

This document contains the consolidated text resulting from the 30th round of negotiations (6-10 November 2017) on technical barriers to trade in the Trade Part of the EU-Mercosur Association Agreement. This is without prejudice to the final outcome of negotiations. Both sides reserve the right to make subsequent modifications to their proposals.

MERCOSUR-EU NEGOTIATIONS

JOINT EU- MERCOSUR PROPOSAL FOR THE CHAPTER ON TBT

ARTICLE 1 – OBJECTIVE

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

ARTICLE 2 - RELATIONSHIP WITH THE WTO TBT AGREEMENT

The Parties reaffirm their rights and obligations [EU: with respect to each other] under the TBT Agreement [MCS: which is] [EU: . Articles 2 to 9 and Annexes 1 and 3 of the TBT Agreement are] hereby incorporated into and made part of this Agreement.

[EU: 2. References to “this Agreement” in the TBT Agreement, as incorporated into this Agreement, are to be read, as appropriate, as references to the Agreement between the European Union and its Member States and MERCOSUR.]

[EU: 3. The term “Members” in the TBT Agreement, as incorporated into this Agreement, shall mean the Parties to this Agreement.]

ARTICLE 3– SCOPE, COVERAGE AND DEFINITIONS

1. This Chapter applies to the preparation, adoption and application of standards, technical regulations and conformity assessment procedures that may affect trade in goods between the Parties.
2. For the purpose of this Chapter, the definitions of Annex I of the TBT Agreement shall apply.
3. Notwithstanding paragraph 1, this Chapter does not apply to:
 - purchasing specifications prepared by governmental bodies for production or consumption requirements of such bodies; or
 - sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures.

ARTICLE 4 – [MCS: TRADE FACILITATING INITIATIVES] [EU: REGULATORY COOPERATION]

1. The Parties recognize the importance [MCS: to intensify their collaboration with a view to increasing mutual understanding of their respective systems and to identify trade facilitating initiatives that contribute to fulfilling the objectives of this Chapter] [EU: of regulatory cooperation to help eliminate or avoid the creation of technical barriers to trade and to increase mutual understanding of their regulatory systems]. [MCS: In this regard, the Parties shall work towards the identification, development, whenever possible, negotiation and promotion of trade facilitating [EU: sector specific] initiatives, on a case-by-case basis].

2. [MCS: The demanding Parties, through their regulatory and competent governmental authorities, at the national and/or regional level, [EU: A Party] may propose to the other Party [MCS: products and/or] sector specific initiatives in areas covered by this Chapter. Those proposals [EU: shall be transmitted to the Chapter Coordinator- depending on the final institutional structure of the TBT Chapter - and shall consist of] [MCS: may include among others]:

- a) information exchanges on regulatory approaches and practices;
- b) initiatives to further align technical regulations and conformity assessment procedures with relevant international standards;
- c) [MCS: regulatory convergence activities];
- d) [EU: the promotion of] the use of accreditation to [EU: assess the competence of] [MCS: qualify] conformity assessment bodies; and
- e) [MCS: mutual or unilateral recognition of conformity assessment procedures and their results.]

3. [MCS: Whenever the subject involves national regulations of an EU Member State and/or a MERCOSUR State Party, in addition to the common rules, trade facilitating initiatives, as provided in paragraph 2, could be launched with the participation of the Signatory Parties interested in the particular facilitation initiative.

[EU: This article shall apply to cooperation between relevant regulatory authorities of the Parties with respect to any matter covered by this Chapter. For the purposes of this provision, the relevant regulatory authority for the EU Party is the European Commission.]

4. Whenever one of the Parties suggests a joint analysis of a sector or products, the other Party shall duly consider the proposal. If one Party rejects this analysis, it shall promptly justify the reasons for its decision.

5. Whenever one of the Parties suggests a specific initiative for a sector or products, the other Party shall duly consider the proposal. If one Party rejects this analysis, it shall promptly justify the reasons for its decision and accept to consider alternatives to go forward. [EU: The other Party shall reply to the proposal in a reasonable time]

6. The terms of the work envisaged in this article will be defined by the engaged Parties, which shall establish sectoral or thematic working groups, their work schedule, conditions and, whenever appropriate, the compliance criteria. Beside Government officials, representatives of private sector, academia and civil society, among others, may be invited, when previously agreed, to take part in these groups.

7. The results of the understandings reached under the above paragraph must then be incorporated into the appropriate legal instrument, depending on the subject matter and the agreed tool.

[EU: Nothing in this Article shall be construed as to require a Party to:

- a) deviate from domestic procedures for preparing and adopting regulatory measures,
- b) take actions that would undermine or impede the timely adoption of regulatory measures to achieve its public policy objectives, or
- c) achieve any particular regulatory outcome.]

8. When agreed, the involved Parties shall facilitate the access of technical teams to their territories to demonstrate their conformity assessment schemes and system.

9. The European Commission will evaluate upon request from MERCOSUR, if compliance with specific regional standards or technical regulations of MERCOSUR implies conformity with the European Union regulation. The conclusions of such evaluation will be publicly available and the reasons for an eventually negative evaluation have to be addressed to MERCOSUR].

10. [MCS: For the purposes of this article, the Parties agree to proceed to a joint analysis of the automotive sector aiming at possible Trade Facilitating Initiatives].

ARTICLE 5 – TECHNICAL REGULATIONS

1. The Parties agree to make best use of good regulatory practices with regard to the preparation, adoption and application of technical regulations, as provided for in the TBT Agreement, including, for example, preference for performance-based technical regulations, use of impact assessments or stakeholder consultation. In particular, the Parties agree to:

a) use relevant international standards as a basis for their technical regulations including any conformity assessment elements therein, except when such international standards would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued. Where international standards have not been used as a basis for a technical regulation, which may have a significant effect on trade, a Party shall, upon request of the other Party, explain the reasons why such standards have been judged inappropriate or ineffective for the aim pursued.

b) when reviewing their technical regulations, in addition to the Article 2.3 and without prejudice to the Articles 2.4 and 12.4 of the TBT Agreement, to increase their alignment with relevant international standards. The Parties shall consider, inter alia, any new development in the relevant international standards and whether the circumstances that have given rise to any divergence from any relevant international standard continue to exist.

c) promote the development of regional technical regulations and that these are adopted at national level and/or replace existing ones, in order to facilitate trade between the Parties; and

d) 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.

e) to carry out the impact analysis of planned technical regulations in accordance with its respective rules and procedures.

ARTICLE 6 – STANDARDS

[MCS: 1. The Parties recognize their responsibility, under Article 4.1 of the TBT Agreement, for taking all reasonable measures to ensure that all governmental or non-governmental standardization bodies and other private entities which develop and apply standards in their commercial relations accept and comply with the Code of Good Practice for the Preparation and Adoption of Standards in Annex 3 to the TBT Agreement].

2. International standards developed by ISO, IEC, 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..

3. A standard developed by other international organisations, **[UE: such as those listed in Annex 1, should] [MCS: could]** also be considered relevant international standard within the meaning of Article 2, Article 5 and Annex 3 of the TBT Agreement, provided that

[UE: (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.

4. [UE: At the request of either Party the [Joint Trade Committee (or appropriate institutional mechanism) shall consider updating the list of Annex 1.]

5. With a view to harmonizing standards on as wide a basis as possible the Parties shall encourage, within the limits of their competence and resources, the standardizing bodies within their territories, as well as the regional standardizing bodies of which they or the standardizing bodies within their territories are Members, to:

a) to participate, within the limits of their resources, in the preparation of international standards by relevant international standardizing bodies;

b) cooperate with the relevant national and regional standardization bodies of the other Party in international standardization activities;

c) 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 **[MCS 1: or trade and development concerns of developing countries] [MCS 2: recognizing also the provisions of TBT article 12.4];**

d) avoid duplication of, or overlap with the work of international standardizing bodies;

e) promote the development of standards at regional level and the adoption of such standards by national standardizing bodies thereby replacing existing national standards;

f) to review national and regional standards not based on relevant international standards at regular intervals, with a view to increasing their alignment with relevant international standards; and

g) to foster bilateral cooperation with the standardization bodies of the other Party.

6. The Parties should exchange information on:

a) their use of standards as a basis for, or in support of, technical regulations;

b) cooperation agreements implemented by either Party on standardization, for example on standardization issues in free trade agreements with third parties, and

c) each other's standardization processes, and the use of international, regional or sub-regional standards as a basis for their national standards.

[MCS: 7. The parties shall ensure that the commitments under this article are not undermined by the use within their territories, of standards developed and applied by private entities not complying with the Code of Good Practice for the Preparation and Adoption of Standards from Annex 3 to the TBT Agreement. In light of governmental authority related to public safety, health, consumer protection, sustainability and the abuse of dominant economic position, the Parties shall ensure that products marketed under those standards in their territories do not conflict with technical regulation in force, misguide the consumer, distort market competition or generate unnecessary barriers to trade.]

ARTICLE 7 – CONFORMITY ASSESSMENT PROCEDURES AND ACCREDITATION

[MCS: 1. The Parties undertake to intensify their exchange of information on different mechanisms with a view to facilitating the acceptance of conformity assessment results.

2. In line with Article 5.1.2 of the TBT Agreement, the Parties agree to require that conformity assessment procedures are not stricter or be applied more strictly than is necessary to give the importing Party adequate confidence that products conform with the applicable technical regulations or standards, taking account of the risks non-conformity would create.]

1. The provisions set out in Article 5 (Technical Regulations) with respect to the preparation, adoption and application of technical regulations shall also apply 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;
- b) consider in the regulatory process the use of the supplier's declaration of conformity as assurance of conformity among other options for showing compliance with technical regulations; and
- c) if requested, provide information to the other Party on the reasons for selecting a particular conformity assessment procedure 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 testing, inspection and certification bodies to join any functioning international agreements or arrangements for harmonization and/or facilitation of acceptance of conformity assessment results;
- d) promote that, within the territory of each of the Parties, conformity assessment bodies designated by the authorities for a particular product or set of products may compete to enable economic operators to choose amongst them;
- e) ensure that conformity assessment bodies are independent of manufacturers, importers and distributors in the sense that they carry out their activities with objectivity and independence of judgement;
- f) ensure that there are no conflicts of interest between accreditation bodies and conformity assessment bodies as well as between activities of market surveillance authorities and activities of conformity assessment bodies;
- g) allow to the extent possible that conformity assessment bodies 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
- h) publish in a 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:

XXX CNB – TBT NEGOTIATING TEXT – November 2017

- a) establish the conformity assessment fees in accordance with the approximate cost of the services rendered and upon the request of an applicant for conformity assessment, provide the different elements included in them; and
- b) in principle make the conformity assessment fees publicly available. When not publicly available, these fees shall be provided upon request.

[MCS: 5. MERCOSUR Parties may communicate to the European Commission his designated or accredited conformity assessment bodies in order to have his evaluation results recognized in the European Union.

[MCS: 6. When supplier's declaration of conformity is considered a valid conformity assessment procedure in the European Union, declaration from MERCOSUR producers will be accepted.]

[EU June 2017: 7. Notwithstanding the provisions of paragraphs 2-4, the Parties shall accept Supplier's Declaration of Conformity as proof of compliance with existing technical regulations for the fields and according to modalities specified in Annex 2.]

[EU November 2017 – alternative proposal: 7. Notwithstanding the provisions of paragraphs 2-4, provisions of Annex 2 shall apply for the fields and modalities specified therein.]

ARTICLE 8 – TRANSPARENCY

1. The Parties reaffirm their transparency obligations under the TBT Agreement with regard to the preparation, adoption and application of standards, technical regulations and conformity assessment procedures, and agree to:

- a) take the other Party's views into account where a part of the process of developing a technical regulation is open to public consultation;
- b) to ensure, in accordance with its respective rules and procedures, when developing major technical regulations and conformity assessment procedures which may have a significant effect on trade that transparency procedures exist that allow persons of the Parties to provide input through a formal 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 whenever possible make the results of that consultation process public;
- c) allow in principle a period of at least 60 days for the other Party to provide written comments on the proposed technical regulations and conformity assessment procedures. Where urgent problems of safety, health, environmental protection or national security arise or threaten to arise, articles 2.10 and 5.7 of the TBT agreement apply. A Party shall consider a reasonable request to extend the comment period;
- d) provide, in case the notified text is not in one of the official WTO languages, a clear and comprehensive description of the content of the measure in the WTO notification format;
- e) if a Party receives written comments on its proposed technical regulation or conformity assessment procedure from the other Party:
 - i. if requested by the other Party, discuss the written comments, whenever possible with the participation of its competent regulatory authority and at a time when they can be taken into account
 - ii. reply in writing to the comments whenever possible no later than the date of publication of the technical regulation or conformity assessment procedure;
- f) **[EU: publish in a website its responses to comments from other WTO Members it receives on its TBT notifications no later than the date of publication the adopted technical regulation or conformity assessment procedure;]**

XXX CNB – TBT NEGOTIATING TEXT – November 2017

- g) provide, if requested by the other Party, 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;
 - h) 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;
 - i) consider 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;
 - j) provide means for free access to the electronic version of the notified text with the notification; and
 - k) if standards are made mandatory through incorporation or referencing in a draft technical regulation or conformity assessment procedure, the transparency obligations related to TBT notification set out in this Article and in Articles 2 or 5 of the TBT Agreement shall be fulfilled.
2. The Parties shall ensure that all technical regulations and mandatory conformity assessment procedures adopted and in force are publicly available on an official website free of charge. The Parties shall always provide unrestricted access to all information relevant to the achievement of conformity with a technical regulation. When standards provide presumption of conformity with technical regulations and these standards are not referred to in those technical regulations, Parties shall ensure access to the information on corresponding standards.
3. A Party shall, upon reasonable request of the other Party or its economic operators, provide information on technical regulations in force and, as appropriate and available, written guidance on compliance with the technical regulations, without undue delay.

[EU: ARTICLE 9: MARKING AND LABELLING

- 1. The Parties affirm that their technical regulations including or dealing exclusively with mandatory marking or labelling will observe the principles of Article 2 of the TBT Agreement.**
- 2. In particular, 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 of markings of the products, nor any fee disbursement, as a precondition for placing on the market products that otherwise comply with its mandatory technical requirements unless it is necessary in view of the risk of the products to human, animal or plant health or life, the environment or national safety. Where a Party has introduced such prior approval, registration or certification requirements, it shall ensure that the requests submitted by the economic operators of the other Party are decided without undue delay and on a non-discriminatory basis;**
 - c) where the Party requires the use of a unique identification, 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 country of the goods and the legitimate objectives under the TBT Agreement are not compromised thereby, the Party shall permit the following:**
 - i. information in other languages in addition to the language required in the**

- importing country of the goods;
- ii. nomenclatures, pictograms, symbols or graphics adopted in international standards;
- iii. additional information to that required in the importing country of the goods;
- e) the Party, whenever possible, shall accept that labelling, including supplementary labelling, and corrections to labelling take place in customs warehouses at the point of import as an alternative to labelling in the country of origin;
- f) the Party shall, in cases where it considers that legitimate objectives under the TBT Agreement are not compromised thereby, endeavour to accept non-permanent or detachable labels, rather than labels physically attached to the product, or inclusion of relevant information in the accompanying documentation.

EU April 2017: g) Where a Mercosur Party requires a mark of origin on the importation of goods of the European Union, that Mercosur Party shall accept the origin mark "Made in the EU" according to the respective Mercosur-Party's origin marking requirements under the conditions that are no less favorable than those applied to EU national marks of origin. For the purposes of the origin mark "Made in the EU", each Mercosur Party shall treat the European Union as a single territory.^{1]}

3. This article shall not apply to marking or labelling of medicinal products.

[MCS: ARTICLE 10– SPECIAL AND DIFFERENTIAL TREATMENT

1. The Parties reaffirm the principle of special and differential treatment and recognize the essential importance of pertinent disciplines contained in the TBT Agreement for MERCOSUR countries. Consequently, Articles 11 and 12 of the TBT Agreement shall apply as regards to the implementation of this Chapter.

2. Additionally, the Parties agree that:

- a) shall encourage their standardizing bodies and regional standardizing bodies to take into account the developing condition of MERCOSUR countries, in particular, that standards they develop do not create unnecessary obstacles to exports to the European Union;
- b) before a technical regulation or conformity assessment procedure enters into force, all available measures to minimize the impact of the proposed on exports from developing countries in each Party shall be adopted;
- c) MERCOSUR countries may take into account the provisions of Article 12.4 of the TBT Agreement in the preparation or application of technical regulations, standards and conformity assessment procedures;

ARTICLE 11 – COOPERATION AND TECHNICAL ASSISTANCE

- 1. To contribute to fulfilling the objectives of this Chapter, the Parties agree to, inter alia:
 - a) Promote cooperation and joint activities and projects between their respective organizations, public and/or private, national and/or regional, in the fields of technical regulations, standardization, conformity assessment, metrology and accreditation;

¹ Text transferred from the Chapter on Trade in Goods

- b) Promote **[MCS: regulatory cooperation and]** good regulatory practices through the exchange of information, experiences and best practices about, inter alia, regulatory impact assessment, **[MCS: regulatory stock management]** and risk assessment and public consultation;
 - c) Exchange views on market surveillance;
 - d) Strengthen the technical and institutional capacity of the national regulatory, metrology, standardization, conformity assessment and accreditation bodies, supporting the development of their technical infrastructure, including labs and testing equipment, and sustaining the continuous training of human resources;
 - e) **[MCS: Promote mechanisms for improving the exchange of information on different technical regulations in force, in particular, when presumption of conformity with a technical regulation is granted by the means of conformity with a determined standard not referred to in that technical regulation];**
 - f) Promote, facilitate and, whenever possible, coordinate their participation in international organizations and other fora related to technical regulations, conformity assessment, standards, accreditation and metrology;
 - g) **[MCS: Promote and support the use and implementation of relevant international standards];**
 - h) Support technical assistance activities by national, regional and international organizations in the areas of technical regulations, standardization, conformity assessment, metrology and accreditation;
 - i) **[MCS: encourage testing, inspection and certification bodies to exchange experiences on the procedures used to assess conformity.]**
 - j) **[MCS: take due account of the specific concerns of micro, small and medium sized enterprises;**
 - k) **Share available scientific evidences and technical information among regulatory authorities of the Parties, national or regional;]**
2. A Party shall give appropriate consideration to proposals of the other Party for cooperation under this Chapter.

[EU MARCH 2017: ARTICLE X: FREE CIRCULATION OF GOODS

To be developed further]

[EU: ARTICLE 12: TECHNICAL DISCUSSIONS AND CONSULTATIONS MECHANISMS

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 13.

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).]

[EU: ARTICLE 13: 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 11;

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.]

[EU June 2017:

Annex 1

1. International Organisation for Standardisation (ISO)
2. International Electrotechnical Commission (IEC)
3. International Telecommunication Union (ITU)
4. Codex Alimentarius Commission
5. the 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)]

[EU Alternative proposal - November 2017:

Annex 1

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

[EU June 2017:

Annex 2

(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
- 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;
- 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;

- 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', which the exception of their components, shall not be considered as equipment or machinery.

(6) At the request of either Party the [Joint Committee or appropriate institutional mechanism] 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 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
- (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.

[EU alternative proposal - November 2017:

Annex 2

(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 in the following fields:

- (a) safety aspects of electrical and electronic equipment defined in paragraph 3
- (b) safety aspects of machinery as defined in paragraph 4
- (c) electromagnetic compatibility of equipment defined in paragraph. 5
- (d) energy efficiency including eco-design requirements
- (e) restriction of the use of certain hazardous substances in electrical and electronic equipment

and where a Mercosur Party requires mandatory third party testing or certification for these fields, the Mercosur Party shall, as an assurance that a product conforms with the requirements of ~~Mercosur Parties~~ a Mercosur Party'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.

(2) Paragraph 1 also apply where a Mercosur Party introduces new requirements for mandatory third party testing or certification for the fields specified in paragraph 1, in accordance with paragraph 8.

(3) 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;
- j) custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

(4) 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]

(5) 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;
- j) custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

(6) For the purposes of this Annex:

'aircraft', 'vessels', 'vehicles', 'railways', which the exception of their components, shall not be considered as equipment or machinery.

(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

(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.]