Association of South East Asian Nations (ASEAN)

QUESTION & ANSWER (Q&A) ON SPECIFIC PROVISIONS OF THE ASEAN COSMETIC DIRECTIVE (ACD)

FINAL VERSION

DOCUMENT INFORMATION

This Q & A on specific provisions of the ACD was adopted at the 27th ASEAN Cosmetic Committee Meeting, held on 16-17 November 2017 in Bandung, Indonesia.

BACKGROUND

The Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme ("AHCRS") was signed on 2 September 2003. The ASEAN Cosmetic Directive (ACD) forms part of the AHCRS.

Since 1 January 2008, the ASEAN Member States have been implementing the ACD together with its accompanying annexes and appendices.

OBJECTIVE

The objective of developing the Question and Answer document on the specific provisions of the ASEAN Cosmetic Directive is to provide clarity on the ACD to ensure that the implementation is in line with the intended philosophy and spirit of the ACD in the application of the relevant technical requirements of the ACD.

QUESTION 1

Q: **What is the relevance of referring to Article 10 (Institutional Arrangements) in Article 1.2?**

A: The reference made to Article 10 (Institutional Arrangements) may not be relevant within the context of the provision of Article 1.2. Article 1.2 may have intended to refer to Article 11 (Special Cases) concerning special cases when a Member State may provisionally prohibit the marketing of the cosmetic products in its territory.

QUESTION 2

Q: **When Article 11.1 is read with Article 1.2, would the Member States still be able to refuse, prohibit or restrict the marketing of any cosmetic products which comply with the requirements of this Directive and its Annexes and Appendices?**

A. The ACD has been drawn up with safety consideration in mind. For example, in Article 3 (Safety Requirements) provides that "a cosmetic product placed on the market must not cause damage to human health when applied under normal or reasonable foreseeable conditions of use". Article 11 provides an additional safeguard, in that it allows Member States to provisionally prohibit the marketing of cosmetic products even though they comply with the requirements of the ACD, if the Member State have substantiated justification, i.e. a hazard to health or for reason specific to religious or cultural sensitivity.

QUESTION 3

Q: **According to Article 8.1, the company or person responsible for placing the cosmetic product in the market shall keep the following information readily accessible to the regulatory authority of the Member States concerned at the address specified on the label in accordance with Article 5 of this Directive. How should the requirements be implemented?**

A: The information required for the company to provide evidence to demonstrate the safety, quality, and benefit of the product, is within the jurisdiction of each national authority. The company or person responsible for placing the cosmetic products in the market should develop and prepare the product information as may be required by the regulatory authority. National authorities may use their post market surveillance measures to remove unsafe products from their respective territories.

QUESTION 4

Q: **According to Article 8.1, the company or person responsible for placing the cosmetic product in the market shall keep the following information readily accessible to the regulatory authority of the Member States concerned at the address specified on the label in accordance with Article 5 of this Directive. Is it appropriate to refer to Article 5 of the Directive with regards to labelling?**

A: Article 5 of the Directive is related to cosmetic ingredients whereas information on labelling is described in Article 6. Therefore, Article 8.1 shall refer to Article 6 for information on labelling requirements.

QUESTION 5

Q: **The EU Cosmetic Directive is mentioned in Article 4.1. Will there be changes to the current process for including or excluding cosmetic ingredients into the ACD Annexes?**

A: The ACSB may conduct safety review and recommend changes to the Annexes by referencing the cosmetic ingredients listing of the EU Cosmetic Regulations as well as cosmetic ingredients listing of other regions. The aforementioned listing may be used as the starting basis for the acceptance of new ingredients and any other amendment to the Annexes.

QUESTION 6

Q: **What are the provision(s) of the ACD which are no longer applicable?**

A: Article 5 of the ACD – ASEAN Handbook of Cosmetic Ingredients.