FDA CIRCULAR
No. 2025-002

04 MAR 2025

SUBJECT: **Updates and Amendments to the ASEAN Cosmetic Directive (ACD) as Adopted during the 39th 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 (NRAs), 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.

To effectively implement the ACD, the ASEAN Cosmetic Committee (ACC) consisting of representatives from each Member State's regulatory authority and the ASEAN Cosmetic Industry regularly convenes for the ACC Meeting. Relatively, the 39th ACC Meeting and Its Related Meetings, were held virtually, through the ASEAN Secretariat, as follows:

Date	Meeting
7-8 May 2024	22nd ASEAN Cosmetic Testing Laboratories Committee (ACTLC) Meeting
13-14 May 2024	39th ASEAN Cosmetic Scientific Body (ACSB) Meeting
15-16 May 2024	ASEAN Cosmetic Committee Heads of Delegations (HODs) Meeting
20-21 May 2024	39th 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 39th ACC Meeting.

II. OBJECTIVES

This Circular aims to provide the updates and amendments to the ACD as adopted in the 39th 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. **N,N-diethyl-m-toluamide/Diethyltoluamide (DEET) (Annex II – List of substances which must not form part of the composition of cosmetic products, Ref. No. A1144)**

   Malaysia provided information regarding the outcome of their internal country consultation wherein they agreed to include DEET in ACD Annex II with no grace period. It was noted that during the 38th ACSB Meeting, all the AMS except Malaysia, agreed to include DEET in ACD Annex II due to its classification as pesticides.

2. **Amendment to Annex III - List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down**

   a. **Silver Zinc Zeolite (SZZ), Ref. No. 340**

      ACA presented the update on the SCCS final opinion and preparation status of the EU Cosmetic regulation on SZZ.

      Since SZZ is an insoluble powder, current proposed product type for Annex III is powder foundation and deodorant. ACA agreed to the Indonesia's comment that the product type of "foundation" under the existing SZZ of ACD Annex III shall be amended to "powder foundation".

      The latest of SCCS final opinion on SZZ was published in December 2023. Based on the EU cosmetic use, up to 1% of SZZ in spray deodorant

and powder foundation is evaluated as safe. ACA will present the update on the Annex V of EU Cosmetic Product Regulation (CPR) when available. The ACD Annex III will be updated regarding the product type to be specified as "powder foundation."

b. Zinc Pyrithione (ZPT), Ref. No. 101

The Technical Working Group (TWG) composed of ASEAN Cosmetic Association (ACA), Singapore, Brunei Darussalam, and Philippines presented an in-depth safety assessment review of ZPT by applying the ASEAN criteria for CMR substances under category 1B for the cosmetic products.

ACA supports the findings of the SCCS Final Opinions (2014, 2018 & 2020). ZPT has a long history of safe use. Based on the risk calculations done for exposure to different product categories, it was concluded that there is a sufficiently high margin of safety with the proposed concentration limits.

The AMS agreed with the TWG proposal and allowed to continue ZPT usage in the ASEAN as follows: (a) at concentrations up to 1.0% in hair rinse-off products & (b) 0.1% in leave-on hair products (ACD Annex III, Ref. No. 101), and as a preservative in (c) rinse-off products up to 1.0% in hair products, and (d) rinse-off non-hair care products (excluding oral hygiene products) for up to 0.5% (ACD Annex VI, Ref. No. 8).

All AMS and ACA **except for the Philippines** agreed to adopt the TWG's proposal to continue the usage of ZPT following the restrictions stated above, with a grace period of 24 months. - Effective 14 May 2026, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market. The Philippines requested to defer the Philippines's action on this agenda item, pending results of their internal consultations.

3. Acid Yellow 3 (Inclusion to Annex III - List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down, Ref. No. 341 [326])

ACA presented the safety assessment review of Acid Yellow 3 based on ASEAN usage and information provided by AMS and the calculation of margin of safety (MOS) for Acid Yellow 3. Acid Yellow 3 is found safe when used in non-oxidative hair dye products at concentrations up to 0.5%.

ACA proposed to add Acid Yellow 3 to ACD Annex III, with restriction of 0.5% for non-oxidative hair dye product with 24 months grace period.

All AMS agreed to ACA's proposal and adopted to move the Acid Yellow 3 into ACD Annex III with a grace period of **24 months** - **Effective 14 May 2026**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

4. ASEAN Criteria for CMR Substance 1A and 1B

The TWG composed of ACA, Singapore, Brunei Darussalam, and Philippines presented the proposed ASEAN criteria for the continued use of CMR substances under categories 1A and 1B for cosmetic products in ASEAN. The TWG has discussed the criteria for CMR Categories 1A and 1B following ACSB Chair's comments during the 38th ACSB meeting and Indonesia's comments to the TWG in Jan 2024.

The proposed ASEAN criteria for CMR substances are only applicable to substances that the cosmetics industry has specific use in cosmetic products marketed in ASEAN. CMR substances that are not used in cosmetic products may be added to the list of prohibited ingredients under Annex II of the ACD.

When a CMR substance is used in cosmetic products in ASEAN, its use in cosmetic products shall be reviewed based on the criteria stated below:

CMR Category 1A:

a. The application is made for a particular use with a known exposure;
b. Substance has been evaluated by ACSB and found safe for use in cosmetic products, in particular in view of exposure to those products; and
c. There are no alternative substances available.

CMR Category 1B:

a. The application is made for a particular use with a known exposure; and
b. Substance has been evaluated by ACSB and found safe for use in cosmetic products, in particular in view of exposure to those products.

CMR Category 2: Substances have been evaluated by the ACSB and found safe for use in cosmetic products.

In the 38th ACSB meeting, the Chair requested the TWG to consider substances under Category 1A as to whether genotoxic chemicals which as a general concept that is considered to have no safe exposure threshold and therefore assumed to pose a cancer risk for humans even at very low doses would still be considered at ASEAN, while comparing with non genotoxic carcinogens where we may be able to establish a safe exposure threshold or dose. The TWG then recommended that no further criteria be developed for genotoxic carcinogens. The safety assessment of these genotoxic carcinogens would result in the conclusion that it is "not safe for use in ASEAN Cosmetics" as there is no safe exposure threshold.

The ACSB Chair presented the statement on behalf of the Philippines delegation confirming solid concern on carcinogenic risk for human of genotoxic chemicals. It was informed that there are on-going discussions with various parties in the Philippines on the use of substances classified as CMR Categories 1A and 1B in consumers products. Thus, the Philippines may need internal consultation for further clarification on the ASEAN Criteria for CMR Categories 1A and 1B as proposed by the TWG, pending on-going discussions on the matter.

Indonesia had proposed to add point c) for CMR category 1B in her comments to the TWG in Jan 2024. This is because CMR Category 1A and Category 1B are substances that are known or presumed as human CMR. Therefore, the usage of those substances should only be allowed if there are no alternative substance available. The TWG clarified that CMR Category 1B is based on animal data while CMR Category 1A is based on human studies according to the definition of CMR substances found in the latest EU's Guidance on the Application of the CLP Criteria Version 6.0 (Jan 2024). The basic principle of CMR management within ASEAN is a risk assessment approach based on consumer safety. Indonesia agreed with the proposal of TWG. However, it must still be ensured that the use of category 1B CMR substance is permitted only according to its intended purposes and usage limitations while monitoring the effects of CMR through cosmetovigilance.

All AMS **except the Philippines** agreed to the TWG proposal to adopt the ASEAN Criteria for CMR Categories 1A and 1B for cosmetic products.

5. ACD Annexes Review and Rectification

a. Amendment to Annex III - List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down

ACA proposed to add Salicylic Acid in ACD Annex III for Nail Care Product with 0.5% with grace period 24 months.

Indonesia informed in the meeting that the additional product type in point (c) under this entry shall be "Nail Polish", instead of "Nail Care" since the safety assessment review provided by ACA in the presentation is based on Nail Polish data.

The AMS agreed to ACA proposal to add the use of Salicylic Acid with 0.5% for nail polish under point (c) of this entry with 18 months grace period (or additional 12 months from the grace period adopted in the 37th ACSB Meeting for the same entry) - **Effective 21 November 2025.**

Indonesia raised a concern on other nail products i.e. top coat, base coat, nail dryer as to whether it would be considered under point (c) of this entry. ACA informed that for other nail products beside the nail polish, such nail products will be under point (b) of this entry. This implementation for nail products is based on safety assessment logic of nail products where there is no penetration potential to deeper skin.

b. Titanium Dioxide (Amendment to Annex VII - List of UV filters which cosmetic products may contain, Ref. No. 27)

The ACSB Secretary presented the proposal from Thailand to Remove the Wording of "column (d)" from Titanium Dioxide.

The Secretary informed the Meeting that, there are two (2) options for ACSB to consider as follows:
Option 1: The wording "column (d) of" shall be removed, or

Option 2: To change the "column (d)" to "column (c)"

All AMS and ACA agreed to Option 2. The ACD Annex VII Ref. No. 27 will be amended to reflect the ACSB decision accordingly.

c. Inclusion of Chemical Abstracts Service (CAS) Nos. and list of compounds

i. Annex II – List of substances which must not form part of the composition of cosmetic products, Ref. Nos. 250, 255, 281, 420, and 450
ii. Annex VI – List of preservatives allowed for use in cosmetic products, Ref. Nos. 1a, 2-4, 7, 9, 11, 13, 14-15, 18-24, 26-27, 29-30, 32-35, 37-38, 42-50, 52, and 54-55
iii. Annex VII - List of UV Filters Which Cosmetic Products May Contain, Ref. Nos. A29, A29a, 2-3, 6-8, 9, 11-18, 20-22, 24-25, and 27a

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 FDA Circular 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 Circular, 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.

DR. SAMUEL A. ZACATE
Director General