinguishing mark'. "²¹

16. The Panel in *Australia – Tobacco Plain Packaging* confirmed that "the enforceability of a measure through sanctions, in particular criminal sanctions, [is] indicative of mandatory compliance". The Panel further noted that "the fact that certain measures are legally enforceable and binding under [a Member's] law ... is an important component of the 'mandatory' character of the measures".²²

17. In *US – Tuna II (Mexico)*, the Appellate Body agreed with the Panels' conclusion that the US "dolphin-safe" labelling provisions established "labelling requirements, compliance with which is mandatory" and therefore constituted a "technical regulation".²³ The Appellate Body also provided a general observation on how panels should assess whether a measure constitutes a technical regulation, in light of the third element of the three-tier test:

"[A] panel's determination of whether a particular measure constitutes a technical regulation must be made in the light of the characteristics of the measure at issue and

¹⁸ Appellate Body Report, *EC – Asbestos*, para. 68.

¹⁹ Panel Report, *EC – Sardines*, para. 7.30; and Appellate Body Report, *EC – Sardines*, para. 194.

²⁰ Panel Report, *EC – Trademarks and Geographical Indications (Australia)*, para. 7.453.

²¹ Panel Reports, *US – COOL*, paras. 7.174-7.176.

²² Panel Reports, *Australia – Tobacco Plain Packaging*, para. 7.168.

²³ Panel Report, *US – Tuna II (Mexico)*, paras. 7.145 and 7.188; and Appellate Body Report, *US – Tuna II (Mexico)*, para. 199.

the circumstances of the case. In some cases, this may be a relatively straightforward exercise. In others, the task of the panel may be more complex. Certain features exhibited by a measure may be common to both technical regulations falling within the scope of Article 2 of the *TBT Agreement* and, for example, standards falling under Article 4 of that Agreement. Both types of measure could, for instance, contain conditions that must be met in order to use a label. In both cases, those conditions could be 'compulsory' or 'binding' and 'enforceable'. Such characteristics, taken alone, cannot therefore be dispositive of the proper legal characterization of the measure under the *TBT Agreement*. Instead, it will be necessary to consider additional characteristics of the measure in order to determine the disciplines to which it is subject under that Agreement. This exercise may involve considering whether the measure consists of a law or a regulation enacted by a WTO Member, whether it prescribes or prohibits particular conduct, whether it sets out specific requirements that constitute the sole means of addressing a particular matter, and the nature of the matter addressed by the measure."²⁴

18. In response to the United States' argument that compliance with a labelling requirement is not mandatory in situations where producers retain the option of not using the label but nevertheless are able to sell the product on the market, the Appellate Body in *US – Tuna II (Mexico)* stated:

"The text of Annex 1.1 to the *TBT Agreement* does not use the words 'market' or 'territory'. Nor does it indicate that a labelling requirement is 'mandatory' *only* if there is a requirement to use a particular label in order to place a product for sale on the market. To us, the mere fact that there is no requirement to use a particular label in order to place a product for sale on the market does not preclude a finding that a measure constitutes a 'technical regulation' within the meaning of Annex 1.1. Instead, in the context of the present case, we attach significance to the fact that, while it is possible to sell tuna products without a 'dolphin-safe' label in the United States, any 'producer, importer, exporter, distributor or seller' of tuna products must comply with the measure at issue in order to make any 'dolphin-safe' claim."²⁵

19. With respect to the measure at issue in *US – Tuna II (Mexico)*, the Appellate Body found:

"[T]he US measure is composed of legislative and regulatory acts of the US federal authorities and includes administrative provisions. In addition, the measure at issue sets out a single and legally mandated definition of a 'dolphin-safe' tuna product and disallows the use of other labels on tuna products that do not satisfy this definition. In doing so, the US measure prescribes in a broad and exhaustive manner the conditions that apply for making any assertion on a tuna product as to its 'dolphin-safety', regardless of the manner in which that statement is made. As a consequence, the US measure covers the entire field of what 'dolphin-safe' means in relation to tuna products. For these reasons, we *find* that the Panel did not err in characterizing the measure at issue as a 'technical regulation' within the meaning of Annex 1.1 to the *TBT Agreement*."²⁶

1.3.5 Need to consider measure as a whole

20. In *EC – Asbestos*, the complainant (Canada) contended that the TBT Agreement applied to the measure at issue, because it was a "technical regulation" within the meaning of Annex 1, paragraph 1. The measure contained a general prohibition on the importation, marketing and use of asbestos, but provided for a few limited exceptions to this ban. The Panel rejected Canada's argument and held that "the part of the Decree relating to the ban on imports of asbestos and asbestos-containing products" did not constitute a "technical regulation".²⁷ The Appellate Body reversed the Panel's finding and held that it was necessary to consider the measure at issue in its entirety, i.e. both "the prohibitive and the permissive elements that are part of it":

²⁴ Appellate Body Report, *US – Tuna II (Mexico)*, para. 188.

²⁵ Appellate Body Report, *US – Tuna II (Mexico)*, para. 196.

²⁶ Appellate Body Report, *US – Tuna II (Mexico)*, para. 199.

²⁷ Panel Report, *EC – Asbestos*, para. 8.72(a).

"[T]he proper legal character of the measure at issue cannot be determined unless the measure is examined as a whole ... the scope and generality of those prohibitions can only be understood in light of the exceptions to it which, albeit for a limited period, *permit, inter alia*, the use of certain product products containing asbestos and, principally, products containing chrysotile asbestos fibres. The measure is, therefore, *not* a *total* prohibition on asbestos fibres, because it also includes provisions that *permit*, for a limited duration, the use of asbestos in certain situations. Thus, to characterize the measure simply as a general prohibition, and to examine it as such, overlooks the complexities of the measure, which include both prohibitive and permissive elements. In addition, we observe that the exceptions in the measure would have no autonomous legal significance in the absence of the prohibitions. We, therefore, conclude that the measure at issue is to be examined as an integrated whole, taking into account, as appropriate, the prohibitive and the permissive elements that are part of it."²⁸

21. In *EC – Seal Products*, the Panel found that the measure at issue (the EU Seal Regime) comprised both prohibitive and permissive aspects: (i) a prohibition of all seal products, whether they are made exclusively of seal or contain seal as an input (prohibitive aspect); and (ii) an exception with regard to the import and/or placing on the market of seal products in three situations, namely when they result from IC hunts, MRM hunts, or in the case of Travellers imports (the permissive aspect).²⁹ The Panel considered that the Appellate Body's analysis of the measure at issue in *EC – Asbestos* does not suggest that for a measure consisting of a ban and certain exceptions to qualify as a technical regulation, both the prohibition and the exceptions must individually lay down product characteristics or their related PPMs.³⁰ The Panel found that the prohibition on seal-containing products under the EU Seal Regime lays down a product characteristic in the negative form by requiring that all products not contain seal, and concluded that the EU Seal Regime was a technical regulation.³¹

22. The Appellate Body disagreed with the Panel's approach and considered that the Panel should have sought to identify the "integral and essential" aspects of the measure as a whole before reaching a final conclusion as to its legal characterization:

"As noted, the Appellate Body has emphasized that a determination of whether a measure constitutes a technical regulation 'must be made in the light of the characteristics of the measure at issue and the circumstances of the case'. In *EC – Asbestos*, the Appellate Body placed particular emphasis on the 'integral and essential' aspects of the measure, 'taking into account, as appropriate, the prohibitive and the permissive elements that are part of it'.³² In order to determine the proper legal characterization of the EU Seal Regime, the Panel should therefore have examined the design and operation of the measure while seeking to identify its 'integral and essential' aspects before reaching a final conclusion as to the legal characterization of the measure in respect of, and having considered, the measure as a whole. Although a measure that comprises, among other elements, a prohibition of seal-containing products may include a component that appears to prescribe product characteristics, we consider the Panel to have erred, to the extent it reached a final conclusion as to the legal character of the measure on the basis of an examination of the aspect of the EU Seal Regime that sets out a 'prohibition on seal-containing products' taken alone. The Panel could not have properly reached a conclusion as to the legal character of

²⁸ Appellate Body Report, *EC – Asbestos*, para. 64.

²⁹ Panel Reports, *EC – Seal Products*, paras. 7.54 and 7.105.

³⁰ Panel Reports, *EC – Seal Products*, paras. 7.99-7.100 (referring to Appellate Body Report, *EC – Asbestos*, paras. 64 and 75).

³¹ Panel Reports, *EC – Seal Products*, paras. 7.106 and 7.125.

³² (footnote original) Appellate Body Report, *EC – Asbestos*, para. 64. In reaching this conclusion, the Appellate Body took into account the content of Canada's request for the establishment of a panel (i.e. Canada's identification of the Decree concerned as "the measure at issue") as well as the content of the measure itself (consisting of prohibitions and limited exceptions). The Appellate Body then examined each component (i.e. prohibitions and exceptions) of the measure before making an overall assessment of whether the measure, viewed as an integrated whole, was a "technical regulation" within the meaning of Annex 1.1.

the measure at issue without analysing the weight and relevance of the essential and integral elements of the measure as an integrated whole."³³

23. The Appellate Body in *EC – Seal Products* was unpersuaded that the prohibition on the placing on the EU market of seal-containing products constituted "the main feature of the measure at issue" and found that "the measure as a whole" did not lay down product characteristics:

"To the extent the measure prohibits the placing on the EU market of seal-containing products, it could be seen as imposing certain 'objective features, qualities or characteristics' on all products by providing that they may not contain seal. However, as stated above, we are not persuaded that this part of the Regulation constitutes the main feature of the measure at issue. Moreover, the EU Seal Regime's prohibition of 'mixed' products differs, to a considerable extent, from the prohibitive aspects of the French Decree under *EC – Asbestos*. More importantly, as noted by the Panel, the EU Seal Regime 'consists of both prohibitive and permissive components and should be examined as such'. As we see it, when the prohibitive aspects of the EU Seal Regime are considered in the light of the IC and MRM exceptions, it becomes apparent that the measure is not concerned with banning the placing on the EU market of seal products as such. Instead, it establishes the conditions for placing seal products on the EU market based on criteria relating to the identity of the hunter or the type or purpose of the hunt from which the product is derived. We view this as the main feature of the measure. That being so, we do not consider that the measure as a whole lays down product characteristics."³⁴

1.4 Annex 1.2: "standard"

24. In the context of assessing whether Codex Stan 94 was a relevant international standard within the meaning of Article 2.4, the Panel in *EC – Sardines* observed that international standards are developed by international bodies and began by analysing whether Codex Stan 94 fell within the scope of the definition of "standard" provided in Annex 1.2 of the TBT Agreement.³⁵ Citing the definition of the term "standard" in Annex 1.2, the Panel held:

"A standard comes within the definition set out in paragraph 2 of Annex 1 of the TBT Agreement if it provides 'for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods'; compliance is not mandatory; and is approved by a 'recognized body'. We note that the parties are in agreement that Codex Stan 94 is a 'standard' and see no reason to disagree with that assessment for the purposes of this dispute. We therefore find that Codex Stan 94 is a standard within the meaning of Annex 1.2 of the TBT Agreement."³⁶

25. The Appellate Body in *EC – Sardines* agreed with the Panel's conclusion that the definition of a "standard" in Annex 1.2 does not require approval by consensus for standards adopted by a "recognized body" of the international standardization community.³⁷ The Appellate Body considered that the terms defined in Annex 1 apply for the purposes of the TBT Agreement only if their definitions depart from those the ISO/IEC Guide, and further elaborated:

"The term 'standard' is defined in the ISO/IEC Guide as follows:

Document, established by *consensus* and approved by a *recognized* body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. (emphasis original)

Thus, the definition of a 'standard' in the ISO/IEC Guide expressly includes a consensus requirement. Therefore, the logical conclusion, in our view, is that the omission of a consensus requirement in the definition of a standard in Annex 1.2 of

³³ Appellate Body Reports, *EC – Seal Products*, para. 5.29.

³⁴ Appellate Body Reports, *EC – Seal Products*, para. 5.58.

³⁵ Panel Report, *EC – Sardines*, para. 7.63.

³⁶ Panel Report, *EC – Sardines*, paras. 7.64-7.65.

³⁷ Appellate Body Report, *EC – Sardines*, para. 227.

the TBT Agreement was a deliberate choice on the part of the drafters of the TBT Agreement, and that the last two phrases of the Explanatory note were included to give effect to this choice. Had the negotiators considered consensus to be necessary to satisfy the definition of 'standard', we believe they would have said so explicitly in the definition itself, as is the case in the ISO/IEC Guide. Indeed, there would, in our view, have been no point in the negotiators adding the last sentence of the Explanatory note."³⁸

26. In *Australia – Tobacco Plain Packaging*, the Panel considered Annex 2.1 in detail.³⁹ The Panel began by considering the meaning of the term "document". It first recalled the Appellate Body's statement in *US – Tuna II (Mexico)* that the term as used in Annex 1.1 of the TBT Agreement is:

"[D]efined quite broadly as 'something written, inscribed, etc., which furnishes evidence or information upon any subject'. The use of the term 'document' could therefore cover a broad range of instruments or apply to a variety of measures".⁴⁰

27. Noting that this statement was "equally relevant" in the context of Annex 1.2, the Panel stated that:

"[T]he 'document' that constitutes a standard may take a variety of forms. It could thus be contained within an instrument that simultaneously addresses other issues, and one which, together with various other instruments, forms part of a broader context or framework".⁴¹

28. The Panel explained that because of the breadth of the term "document", a showing that a standard exists requires, as a first step, a "sufficiently clear and distinctive identification of the components or elements of the instrument(s) claimed to constitute the standard".⁴² In the Panel's view, this would be particularly important where the document allegedly constituting the standard is contained in multiple legal instruments, each of which may address more than one matter, including some that are distinct from, even if related to, the specific matter at issue in the challenged technical regulation.⁴³ The elements of the alleged standard must be identified with sufficient precision to enable a comparative assessment to be conducted between the measure at issue and the alleged standard.⁴⁴

29. Turning next to the reference in Annex 1.2 to "rules, guidelines or characteristics for products", the Panel noted that these words imply that the document(s) at issue must have a certain degree of normative content. The Panel noted that "guidelines" "would establish broad frameworks or parameters for the adoption of a given measure with a degree of flexibility", whereas "rules" "would define more clearly a norm or measure to be followed". The Panel observed that because both guidelines and rules are referenced in Annex 1.2, the fact that a document may "entail a certain degree of flexibility" would not take it outside the scope of Annex 1.2.⁴⁵

30. With respect to the reference in Annex 1.2 to "characteristics for products or related processes and production methods", the Panel held that this phrase should be given the same meaning in Annex 1.2 as it has been given in the context of Annex 1.1 of the TBT Agreement.⁴⁶

31. Finally, the Panel noted that Annex 1.2 refers to rules or guidelines "for common and repeated use". With respect to the meaning of this phrase, the Panel held that:

³⁸ Appellate Body Report, *EC – Sardines*, paras. 224-225.

³⁹ Panel Reports, *Australia – Tobacco Plain Packaging*, paras. 7.291-7.397.

⁴⁰ Appellate Body Report, *US – Tuna II (Mexico)*, para. 185 (cited in Panel Reports, *Australia – Tobacco Plain Packaging*, para. 7.293).

⁴¹ Panel Reports, *Australia – Tobacco Plain Packaging*, para. 7.293.

⁴² Panel Reports, *Australia – Tobacco Plain Packaging*, para. 7.294.

⁴³ Panel Reports, *Australia – Tobacco Plain Packaging*, para. 7.294.

⁴⁴ Panel Reports, *Australia – Tobacco Plain Packaging*, para. 7.331.

⁴⁵ Panel Reports, *Australia – Tobacco Plain Packaging*, para. 7.338.

⁴⁶ Panel Reports, *Australia – Tobacco Plain Packaging*, paras. 7.339-7.340.

"[A] document provides product characteristics (or other relevant features, such as packaging requirements) 'for common and repeated use' when these are designed for the specific purpose of being frequently shared alike by all persons or things in question, with the aim of achieving the optimum degree of order in a given context. The need for the characteristics at issue to be amenable 'for common and repeated use' further suggests that they need to possess a degree of clarity and precision sufficient to allow them to be implemented in a consistent and predictable manner, as documents lacking these attributes are unlikely to achieve the optimum degree of order required to address the 'actual or potential problem' giving rise to them. At the same time, ... the exact degree of specificity needed for such requirements to be 'for common and repeated use' can only be assessed on a case-by-case basis, depending on the type of 'problem' addressed by the document claimed to be a standard, and the 'context' under which this problem arises."⁴⁷

32. The Panel suggested that a document containing guidelines that provided a "range of options" to Members, and thus allowed different Members to implement those guidelines in ways that were "significantly different", would not meet this standard, as such a document would not contribute to achieving the "optimum degree of order", instead reflecting "flexibility".⁴⁸

1.5 Annex 1.3: "conformity assessment procedures"

33. The Panel in *EC – Trademarks and Geographical Indications (Australia)* distinguished "conformity assessment procedures" from technical regulations and standards in the context of rejecting the argument that a requirement to maintain product inspection structures was a technical regulation. Noting the definition of "conformity assessment procedures" in Annex 1.3, the Panel observed:

"This definition shows that 'conformity assessment procedures' assess conformity with 'technical regulations' and 'standards'. This suggests that they are not only distinct from one other, but mutually exclusive. Whilst a single measure can combine both a technical regulation and a procedure to assess conformity with that technical regulation, it would be an odd result if a conformity assessment procedure could fall within the definition of a technical regulation as well.

The object and purpose of the TBT Agreement is, in large part, disclosed by the two main groups of substantive provisions that it contains: one that relates to technical regulations and standards in Articles 2 to 4, and another that relates to conformity assessment procedures in Articles 5 to 9. It is also reflected in the preamble, of which the fifth recital, and also the third and fourth recitals, draw this distinction. If the Panel were to embed measures subject to Articles 5 to 9 in the definition of a technical regulation and thereby subject them to the technical regulations provisions in Articles 2 to 4 as well, it would lead to an unreasonable result. In this respect, we note that the explanatory note refers to 'procedures for ... inspection' as an example of conformity assessment procedures. This suggests that a procedure for inspection is not a technical regulation."⁴⁹

34. In the context of a finding declared by the Appellate Body "moot and of no legal effect", the Panel in *EC – Seal Products* held that the provisions establishing the procedure for determining whether specific requirements under the measure found to be a technical regulation were fulfilled, constituted conformity assessment procedures (CAP) within the meaning of the TBT Agreement:

"The Panel found that the EU Seal Regime as a whole is a technical regulation laying down product characteristics. In addition, Articles 3, 5, and 6 of the Implementing Regulation establish the procedure for determining whether the specific requirements under the EU Seal Regime are fulfilled. Accordingly, we find that these provisions

⁴⁷ Panel Reports, *Australia – Tobacco Plain Packaging*, para. 7.370.

⁴⁸ Panel Reports, *Australia – Tobacco Plain Packaging*, paras. 7.376 and 7.378.

⁴⁹ Panel Report, *EC – Trademarks and Geographical Indications (Australia)*, paras. 7.511 -7.513.

under the EU Seal Regime constitute a CAP within the meaning of the TBT Agreement."⁵⁰

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⁵⁰ Panel Reports, *EC – Seal Products*, para. 7.510; and Appellate Body Reports, *EC – Seal Products*, para. 6.1.