Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2023-007

04 APR 2023

SUBJECT: **Updates and Amendments of the ASEAN Cosmetic Directive (ACD) as Adopted during the 36th ASEAN Cosmetic Committee (ACC) Meeting and Its Related Meetings**

I. BACKGROUND

In 2005, the Department of Health (DOH) – Food and Drug Administration (FDA), then Bureau of Food and Drugs (BFAD), has adopted and implemented the Association of Southeast Asian Nations (ASEAN) Harmonized Cosmetic Regulatory Scheme and the ASEAN Common Technical Documents, including the ASEAN Cosmetic Directive (ACD), through Administrative Orders No. 2005-0015 and 2005-0025, respectively. The harmonization scheme aims to eliminate restrictions to trade of cosmetic products and enhance cooperation within the ASEAN Member States (AMS) in ensuring the safety, quality and claimed benefits of cosmetic products.

Under the ACD, the AMS, through the National Regulatory Authorities (NRA), shall undertake all necessary measures to ensure that only cosmetic products that conform to the provisions of the ACD, its Annexes and Appendices may be placed in the market.

Amidst challenges brought about by the current COVID-19 pandemic, the ASEAN Cosmetic Committee (ACC) Meeting and Its Related Meetings, through the ASEAN Secretariat, were held virtually 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

To provide the industry with timely and relevant information on standards, rules, and regulations and to establish the implementation timeline or grace period to allow sufficient time for the industry to conduct operational activities (i.e. reformulation and phase out of products with old formulation), the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR), hereby, reports the highlights of the aforementioned meetings and presents the updates to the ASEAN Cosmetic Directive (ACD) as adopted in the 36th ACC Meeting.

II. OBJECTIVES

This Circular aims to provide the updates and amendments to the ACD as adopted in the 36th ACC meeting and its related meetings, including its implementation timeline or grace period to allow sufficient time for the industry to conduct relevant operational activities and ensure continued compliance with the ACD, which covers cosmetic products made available in the local market.

III. SCOPE

This Circular applies to establishments that are engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, and where applicable, the use, testing, promotion, advertising, or sponsorship of cosmetic products.

IV. UPDATES AND AMENDMENTS TO THE ACD

A. Updates and Amendments to the ACD Ingredient Annexes

The following are the updates and amendments on cosmetic ingredients and their restrictions as indicated in the ACD Ingredient Annexes. The latest revision of the ACD Ingredient Annexes is accessible at the FDA website.

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.

V. PENALTY CLAUSE

Any person found in violation of this Circular shall be deemed in violation of Republic Act No. 3720 as amended by Republic Act No. 9711 and shall be penalized accordingly following the Uniform Rules of Procedures laid down under Book III of the Implementing Rules and Regulations of Republic Act No. 9711.

VI. SEPARABILITY CLAUSE

The provisions of this "Updates and Amendments to the ASEAN Cosmetic Directive (ACD) Ingredient Annexes" are hereby declared separable and in the event of any such provision is/are declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions including other provisions of the ACD which are not affected by this updates/amendments, shall remain in full force and in effect.

VII. REPEALING CLAUSE

All other administrative issuances, circulars and memoranda and other regulations which are inconsistent with the remaining and valid provisions of ACD and this update/amendment are hereby withdrawn, repealed and/ or modified accordingly.

VIII. EFFECTIVITY

This Circular shall take effect after fifteen (15) days after its publication in a newspaper of general circulation and filing with the University of the Philippines, Office of the National Administrative Register.

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Director General

DTN 20230213101031