This document is the European Union's proposal for an annex on cosmetics. It was tabled for discussion with the US in the negotiating round of 11-15 July 2016 and made public on 14 July 2016. The actual text in the final agreement will be a result of talks between the EU and US.

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

The relationship between sectorial annexes and the architecture of TTIP, including the applicability or not of general exceptions and dispute settlement, will be considered at a later stage.

EU PROPOSAL FOR AN ANNEX ON COSMETICS

Article 1
General principles and objectives

1. Co-operation activities between the Parties shall aim at improving, and not reducing, undermining or otherwise compromising, the level of protection in public policy areas such as the protection of workers' and consumers' health, public health, and the protection of the environment, as considered appropriate by either Party. The Parties share the intention of achieving a high level of protection in these areas.

2. Nothing in this Annex shall affect the ability of each Party to apply its fundamental principles governing regulatory measures in its jurisdiction, for example in the areas of risk assessment and risk management[1].

3. Nothing in this Annex shall affect the ability of each Party to take appropriate and immediate measures when it determines that a product falling under the scope of this Annex is not safe for the consumer or does not comply with its regulatory framework. Such measures may include withdrawing the product from the market or prohibiting its placement in the market.

4. The objectives of this Annex are, in particular, to promote:

   a) convergence of technical requirements and relevant standards applicable to products falling under the scope of this Annex;

   b) alignment of ingredients labelling;

   c) use of validated alternative methods to animal testing;

   d) existing multilateral and bilateral regulatory cooperation relating to regulation of products falling under the scope of this Annex;

[1] For the EU, such principles include those established in the Treaty on the Functioning of the European Union as well as in Regulations and Directives adopted pursuant to Article 289 of the Treaty on the Functioning of the European Union.

e) cooperation on the review and assessment of ingredients subject to market authorization;

f) cooperation on new and emerging issues and on any other matter of common interest to the Parties

g) cooperation related to safety assessment methodologies;

while ensuring legitimate policy objectives such as a high level of protection of public health and consumers' safety and contributing to the promotion of innovation, competitiveness and trade in products falling under the scope of this Annex.

Article 2
Definitions

For the purpose of this Annex:

'Cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

'**Medicinal product not subject to prescription**' means, in the context of this Annex, products under Chapters 33 and 34 of the Harmonized System (HS) of tariff nomenclature which a Party classifies as a 'medicinal product' and which can be sold to a consumer without a prescription from a healthcare professional.

'Ingredients subject to market authorisation' means a chemical element and its compounds in the natural state or obtained by manufacturing process, for which a market approval is required prior to their use in a cosmetic product or in a product considered by one of the Parties as 'medicinal product not subject to prescription'.

'Responsible authorities' means the European Commission and the competent authorities of the EU Member States and the US Food and Drug Administration.

'International Cooperation on Cosmetics Regulation (ICCR)' is a voluntary international group of cosmetics regulatory authorities from different countries that meet on an annual basis to discuss common issues on cosmetics safety and regulation.

'INCI' is the International Nomenclature of Cosmetic Ingredients.

Article 3
Scope

This Annex applies to products falling under Chapters 33 and 34 of the Harmonized System (HS) of tariff nomenclature, regardless of whether they are classified in a Party as 'cosmetic product' or as a 'medicinal product not subject to prescription'.

Article 4
Relevant international organisations and bodies

The Parties recognise that international organisations and bodies, in particular the International Cooperation on Cosmetics Regulation (ICCR), the Organisation for Economic Cooperation and Development (OECD), the International Organisation for Standardisation (ISO), the International Nomenclature of Cosmetic Ingredients (INCI) Committee are relevant for developing scientific and technical guidelines or standards with respect to products falling under the scope of this Annex.

Article 5
Participation in relevant international organisations and bodies and regulatory convergence

1. Each Party shall actively participate, in the development of scientific or technical guidelines with respect to the assessment and the regulation of products falling under the scope of this Annex in the International Cooperation on Cosmetics Regulation.

2. The Parties shall cooperate with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed scientific or technical guidelines relating to products falling under the scope of this Annex including, where feasible, through the presentation of joint initiatives, proposals and approaches in the International Cooperation on Cosmetics Regulation.

3. Each Party shall implement guidelines of the International Cooperation on Cosmetics Regulation, unless such guidelines would be ineffective or inappropriate for the achievement of the Party's legitimate objectives.

4. Each Party shall encourage active participation of the standardisation bodies located within their respective territories in the work of the International Organisation for Standardisation in order to contribute to the harmonization, at international level, of standards applicable to products falling under the scope of this Annex.

5. Each Party shall take into account the relevant International Organisation for Standardisation standards when developing its own technical regulations and safety assessment procedures and referencing standards applicable to products falling under the scope of this Annex, unless those standards are not yet available or would be ineffective or inappropriate for the achievement of the Party's legitimate objectives. In

particular, each Party shall seek to use or formally recognise, for regulatory purposes, the international standard on good manufacturing practices for products falling under the scope of this Annex and the international standard on the efficacy of sunscreen products testing.

6. The Parties shall cooperate on areas of relevance for the regulation of products falling under the scope of this Annex, such as allergens labelling, traces or microbial contaminants.

Article 6
Safety assessment of ingredients subject to market authorisation

1. Each Party's responsible authorities shall inform the other Party's responsible authorities when updating the list of ingredients subject to market authorisation, for which the Party intends to carry out a safety assessment and possibly take a regulatory action.

2. Upon request of a Party, the responsible authorities of the Parties shall enter into discussions when an ingredient subject to current or future market authorisation, is being assessed by one of the Parties' scientific experts or bodies. Those discussions may entail sharing of the latest available scientific data concerning the safety assessment of that ingredient and of preliminary scientific findings and assessments relating to that ingredient.

3. The Parties shall not be obliged to achieve any particular joint outcome regarding the safety assessment and subsequent regulatory action regarding a given ingredient subject to market authorisation.

4. No Party shall be required to advance, suspend or delay its activities related to the safety assessment of an ingredient and subsequent regulatory action as a result of a request for discussions in accordance with paragraph 2.

Article 7
Safety assessment methodologies

1. Each Party's responsible authorities shall inform the other Party responsible authorities when reviewing the safety assessment methodologies or technical guidance documents of relevance to the regulation of ingredients subject to market authorisation.

2. Upon request of a Party, the Parties shall enter into discussions when assessment methodologies are reviewed or technical guidance documents are developed or reviewed by either Party, with a view to avoid divergences, where feasible while aiming at a high level of protection.

3. When updating or reviewing safety assessment methodologies or technical guidance documents, each Party shall take into account the work done in the international organisations and bodies referred to in Article 4, where relevant.

4. No Party shall be required to advance, suspend or delay its activities related to the safety assessment methodologies of ingredients as a result of a request for discussions in accordance with paragraph 2.

Article 8
Labelling

1. Each Party shall support international efforts to establish and maintain a globally harmonised nomenclature for labelling products falling under the scope of this Annex, in particular by active participation in the work of the International Nomenclature of Cosmetic Ingredients Committee.

2. Each Party shall take all necessary steps to align, to the greatest extent possible, its labelling requirements for products falling under the scope of this Annex with the International Nomenclature of Cosmetic Ingredients Committee nomenclature.

Article 9
Cooperation on standards relevant to products falling under the scope of this Annex

1. The Parties shall encourage cooperation between the standardisation bodies located within their respective territories and with standardisation bodies from other International Cooperation on Cosmetics Regulation members, with a view to jointly developing new international standards and adopting them, to the greatest extent possible. This cooperation may include sharing information, at an early stage, regarding standards to be developed or referenced in each Party's legislation.

2. The Parties shall encourage cooperation between the standardisation bodies located within their respective territories with a view to further aligning their existing standards with the standards adopted by the International Organisation for Standardisation.

Article 10
Alternative methods to animal testing

1. Each Party shall continue to actively support the research, development, validation and regulatory acceptance of alternative methods to animal testing.

2. Each Party shall accept, for the purpose of the safety assessment of products falling under the scope of this Annex, test results generated from validated alternatives to animal testing.

3. No Party shall require that a product falling under the definition of a cosmetic product in this Annex be tested on animals to determine the safety of that product.

4. In exceptional circumstances, where serious concerns arise as regards the safety of an existing cosmetic ingredient, a derogation from the requirements in paragraph 3 may be granted only where

   a. the ingredient is in wide use and cannot be replaced by another ingredient capable of performing a similar function, or

   b. the specific human health problem is substantiated and the need to conduct animal test is justified and is supported by a detailed research protocol proposed as the basis for the evaluation.

Article 11
Cooperation on emerging issues

1. The Parties shall enter into discussions, if so requested by either Party, on scientific information and data in the context of new and emerging issues related to the regulation of products falling under the scope of this Annex, with a view to creating a common pool of knowledge and promoting, if feasible and to the extent possible, a common understanding of the science and safety concerns related to such issues.

2. Each Party shall inform the other Party when it considers adopting regulatory measures with regard to such new and emerging issues. If both Parties consider adopting such regulatory measures, discussions shall be organised in order to avoid, if feasible and being mindful of the general principles in Article 1, divergent regulatory approaches which could create unnecessary barriers to trade.

Article 12
Exchange of regulatory information between the Parties

1. The Parties shall ensure that their responsible authorities are allowed to exchange regulatory information, including confidential information of commercial, technical or scientific nature, including trade secrets, which is not in the public domain related to products falling under the scope of this Annex.

2. A Party shall not publicly disclose confidential information of commercial, technical or scientific nature, including trade secrets, which is not in the public domain, and which it has received from the other Party, if and in so far as that information is protected under its applicable legislation on access to information or access to documents.

[NB: In the EU context, Article 4 of Regulation (EC) n° 1049/2001 as interpreted by the Court of Justice of the European Union]

Article 13
Regulatory cooperation

[NB: this Article may need to be adjusted as discussions on the Institutional, General and

Final Provisions Chapter and on the Regulatory Cooperation Chapter proceed. This Article is to be read in conjunction with the functions and roles of the Joint Committee, the Transatlantic Regulators' Forum and the Working Group on sectors as defined in the Chapter on Institutional, General and Final Provisions]

1. The regulatory cooperation between the responsible authorities of the Parties shall be guided by a joint regulatory cooperation work plan which sets out short and medium term priorities for regulatory cooperation under this Annex.

2. The joint regulatory cooperation work plan shall be endorsed by the responsible authorities of the Parties at political level.

3. The responsible authorities of the Parties shall transmit the joint regulatory cooperation work plan to the Transatlantic Regulators' Forum *[*established under the Institutional, General and Final Provisions Chapter*]* and publish it on their respective websites.

4. The responsible authorities of the Parties shall regularly review the joint regulatory cooperation work plan. In this review, the responsible authorities of the Parties shall take into account, *inter alia*, progress achieved [during the preceding years] and consider new areas that would benefit from regulatory cooperation. For the review of the joint regulatory cooperation work plan, the responsible authorities of each Party shall consult stakeholders including small and medium size enterprises, employers and workers representatives and public interest groups.