



13 DEC 2021

FDA CIRCULAR
No. 2021-026

SUBJECT: Updates and Amendments of the ASEAN Cosmetic Directive (ACD) as Adopted during the 33rd 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 ASEAN Harmonized Cosmetic Regulatory Scheme and the ASEAN Common Technical Documents through Administrative Orders No. 2005-0015 and 2005-0025, respectively. The harmonization scheme involves the conduct of alignment meetings for the purpose of eliminating trade barriers and enhancing cooperation within the ASEAN Member States (AMS) in ensuring the safety, quality and claimed benefits of cosmetic products.

Amidst challenges brought about by the current pandemic state, the ASEAN Cosmetic Committee Meeting (ACC) and Its Related Meetings, through the ASEAN Secretariat, were held virtually as follows:

Date	Meeting
04-05 March 2021	Special ASEAN Cosmetic Committee Heads of Delegations (HODs) Meeting
27-28 May 2021	33 rd ASEAN Cosmetic Scientific Body (ACSB) Meeting
01-02 June 2021	16 th ASEAN Cosmetic Testing Laboratories Committee (ACTLC) Meeting
03-04 June 2021	33 rd ACC Meeting

As part of FDA's continuous commitment to provide timely and relevant information on standards, rules, and regulations, 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).

II. OBJECTIVES

This Circular aims to provide the updates and amendments to the ACD as adopted in the 33rd ACC meeting and its related meetings which covers cosmetic products made available in the local market.



III. SCOPE

This Circular shall guide 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 items 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 is listed in Annex A.

1. Biphenyl-2-ol and its salts (EU 2018/1847)

(ACD Annex VI - List of preservatives allowed for use in cosmetic products, Ref. No. 7)

Indonesia informed the Meeting that she is withdrawing the discussion on Biphenyl-2-ol and its salts as the use of the salts in Indonesia is until December 2021. The Meeting requested the Secretary to update the ACD Annex VI and remove “Except for Indonesia” in this substance entry.

2. Annex VI (List of preservatives allowed for use in cosmetic products) Format

The Meeting agreed to adopt the revised Annex VI with the following revisions: include the formaldehyde releasers compounds provided by Thailand in the 5th statement of the Preamble and remove the (+) sign for the substances that have corresponding footnote.

3. 2-hydroxyethyl methacrylate (HEMA) and 11,14-Dioxo-2,9-diazaheptadec-16-enoic Acid, 4,4,6,16-tetramethyl-10,15-dioxo, 2-[(2-methyl-1-oxo-2-propenyl)oxy]ethyl ester (Di-HEMA Trimethylhexyl Dicarbamate or Di-HEMA TMHDC) - EU 2020/1682 Amending Annex III to Regulation (EC) 1223/2009

(Annex III - List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down, Ref. Nos. 328 and 329, respectively)

- a. The AMS, except for Singapore, agreed to include the entries of HEMA and Di-HEMA Trimethylhexyl Dicarbamate for use on nail products.
- b. Restricted for professional use only and to include the following conditions of use and warning on the label: “For professional use only” and “Can cause an allergic reaction”
- c. Grace period: Effective **28 November 2022 (18 months)**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

d. Singapore will further review the data and feedback to the next ACSB Meeting.

4. Hair Dye Products - EU 2020/1683 Amending Annexes II and III to Regulation (EC) 1223/2009

(Annex II - List of substances which must not form part of the composition of cosmetic products, Ref. Nos. 1642-1644)

- a. The AMS agreed to the following, except for Singapore: add substances Ref. Nos. 1642, 1643 and 1644 into Annex II with the grace period: Effective **28 May 2022 (12 months)**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.
- b. Singapore will further review the data and give feedback to the next ACSB Meeting.

5. Carbon Black

(Annex IV - List of colouring agents allowed for use in cosmetic products)

Thailand informed that per her review of the carbon black entries (77266 and 77266 <nano>) in ACD Annex IV (Colorants), the total Hg is reflected as <10ppm, while the reference EU Regulation 1120/2016 reflects total Hg as <1ppm. The Secretary informed that this ingredient has been agreed to be included in ANNEX IV during the 25th ACSB Meeting following the EU 1120/2016. In this case, the total Hg as <10ppm is a typo error. The Meeting agreed for the Secretary to correct the carbon black entries and reflect total Hg as <1ppm in Annex IV.

V. PENALTY CLAUSE

Establishments 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 which are found to be operating in violation of the rules and regulations of FDA shall be subjected to sanctions and penalties as prescribed by Republic Act No. 9711, otherwise known as the “Food and Drug Administration Act of 2009.”

VI. 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.

VII. 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 of 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.

VIII. EFFECTIVITY

This Administrative Circular shall take effect after fifteen (15) days following completion of their publication in a newspaper of general circulation and filing with the University of the Philippines, Office of the National Administrative Registrar (UP-ONAR).


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<i>Related issuances, laws, directives</i>	RA 9711, AO 2005-0015, AO 2005-0025, ACD