

*This **document** is the European Union's (EU) proposal for a legal text on technical barriers to trade in the EU-ESA5 deepening of interim agreement. It will be tabled for discussion with ESA5. The actual text in the final agreement will be a result of negotiations between the EU and ESA5.*

DISCLAIMER: *The EU reserves the right to make subsequent modifications to this text and to complement its proposals at a later stage, by modifying, supplementing or withdrawing all, or any part, at any time.*

EU PROPOSAL OF NEGOTIATING TEXT

CHAPTER X

TECHNICAL BARRIERS TO TRADE

Article X.1

Objectives

The objective of this Chapter is to facilitate trade in goods between the Parties by preventing, identifying and eliminating unnecessary technical barriers to trade.

Article X.2

Scope

This Chapter applies to the preparation, adoption and application of all standards, technical regulations and conformity assessment procedures as defined in Annex 1 of the TBT Agreement, which may affect trade in goods between the Parties.

2. *Notwithstanding paragraph 1, this Chapter does not apply to:*

- a) purchasing specifications prepared by governmental bodies for production or consumption requirements of such bodies; or*
- b) sanitary and phytosanitary measures as defined in Annex A of the SPS Agreement which are covered by Chapter XX of this Agreement.*

Article X.3

Relationship with the TBT Agreement

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1. *Articles 2 through 9 inclusive and Annexes 1 and 3 of the TBT Agreement are incorporated into and made part of this Agreement mutatis mutandis.*
2. *Terms referred to in this Agreement, shall have the same meaning in this Agreement as they have in the TBT Agreement.*

Article X.4

Technical Regulations

1. *Each Party shall carry out, in accordance with its respective rules and procedures, a regulatory impact assessment of planned technical regulations.*
2. *The Parties shall assess the available regulatory and non-regulatory alternatives to the proposed technical regulation that may fulfil the Party's legitimate objectives, in accordance with Article 2.2 of the TBT Agreement.*
3. *The Parties shall use relevant international standards as a basis for their technical regulations except when the Party developing the technical regulation can demonstrate that such international standards would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued.*
4. *If a Party has not used international standards as a basis for its technical regulations, a Party shall, on request from the other Party, identify any substantial deviation from the relevant international standard and explain the reasons why such standards have been judged inappropriate or ineffective for the aim pursued, and provide the scientific or technical evidence on which this assessment is based.*
5. *International standards developed by the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC), International Telecommunication Unit (ITU), CODEX ALIMENTARIUS shall be considered to be the relevant international standards within the meaning of Article 2, Article 5 and Annex 3 of the TBT Agreement.*
6. *A standard developed by other international organisations, could also be considered relevant international standard within the meaning of Article 2, Article 5 and Annex 3 of the TBT Agreement, provided that*
 - (a) *it has been developed by a standardization body which seeks to establish consensus either:*
 - i. *among national delegations of the participating WTO Members representing all the national standards bodies in their territory that have adopted, or expect to adopt, standards for the subject matter to which the international standardization activity relates, or,*
 - ii. *among governmental bodies of participating WTO Members, and,*
 - (b) *it has been developed in accordance with the TBT Committee Decision on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2, 5, and Annex 3 of the TBT Agreement.*

7. *In addition to Articles 2.3 and 2.4 of the TBT Agreement, the Parties shall review technical regulations to increase their convergence with relevant international standards. The Parties shall, inter alia, take into account any new development in the relevant international standards and whether the circumstances that have given rise to divergences from any relevant international standard continue to exist.*

8. *In accordance with its respective rules and procedures when developing major technical regulations which may have a significant effect on trade each Party shall ensure that transparency procedures exist that allow persons of the Parties to provide input through a public consultation process, except where urgent problems of safety, health, environmental protection or national security arise or threaten to arise. Each Party shall allow persons of the other Party to participate to such consultation in terms no less favourable than those accorded to its own persons, and make the results of that consultation process public.*

Article X.5

Standards

1. *With a view to harmonizing standards on as wide a basis as possible, the Parties shall encourage the standardizing bodies within their territories, as well as the regional standardizing bodies of which they or their standardizing bodies within their territories are members:*

- (a) to participate, within the limits of their resources, in the preparation of international standards by relevant international standardizing bodies;*
- (b) to use relevant international standards as a basis for the standards they develop, except where such international standards would be ineffective or inappropriate, for instance because of an insufficient level of protection or fundamental climatic or geographical factors or fundamental technological problems;*
- (c) to avoid duplication of, or overlap with the work of international standardizing bodies;*
- (d) to review national and regional standards not based on relevant international standards at regular intervals, with a view to increasing their convergence with relevant international standards;*
- (e) to cooperate with the relevant standardization bodies of the other Party in international standardization activities. That cooperation may be undertaken in the international standardization bodies or at regional level; and*
- (f) to foster bilateral cooperation between them and the standardization bodies of the other Party.*

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2. *The Parties should exchange information on:*
 - (a) *their use of standards in support of technical regulations;*
 - (b) *each other's standardization processes, and the extent of use of international standards, regional or sub-regional standards as a base for their national standards.*
3. *If standards are made mandatory through incorporation or referencing in a draft technical regulation or conformity assessment procedure, the transparency obligations set out in Article X.7 and in Articles 2 or 5 of the TBT Agreement shall be fulfilled.*

Article X.6

Conformity Assessment

1. *The provisions set out in Article 4 with respect to the preparation, adoption and application of technical regulations shall also apply, mutatis mutandis, to conformity assessment procedures.*
2. *If a Party requires conformity assessment as a positive assurance that a product conforms with a technical regulation, it shall:*
 - (a) *select conformity assessment procedures proportionate to the risks involved as determined on the basis of a risk-assessment,*
 - (b) *if requested, provide information to the other Party on the criteria used to select the conformity assessment procedures for specific products.*
3. *If a Party requires third party conformity assessment as a positive assurance that a product conforms with a technical regulation, and it has not reserved this task to a governmental body as specified in paragraph 4, it shall:*
 - (a) *preferentially use accreditation to qualify conformity assessment bodies;*
 - (b) *make best use of international standards for accreditation and conformity assessment, as well as international agreements involving the Parties' accreditation bodies, for example, through the mechanisms of the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF);*
 - (c) *consider to join or, as applicable, encourage their conformity assessment bodies to join any functioning international agreements or arrangements for harmonization and/or facilitation of acceptance of conformity assessment results;*
 - (d) *ensure that economic operators have a choice amongst the conformity assessment bodies designated by the authorities for a particular product or set of products;*

- (e) *ensure that conformity assessment bodies are independent of manufacturers, importers and economic operators in general and that there are no conflicts of interest between accreditation bodies and conformity assessment bodies;*
- (f) *allow conformity assessment bodies to use subcontractors to perform testing or inspections in relation to the conformity assessment, including subcontractors located in the territory of the other Party. Nothing in this subparagraph shall be construed to prohibit a Party from requiring subcontractors to meet the same requirements that the conformity assessment body to which it is contracted would be required to meet in order to perform the contracted tests or inspection itself; and,*
- (g) *publish in a single website a list of the bodies that it has designated to perform such conformity assessment and relevant information on the scope of each such body's designation.*

4. *Nothing in this Article shall preclude a Party from requesting that conformity assessment in relation to specific products is performed by specified government authorities of the Party. In such cases, the Party shall:*

- (a) *limit the conformity assessment fees to the approximate cost of the services rendered and upon the request of an applicant for conformity assessment, explain how any fees it imposes for such conformity assessment are limited in amount to the approximate cost of services rendered, and*
- (b) *make publicly available the conformity assessment fees.*

5. *Notwithstanding the provisions of paragraphs 2-4, in the fields listed in Annex 1, where EU accepts Supplier's Declaration of Conformity, i.e. first-party attestation issued by the manufacturer on his sole responsibility based on the results of an appropriate type of conformity assessment activity and excluding mandatory third party assessment, as assurance that a product conforms to a technical regulation and the X shall, as an assurance that a product conforms with the requirements of X's technical regulations, accept certificates issued by conformity assessment bodies that are located in the territory of the EU and which have been accredited by an accreditation body member of the international arrangements for mutual recognition of the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) or, in relation to electrical safety and electromagnetic compatibility aspects, certificates that have been issued under the IECEE CB Scheme.*

Article X.7

Transparency

1. *Each Party shall allow a period of at least 60 days following its transmission to the WTO Central Registry of Notifications of proposed technical regulations and conformity assessment procedures for the other Party to provide written comments, except where urgent problems of*

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safety, health, environmental protection or national security arise or threaten to arise. A Party shall give positive consideration to a reasonable request to extend the comment period.

2. *The Party shall provide, in case the notified text is not in one of the official WTO languages, a detailed and comprehensive description of the content of the measure in the WTO notification format.*

3. *If a Party receives written comments on its proposed technical regulation or conformity assessment procedure from the other Party, it shall:*

(a) if requested by the other Party, discuss the written comments with the participation of its competent regulatory authority, at a time when they can be taken into account; and

(b) reply in writing to the comments no later than the date of publication of the adopted technical regulation or conformity assessment procedure.

4. *Each Party shall publish in a website its responses to comments it receives on its TBT notifications no later than the date of publication the adopted technical regulation or conformity assessment procedure.*

5. *Each Party shall, if requested by the other Party, provide information regarding the objectives of, legal basis and rationale for, a technical regulation or conformity assessment procedure that the Party has adopted or is proposing to adopt.*

6. *Each Party shall ensure that its adopted technical regulations and conformity assessment procedures are published on a website free of charge.*

7. *Each Party shall provide information on the adoption and the entry into force of the technical regulation or conformity assessment procedure and the adopted final text through an addendum to the original notification to the WTO.*

8. *Each Party shall allow a reasonable interval between the publication of technical regulations and their entry into force for economic operators of the other Party to adapt. The phrase "reasonable interval" shall be understood to mean normally a period of not less than 6 months, except when this would be ineffective in fulfilling the legitimate objectives pursued.*

9. *A Party shall give positive consideration to a reasonable request from the other Party, received prior to the end of the comment period following the transmission of a proposed technical regulation, to extend the period of time between the adoption of the technical regulation and its entry into force, except where the delay would be ineffective in fulfilling the legitimate objectives pursued.*

Article X.8

Marking and labelling

1. *The Parties affirm that their technical regulations including or dealing exclusively with marking or labelling will observe the principles of Article 2.2 of the TBT Agreement.*

2. *A Party that requires mandatory marking or labelling of products:*

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- (a) *the Party shall only require information which is relevant for consumers or users of the product or to indicate the product's conformity with the mandatory technical requirements;*
 - (b) *the Party shall not require any prior approval, registration or certification of the labels or markings of products, nor any fee disbursement, as a precondition for placing on its market products that otherwise comply with its mandatory technical requirements unless it is necessary in view of the legitimate objectives referred to in Article 2.2 of the TBT Agreement;*
 - (c) *where the Party requires the use of a unique identification number by economic operators, the Party shall issue such number to the economic operators of the other Party without undue delay and on a non-discriminatory basis;*
 - (d) *provided it is not misleading, contradictory or confusing in relation to the information required in the importing Party of the goods, the Party shall permit the following:*
 - i. *information in other languages in addition to the language required in the importing Party of the goods;*
 - ii. *internationally-accepted nomenclatures, pictograms, symbols or graphics;*
 - iii. *additional information to that required in the importing Party of the goods;*
 - (e) *the Party shall accept that labelling, including supplementary labelling and/or corrections to labelling, take place, in customs warehouses or other designated areas in the country of import as an alternative to labelling in the country of origin.*
 - (f) *the Party shall endeavour to accept non-permanent or detachable labels, or marking or labelling in the accompanying documentation rather than physically attached to the product.*
3. *Paragraph 2 of this Article shall not apply to marking or labelling of medicinal products as defined by the legislation of the respective Parties.*

Article X.9

Technical discussions and consultations

Technical discussions

1. *Each Party may request to discuss any draft or proposed technical regulation or conformity assessment procedure of the other Party that the Party considers might significantly adversely affect trade between the Parties. The request shall be made in writing and identify:*
 - (a) *the measure at issue;*
 - (b) *the provisions of this Chapter to which the concerns relate; and*
 - (c) *the reasons for the request, including a description of the requesting Party's concerns regarding the measure.*

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2. A Party shall deliver its request to the Chapter Coordinator of the other Party designated pursuant to Article XX.

3. At the request of either Party, the Parties shall meet to discuss the concerns raised in the request, in person or via video or teleconference, within {60} days of the date of the request and shall endeavor to resolve the matter as expeditiously as possible. If a requesting Party believes that the matter is urgent, it may request that any meeting take place within a shorter time frame. In such cases, the responding Party shall give positive consideration to such a request.

Consultations

1. A Party may request consultations with the other Party regarding any matter arising under this Chapter by delivering a written request to the Chapter Coordinator of the other Party. The Parties shall make every attempt to arrive at a mutually satisfactory resolution of the matter [and may convene the Committee as appropriate for this purpose].

2. For greater certainty, this Article is without prejudice to a Party's rights and obligations under Chapter XX (Dispute Settlement).

[Article X.10]

Cooperation and Technical Assistance

[The Parties recognize that it is in their common interest to promote mutual cooperation and technical assistance initiatives on issues related to technical barriers to trade. In this respect, the parties have identified a number of cooperation activities which are set out in in Article XX of Title XX of Part XX of this Agreement].

Article X.11

Cooperation on market surveillance¹ and non-food product safety and compliance

1. *The Parties recognise the importance of cooperation on market surveillance, compliance and the safety of non-food products for the facilitation of trade, and of building mutual trust based on shared information.*

2. *To guarantee independent and impartial functioning of market surveillance, the Parties shall ensure:*
 - a) *the separation of market surveillance functions from conformity assessment functions; and*
 - b) *the absence of any interest that would affect the impartiality of market surveillance authorities in the performance of control or supervision of economic operators.*

3. *The Parties may cooperate and exchange information in the area of non-food product safety and compliance, in particular with respect to the following:*
 - a. *market surveillance and enforcement activities and measures;*
 - b. *risk assessment methods and product testing;²*
 - c. *coordinated product recalls or other similar actions;*
 - d. *scientific, technical, and regulatory matters, aiming to improve non-food product safety and compliance;*
 - e. *emerging issues of significant health and safety relevance;*
 - f. *standardisation-related activities³ and*
 - g. *exchange of officials.*

4. *The Parties may establish in Annex XX an arrangement on the systematic exchange of information between the RAPEX alert system, or its successor, and the [to be adapted to ESA situation] system, or its successor, on the safety of non-food consumer products and on preventive, restrictive and corrective measures taken.*

The arrangement shall set out the modalities under which:

¹ "Market surveillance" means activities conducted and measures taken by public authorities including those taken in cooperation with economic operators, on the basis of procedures of a Party to enable that Party to monitor or address compliance or safety of products with the requirements set out in its laws and regulations.

² Depending on the negotiated text, this point might be duplicative with a general cooperation Article in the TBT Chapter (in such case could be removed)

³ Idem

(a) the European Union provides [ESA] with selected information from its RAPEX alert system, or its successor, with respect to consumer products as referred to in Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety or its successor; and

(b) [ESA] provides the European Union with selected information from the [to be adapted to ESA situation] system, or its successor, and information [providing an early warning] on preventive, restrictive and corrective measures before they become public, with respect to consumer products as referred to in [relevant Legal Act].

5. Parties may establish in Annex [XX] an arrangement on the systematic exchange of information, including by electronic means, on measures taken on non-compliant non-food products, other than those covered by paragraph 4.

6. The Parties shall use the information obtained pursuant to paragraphs 3, 4 and 5 for the sole purpose of protection of consumers, health, safety or the environment.

7. Each Party shall treat the information obtained pursuant to paragraphs 3, 4 and 5 as confidential.

8. The arrangements set out in Annex [XX] shall specify the type of information to be exchanged, the modalities for the exchange and the application of confidentiality and personal data protection rules.

The [Joint Committee or other body depending on the final institutional framework of the Agreement] shall have the power to adopt decisions in order to determine or amend arrangements set out in Annex [XX].

Institutional Provisions

TBT Chapter coordinator

1. Each Party shall nominate a TBT Chapter coordinator and inform the other Party if it changes. The TBT Chapter coordinators shall work jointly to facilitate the implementation of this Chapter and cooperation between the Parties in all TBT matters.

2. The functions of the Chapter coordinators shall include:

(a) monitoring the implementation and administration of this Chapter, promptly addressing any issue that either Party raises related to the development, adoption, application or enforcement of standards, technical regulations and conformity assessment procedures, and upon either Party's request, consulting on any matter arising under this Chapter;

(d) exchanging information on developments in non-governmental, regional and multilateral fora related to standards, technical regulations and conformity assessment procedures.

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3. *The Chapter coordinators shall communicate with one another by any agreed method that is appropriate to carry out their functions.*

[Annex 1]

[may be subject to further amendments in order to clarify the coverage]

Agreed fields:

- (a) *safety aspects of electrical and electronic equipment as defined in paragraph 2*
- (b) *safety aspects of machinery as defined in paragraph 3*
- (c) *electromagnetic compatibility of equipment as defined in paragraph 4*
- (d) *energy efficiency including eco-design requirements*
- (e) *restriction of the use of certain hazardous substances in electrical and electronic equipment*

(2) For the purpose of this Annex 'safety aspects of electrical and electronic equipment' means the safety aspects of equipment other than machinery which is dependent on electric currents in order to work properly and equipment for the generation, transfer and measurement of such currents and which is designed for use with a voltage rating of between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current, as well as equipment which intentionally emits or receives electromagnetic waves of frequencies lower than 3000 GHz, with the purpose of radio communication or radiodetermination, with the exception of:

- (a) *equipment for use in an explosive atmosphere;*
- (b) *equipment for use for radiology or medical purposes;*
- (c) *electrical parts for goods and passenger lifts;*
- (d) *radio equipment used by radio amateurs;*
- (e) *electricity meters;*
- (f) *plugs and socket outlets for domestic use;*
- (g) *electric fence controllers;*
- (h) *toys;*
- (i) *custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.*
- (j) *construction products for permanent incorporation in buildings or civil engineering works and the performance of which has an effect on the performance of the building or civil engineering works, such as cables, fire alarms, electric doors*

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(3) *For the purpose of this Annex 'safety aspects of machinery' means the safety aspects of an assembly consisting of at least one moving part, powered by a drive system using one or more sources of energy such as thermal, electric, pneumatic, hydraulic or mechanical energy, arranged and controlled so that they function as an integral whole, with the exception of high risk machinery (to be defined by the Parties)]*

(4) *For the purpose of this Annex 'electromagnetic compatibility of equipment' means the electromagnetic compatibility (disturbance and immunity) of equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents, with the exception of:*

- (a) *equipment for use in an explosive atmosphere;*
- (b) *equipment for use for radiology or medical purposes;*
- (c) *electrical parts for goods and passenger lifts;*
- (d) *radio equipment used by radio amateurs;*
- (e) *measuring instruments;*
- (f) *non-automatic weighing instruments;*
- (g) *inherently benign equipment;*
- (h) *custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.*

(5) *For the purpose of this Annex "energy efficiency" means the ratio of output of performance, service, goods or energy to input of energy of a product with an impact on energy consumption during use, and in light of the efficient allocation of resources.* (6) *For the sake of clarity, this Annex shall not cover whole aircraft, vessels, railways, vehicles as well as specialised maritime, railway, aviation and vehicle equipment*

(7) *At the request of either Party the [Joint Committee or appropriate institutional mechanism] shall review the list of fields in this Annex.*

(8) *Notwithstanding paragraph 1, either Party may introduce requirements for mandatory third party testing or certification for the fields specified in this Annex, for products falling within the scope of this Annex under the following conditions:*

- (a) *there exist compelling reasons related to the protection of human health and safety that justify the introduction of such requirements or procedures;*
- (b) *the reasons for the introduction of any such requirements or procedures are supported by substantiated technical or scientific information regarding the performance of the products in question;*
- (c) *any such requirements or procedures are not more trade-restrictive than necessary to fulfil the Party's legitimate objective, taking account of the risks that non-fulfilment would create; and*

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(d) the Party could not have reasonably foreseen the need for introducing any such requirements or procedures at the time of entry into force of this Agreement.

Before introducing the requirements or procedures, the Party shall notify the other Party and, following consultations, take the comments of the other Party into account, to the greatest extent possible, in devising any such requirements or procedures.