Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

ANNOUNCEMENT

DATE : 13 February 2023

TO : **ALL MANUFACTURERS, TRADERS AND DISTRIBUTORS OF COSMETIC PRODUCTS AND OTHER INTERESTED STAKEHOLDERS**

FROM : **ENGR. ANA TRINIDAD F. RIVERA, MSc**
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SUBJECT : **DISSEMINATION OF THE UPDATES AND AMENDMENTS TO THE ASEAN COSMETIC DIRECTIVE (ACD) AS ADOPTED DURING THE 36TH ASEAN COSMETIC COMMITTEE (ACC) MEETING AND ITS RELATED MEETINGS**

In the interest of service, and in order to provide timely dissemination of the updates and amendments to the ASEAN Cosmetic Directive (ACD), the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) hereby informs all cosmetic manufacturers, traders and distributors and other interested stakeholders, of the following information which have been adopted during the 36th ASEAN Cosmetic Committee (ACC) Meeting and Its Related Meetings hosted by the ASEAN Secretariat via video conferencing and held as follows:

Date	Meeting
21-22 November 2022	36th ASEAN Cosmetic Scientific Body (ACSB) Meeting
23-24 November 2022	19th ASEAN Cosmetic Testing Laboratories Committee (ACTLC) Meeting
28-29 November 2022	ASEAN Cosmetic Committee Heads of Delegations (HODs) Meeting
30 November - 01 December 2022	36th ACC Meeting

The following are the updates and amendments to the ACD. For reference, the new and modified entries as well as the given grace period are listed in **Annex A**.

1. **Amendment of Annex II - List of substances which must not form part of the composition of cosmetic products (EU Amendment of Annex II)**

a. **Consolidated List of Banned Ingredients, Ref. Nos. 1398, 1399, 1458, 1459, 1503, 1645-1656, 1658-1665, 1667, 1668, and 1671-1680 (EU 2019/831, EU 2019/1966, EU 2021/850 and EU 2021/1902)**

The ACSB Secretary presented the summary of consolidated list of banned ingredients to the Meeting and informing that the EU Annex II (EU 2019/831, EU 2019/1966, EU 2020/1683, EU2021/850, EU 2021/1902) were continuously consolidated, reviewed and considered by ACSB in the 32nd ACSB, 33rd ACSB, 34th ACSB, and 35th ACSB Meetings. It was agreed in the meeting that the identified 37 entries in the list of banned substances from EU 2019/831, EU 2019/1966, EU 2021/850, and EU 2021/1902 which were not used in ASEAN are to be moved to ACD Annex II with the grace period of **24 months** – Effective **21 November 2024**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market

In addition, the AMS agreed to adopt Brunei Darussalam's proposal to move entries #1428 and #1490 with reported use in ASEAN into Annex II with a grace period of **24 months** – Effective **21 November 2024**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

b. **Perboric Acid, Sodium Perborate compounds and some Boron compounds, Ref. No. 1397 (EU Annex III 1a and 1b)**

It was agreed in the meeting to include Perboric acid, Sodium Perborate and Boron compounds as a new entry to ACD Annex II with a grace period of **24 months** – Effective **21 November 2024** only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

c. **Octamethylcyclotetrasiloxane (D4), Ref. No. 1388**

ACA presented the updated D4 assessment incorporating the review of the EU Commission Regulation 2018/35. The AMS agreed to the proposal to include D4 as a new entry in ACD Annex II, with a grace period of **24 months** – Effective **21 November 2024,** only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

d. **2-(4-tert-butylbenzyl) propionaldehyde (p-BMHCA), Ref. No. 1666**

Indonesia sought more information on safety review of p-BMHCA whether there was any more (on another species) *in vivo* test beside the one presented by ACA (on rodent) for this ingredient. ACA informed that there are both *in vitro* and *in vivo* test including rodent (rat, mouse) and dog, rabbit, monkey available to support the safety of p-BMHCA. The Chair shared that under the SCCS Opinion (SCCS/1591/17), the Margin of Safety (MOS) for the aggregate exposure was < 100 (MOS = 80), for different product types, hence, it was concluded that considering the deterministic aggregate exposure, arising from the use of different product types together, p-BMHCA at the proposed concentrations cannot be considered as safe.

The ACSB agreed to include p-BMHCA in ACD Annex II, including the grace period of **24 months** – Effective **21 November 2024**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

2. **Titanium Dioxide (Annex IV - Part 1 - List of colouring agents allowed for use in cosmetic products, CI 77891, and Annex VII - List of UV filters which cosmetic products may contain, Ref. No. 27) (EU 2021/850)**

   The AMS agreed to adopt the revisions on the entries of Titanium Dioxide in EU Annexes IV and VI into ACD Annexes IV and VII with a grace period of **24 months** - Effective **21 November 2024**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

   The AMS agreed to adopt the amendment of Titanium Dioxide in Annex IV and VII, except for purity criteria, pending the discussion and clarification of the decision during the 24th ACSB Meeting which excluded the purity criteria in the said Annex.

3. **Salicylic Acid (Annex III - List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down, Ref. No. 98 and Annex VI - List of preservatives allowed for use in cosmetic products, Ref. No. 3) (EU 2021/850)**

   ACA made a scientific presentation on Salicylic Acid relative to the additional products included in the EU Annex III entries, incorporating the information from AMS on their check on the usage of Salicylic Acid in their markets in terms of notified product types and applications.

   ACA provided its summary review on this subject, and based on the literature (Comiskey et al.,2015) on the probabilistic approach used for exposure assessment in SCCS opinion, "body cream" is included in product category of "body lotion".

   It was agreed in the meeting to adopt the corresponding entries for Salicylic Acid into ACD Annexes III and VI with a grace period of **24 months** - Effective **21 November 2024**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

This announcement shall only serve as a **prior notification** to the cosmetic industry and shall be subsequently supplemented by an official FDA Circular. The aim of this document is to give the industry sufficient time / grace period to conduct operational activities (i.e. reformulation, testing of new formulations, phase out of products with old formulation, etc.) to ensure continued compliance with the ACD.

Should you have any inquiries and/or clarifications, you may contact us at **cchuhsrraseannotification2@fda.gov.ph**.

For your information and guidance. Thank you very much.