AUSTRALIA – EUROPEAN UNION

FREE TRADE AGREEMENT

PROPOSAL FOR AN ANNEX ON ELIMINATION OF TECHNICAL BARRIERS TO THE COSMETIC PRODUCTS TRADE

INDUSTRY PROPOSAL (Accord/Cosmetics Europe)

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[1] Accord is the peak Australian industry association representing the manufacturers and marketers of formulated hygiene, cosmetic and specialty products, their raw material suppliers, and service providers.

[2] Cosmetics Europe - The Personal Care Association is the trade association representing the interests of the European cosmetics, toiletry and perfumery industry. The Cosmetics Europe membership consists of more than 4500 companies, ranging from major international cosmetics manufacturers to small, family-run businesses operating in niche markets.

Introduction

This Annex shall apply to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation 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.

A Party's obligations under this Annex shall apply to any product that the Party defines as a cosmetic product. 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.

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.

Recognising that each Party is required to define the scope of products covered by this Annex, for the purposes 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.

Each Party shall identify the agency or agencies that are authorised to regulate cosmetic products in its territory and make that information publicly available.

The Parties shall seek to collaborate through relevant international initiatives, such as those aimed at harmonisation, as well as regional initiatives that support international initiatives, as appropriate, to improve the alignment of their respective regulations and regulatory activities for cosmetic products.

Rules for placing cosmetic products on the market

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

2. Therefore, for products considered as cosmetic, the Parties should automatically consider any product with a safety assessment as low risk and will not impose any additional requirements for ingredient registration before placing the product on the market. Furthermore, if the finished product has a safety assessment this will be taken to mean that an assessment of the ingredients has been carried out by a qualified professional.

3. For products considered as therapeutic in Australia, we would encourage the Australian authorities to consider the cosmetics data provided by recognized international scientific authorities such as the European Scientific Committee on Consumer Safety (SCCS) and others to identify the ingredients that have already been approved and are safely used internationally.

4. 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.

Ingredient Revision System

5. The Parties shall take as reference in their ingredient review systems, the lists of ingredients recognized and / or prohibited in the regions of reference at the international level.

6. Parties should accept any ingredient that has been reviewed and approved by a comparable market for the same use. Mutual recognition should be granted for:
   - Ingredients registered under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and under the Australian industrial chemicals regulator, currently named NICNAS, (occupational safety and environmental safety).
   - Ingredients listed in the EU Cosmetic Product Regulation (1223/2009) annexes and the Australian industrial chemicals regulation (consumer safety).
   - Ingredients in the EU Cosmetic Product Regulation (1223/2009) annexes also registered with the TGA, Therapeutic Goods Administration (consumer safety).

7. More specifically, the Parties should recognize UV filters approved under other regulations. Notably, in the EU and Australia the approval of a new UV filter follows a strict process of evaluation by an independent expert body, respectively the SCCS, Australia's industrial chemicals regulator and the Therapeutic Goods Administration. All three regulatory approaches are comparable in requirements. Therefore, there is no safety justification to have ingredients reviewed and approved twice.

8. Likewise, the Parties shall adopt expeditious mechanisms to include, prohibit or restrict ingredients in their listings.

9. As well, the Parties will adopt a cooperation system that allows for information exchange in an efficient manner on the considerations and motivating factors for making decisions regarding ingredients.

Harmonization of Labelling of Cosmetic Products

10. The Parties shall harmonize, their labelling requirements for cosmetic products, with the objective of having a single label that contains the minimum requirements for consumer protection.

11. The Parties shall work towards greater harmonization and mutual acceptance regarding the Sun Protection Factor (SPF) labelling for sun products

Recognition of International Nomenclature of Cosmetic Ingredients (INCI)

12. The Parties shall recognise the International Nomenclature of Cosmetic Ingredients (INCI) as the source of ingredient names with no requirement for translation into local languages. Ingredient listing is recognised as a public health safety measure. INCI names are not mere "descriptors" but, rather, technical "codes" incorporating scientific and Latin pharmacopeia names, understood by scientists and health professionals worldwide. The Parties recognise that the use of an international nomenclature helps facilitate more agile updating, according to existing and emerging scientific knowledge.

Good Manufacturing Practices

13. 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.

Recognition of Cosmetics International Standards applicable on methodology.

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

15. Each Party shall take into account the relevant ISO standards when developing its own technical regulations and safety assessment procedures and referencing standards applicable to products falling under the scope of this Annex. As a general principle, if valid data are already available for use ,then making or repeating tests at the local level in a country should be avoided. ,.

Animal Testing Ban

16. The Parties should align the scope of their Animal Testing Ban for cosmetic products, including the following principles:
    - Bans on the animal testing of cosmetic products and ingredients should not be retrospective.
    - Animal test data obtain for another purpose than cosmetic use could be used to substantiate the safety of the cosmetic product.

- Substances that might be used in cosmetic products can be subject to many regulatory regimes beyond cosmetics legislation, both in the country considering an animal testing ban as well as in other countries. Such mandatory tests should not trigger restrictions to the marketing of products.
- Each Party should grant an exemption from the testing and marketing bans, in exceptional circumstances, where serious concerns arise as regards the safety of an existing cosmetic ingredients that cannot be replaced.

Alternative methods to animal testing

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

18. 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.

Cooperation on emerging issues

19. 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.

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

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