

EU proposal

Without prejudice

This document contains an EU proposal for a Technical Barriers to Trade Chapter in the Trade Part of a possible modernised EU-Chile Association Agreement. It has been tabled for discussion with Chile. The actual text in the final agreement will be a result of negotiations between the EU and Chile. The EU reserves the right to make subsequent modifications to this proposal.

EU-Chile Free Trade Agreement

EU TEXTUAL PROPOSAL

TECHNICAL BARRIERS TO TRADE

Article X.1

Objective

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

1. 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] (Sanitary and Phytosanitary Measures) of this Agreement.

Article X.3

Relationship with the TBT Agreement

1. Articles 2 to 9 and Annexes 1 and 3 of the TBT Agreement are hereby incorporated into and made part of this Agreement. Those provisions apply unless otherwise agreed by the Parties in this Chapter.
2. References to “this Agreement” in the TBT Agreement, as incorporated into this Agreement, are to be read, as appropriate, as references to this Agreement between the Union and Chile.
3. The term “Members” in the TBT Agreement, as incorporated into this Agreement, shall mean the Parties to this 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. International standards developed by the organisations listed in Annex [X] (Title) shall be considered to be the relevant international standards within the meaning of Article 2, Article 5 and Annex 3 of the TBT Agreement provided that in their development these organisations have complied with the principles and procedures set out in the Decision of the WTO Committee on Technical Barriers to Trade on Principles for the Development of International Standards, Guides and Recommendations with Relation to Article 2, Article 5 and Annex 3 of the TBT Agreement.
5. At the request of either Party the [Trade Committee or body defined by the Agreement] shall consider updating the list of Annex [X] (Title).
6. 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.
7. In addition to Article 2.3 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 and without prejudice to Chapter [XX] (Good Regulatory Practices) 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.
2. The Parties should exchange information on:
- (a) their use of standards in support of technical regulations; and
 - (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 (Transparency) of this Agreement 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 X.4 (Technical Regulations) 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) consider the use of a supplier's declaration of conformity, i.e. a declaration of conformity issued by the manufacturer on his sole responsibility and excluding mandatory third party assessment, as assurance of conformity among the options for showing compliance with a technical regulation; and
 - (c) 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) 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 the services rendered; and
 - (b) make publicly available the conformity assessment fees.
5. Notwithstanding the provisions of paragraphs 2 to 4, the Parties shall accept a supplier's declaration of conformity as proof of compliance with existing technical regulations for the fields and according to modalities specified in Annex [XX] (Title).

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 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 of 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 term “reasonable interval” shall be understood to normally mean 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 publication 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 of the TBT Agreement.
2. The Parties agree that where a Party requires mandatory marking or labelling of products:

- (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;
- (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; and
 - (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 at the point of import in the importing Party; and
- (f) the Party shall endeavour to accept non-permanent or detachable labels, or inclusion of relevant information in the accompanying documentation, rather than labels physically attached to the product.

Article X.9

Technical Discussions and Consultations

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.
2. A Party shall deliver its request to the Chapter Coordinator of the other Party designated pursuant to Article X.10 (TBT Chapter Coordinator).
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 the 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.

4. 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.
5. For greater certainty, this Article is without prejudice to a Party's rights and obligations under Chapter [XX] (Dispute Settlement).

Article X.10

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;
 - (b) enhancing cooperation in the development and improvement of standards, technical regulations and conformity assessment procedures;
 - (c) arranging the establishment of technical discussions as appropriate in accordance with Article X.9 (Technical Discussions and Consultations); and
 - (d) exchanging information on developments in non-governmental, regional and multilateral fora related to standards, technical regulations and conformity assessment procedures.
3. The Chapter coordinators shall communicate with one another by any agreed method that is appropriate to carry out their functions.

TITLE

1. International Organisation for Standardisation (ISO);
2. International Electrotechnical Commission (IEC);
3. International Telecommunication Union (ITU);
4. Codex Alimentarius Commission;
5. International Civil Aviation Organisation (ICAO);
6. World Forum for Harmonisation of Vehicle Regulations (WP.29) within the framework of the United Nations Economic Commission for Europe (UNECE);
7. United Nations Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UN/SCEGHS);
8. International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH);
9. International Maritime Organisation (IMO);
10. International Organisation of Legal Metrology (OIML);
11. International Olive Council (IOC);
12. International Organisation of Vine and Wine (OIV);
13. Universal Postal Union (UPU);
14. World Organisation for Animal Health (OIE).

TITLE

1. The Parties shall accept 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 proof of compliance with existing technical regulations in the following 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; and
 - (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) specialised electrical equipment, for use on ships, aircraft or railways; and
 - (j) custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

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) equipment covered by UNECE Regulation 10;
 - (e) radio equipment used by radio amateurs;
 - (f) specialised electrical equipment, for use on ships, aircraft or railways;
 - (g) measuring instruments;
 - (h) non-automatic weighing instruments;
 - (i) inherently benign equipment; and
 - (j) custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.
5. For the purposes of this Annex, “aircraft”, “vessels”, “vehicles”, “railways”, with the exception of their components, shall not be considered as equipment or machinery.
6. At the request of either Party the [Trade Committee or body defined by the Agreement] shall review the list of fields in this Annex.
7. 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 exists 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
 - (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.