

ANNEX 6.4

COSMETICS

1. This Annex shall apply to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation¹ and notification procedures of central government bodies that may affect trade in cosmetic products between the Parties. This Annex shall not apply to a technical specification prepared by a governmental entity for its production or consumption requirements or a sanitary or phytosanitary measure.
2. A Party's obligations under this Annex shall apply to any product that the Party defines as a cosmetic product pursuant to paragraph 3. For the purposes of this Annex, preparation of a technical regulation, standard, conformity assessment procedure or marketing authorisation includes, as appropriate, the evaluation of the risks involved, the need to adopt a measure to address those risks, the review of relevant scientific or technical information, and the consideration of the characteristics or design of alternative approaches.
3. Each Party shall define the scope of the products subject to its laws and regulations for cosmetic products in its territory and make that information publicly available.
4. Recognising that each Party is required to define the scope of products covered by this Annex pursuant to paragraph 3, for the purposes of this Annex, a cosmetic product may include a product that is intended to be rubbed, poured, sprinkled, sprayed on or otherwise applied to the human body including the mucous membrane of the oral cavity and teeth, to cleanse, beautify, protect, promote attractiveness or alter the appearance.
5. Each Party shall identify the agency or agencies that are authorised to regulate cosmetic products in its territory and make that information publicly available.
6. If more than one agency is authorised to regulate cosmetic products within the territory of a Party, that Party shall examine whether there is overlap or duplication in the scope of those authorities and eliminate unnecessary duplication of any regulatory requirements resulting for cosmetic products.
7. The Parties shall seek to collaborate through relevant international initiatives, such as those aimed at harmonisation, as well as regional initiatives that support of those international initiatives, as appropriate, to improve the alignment of their respective regulations and regulatory activities for cosmetic products.
8. When developing or implementing regulations for cosmetic products, each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts. Each Party is encouraged to consider regionally-developed scientific or technical guidance documents that are aligned with international efforts.

¹ The application of this Annex to marketing authorisations is without prejudice to whether a marketing authorisation meets the definition of a technical regulation, standard or conformity assessment procedure.

9. Each Party shall observe the obligations set out in Article 2.1 and Article 5.1.1 of the TBT Agreement with respect to a marketing authorisation, notification procedure or elements of either that the Party prepares, adopts or applies for cosmetic products and that do not fall within the definition of a technical regulation or conformity assessment procedure.

10. Each Party shall ensure that it applies a risk-based approach to the regulation of cosmetic products.

11. In applying a risk-based approach in regulating cosmetic products, each Party shall take into account that cosmetic products are generally expected to pose less potential risk to human health or safety than medical devices or pharmaceutical products.

12. No Party shall conduct separate marketing authorisation processes or sub-processes for cosmetic products that differ only with respect to shade extensions or fragrance variants, unless a Party identifies a significant human health or safety concern.

13. Each Party shall administer any marketing authorisation process that it maintains for cosmetics products in a timely, reasonable, objective, transparent and impartial manner, and identify and manage any conflicts of interest in order to mitigate any associated risks.

- (a) If a Party requires marketing authorisation for a cosmetic product, that Party shall provide an applicant with its determination within a reasonable period of time.
- (b) If a Party requires marketing authorisation for a cosmetic product and it determines that a marketing authorisation application for a cosmetic product under review in its jurisdiction has deficiencies that have led or will lead to a decision not to authorise its marketing, that Party shall inform the applicant that requests marketing authorisation and provide reasons why the application is deficient.
- (c) If a Party requires a marketing authorisation for a cosmetic product, the Party shall ensure that any marketing authorisation determination is subject to an appeal or review process that may be invoked at the request of the applicant. For greater certainty, the Party may maintain an appeal or review process that is either internal to the regulatory body responsible for the marketing authorisation determination, such as a dispute resolution or review process, or external to the regulatory body.
- (d) If a Party has granted marketing authorisation for a cosmetic product in its territory, the Party shall not subject the product to periodic re-assessment procedures as a condition of retaining its marketing authorisation.

14. If a Party maintains a marketing authorisation process for cosmetic products, that Party shall consider replacing this process with other mechanisms such as voluntary or mandatory notification and post-market surveillance.

15. When developing regulatory requirements for cosmetic products, a Party shall consider its available resources and technical capacity in order to minimise the implementation of requirements that could:

- (a) inhibit the effectiveness of procedures for ensuring the safety or manufacturing quality of cosmetic products; or
- (b) lead to substantial delays in marketing authorisation regarding cosmetic products for sale on that Party's market.

16. No Party shall require the submission of marketing information, including with respect to prices or cost, as a condition for the product receiving marketing authorisation.

17. No Party shall require a cosmetic product to be labelled with a marketing authorisation or notification number.

18. No Party shall require that a cosmetic product receive marketing authorisation from a regulatory authority in the country of manufacture, as a condition for the product receiving marketing authorisation from the Party. For greater certainty, this provision shall not prohibit a Party from accepting a prior marketing authorisation issued by another regulatory authority as evidence that a product may meet its own requirements.

19. No Party shall require that a cosmetic product be accompanied by a certificate of free sale as a condition of marketing, distribution or sale in the Party's territory.

20. If a Party requires a manufacturer or supplier of a cosmetic product to indicate information on the product's label, the Party shall permit the manufacturer or supplier to indicate the required information by relabelling the product or by using supplementary labelling of the product in accordance with the Party's domestic requirements after importation but prior to offering the product for sale or supply in the Party's territory.

21. No Party shall require that a cosmetic product be tested on animals to determine the safety of that cosmetic product, unless there is no validated alternative method available to assess safety. A Party may, however, consider the results of animal testing to determine the safety of a cosmetic product.

22. If a Party prepares or adopts good manufacturing practice guidelines for cosmetic products, it shall use relevant international standards for cosmetic products, or the relevant parts of them, as a basis for its guidelines unless those international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued.

23. Each Party shall endeavour to share, subject to its laws and regulations, information from post-market surveillance of cosmetic products.

24. Each Party shall endeavour to share information on its findings or the findings of its relevant institutions regarding cosmetic ingredients.

25. Each Party shall endeavour to avoid re-testing or re-evaluating cosmetic products that differ only with respect to shade extensions or fragrance variants, unless conducted for human health or safety purposes.