ANNOUNCEMENT

DATE : 06 September 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 37TH 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 37th ASEAN Cosmetic Committee (ACC) Meeting and Its Related Meetings hosted by the ASEAN Secretariat via video conferencing and held as follows:

Date	Meeting
8-9 May 2023	37th ASEAN Cosmetic Scientific Body (ACSB) Meeting
18-19 May 2023	20th ASEAN Cosmetic Testing Laboratories Committee (ACTLC) Meeting
22-23 May 2023	ASEAN Cosmetic Committee Heads of Delegations (HODs) Meeting
24-25 May 2023	37th 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. **Inclusion to Annex II - List of substances which must not form part of the composition of cosmetic products (EU Amendment of Annex II) - Consolidated List of Banned Ingredients, Ref. Nos. 1427, 1457, 1460, 1461, 1462, 1463, 1387, 1539, 1542, 1576, 1386, 1391, 1393, 1491, 1527, 1562, 1565, 1575, 1589 and 1602 (EU 2019/1966 & 2019/831 and EU 2021/850)**

The ACSB Secretary presented the Summary of Consolidated List of Banned Ingredients and informed that EU Annex II (EU 2019/831, EU 2019/1966, EU 2020/1683, EU2021/850, EU 2021/1902) were reviewed and considered by ACSB in the 32nd, 33rd, 34th, 35th, 36th ACSB Meetings. In summary, 295 entries of EU Annex II were reviewed in the previous five ACSB Meetings. The total remaining 23 entries of EU Annex II were reviewed and discussed.

For the 22 entries with reported use in ASEAN, these included products that are currently notified in Cambodia (entries #1457, #1460, #1461, #1462 and #1463) and Thailand (entries #1387, #1539, #1542 and #1576). The AMS agreed to Cambodia and Thailand's proposal and adopted to move the 9 entries into Annex II with a grace period of **24 months** – Effective **08 May 2025**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

The AMS also reviewed and considered the remaining 10 entries of EU Annex II which have existing notified cosmetic products within the ASEAN (entries #1386, #1391, #1393, #1491, #1527, #1562, #1565, #1575, #1589 and #1602) and agreed to move the said entries into ACD Annex II with a grace period of **24 months** – Effective **08 May 2025**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

2. **Amendment of 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 SCCS opinion on the Silver Zinc Zeolite (SZZ) showing that the maximum silver content of 2.5% is safe in spray deodorant and powder foundation when used at the proposed concentration of 1%. In addition, ACA proposed to add SZZ in ACD Annex III as new entry. All AMS, except Indonesia, agreed to ACA proposal to include in ACD Annex III with a **24 months** grace period - Effective **08 May 2025**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market. Indonesia will wait for the adoption of SCCS opinion into Annex III of EU Regulation.

   b. **Methyl-N-methylanthranilate (M-N-MA), Ref. No. 339**

   According to the recent SCCS Opinion (SCCS/1616/20) and the SCCS Conclusion, it was found that M-N-MA has phototoxic properties. However, the data provided show that exposing human skin with concentrations from 0.1% to 0.5% with a UV dose that realistically represents skin exposure during outdoor activities (excluding sunbathing) does not elicit phototoxic reactions. It is not advised to use it as ingredient for sunscreen products or products that are specifically marketed for exposure to natural/artificial UV light, because these products imply prolonged and intense sunlight exposure to UV doses that may be above the doses that were used in the tests. Moreover, M-N-MA is not an essential ingredient for the purpose of such products. For other products intended for use on areas exposed to sunlight, a

maximum concentration of 0.1% M-N-MA can be considered safe, based on the data provided.

There is also a Minutes of Meeting of the Working Group (WG) on Cosmetic Products, 28 February 2018 (Page 6 of EU Official Journal 22 June 2018) specifying that ***"On this occasion, COM would like to reiterate that by 'products marketed for exposure to natural and artificial UV light', we do not mean day care products, such as creams which are to be used during the day"***. The intention was to extend the ban to those products which are marketed for the use in the sun or in sunbeds, but which are not sunscreens. Examples of such products are tan enhancers." Such understanding of "products marketed for exposure to natural or artificial UV light" is confirmed by the discussions of the last working group of November 2018.

The ACSB Meeting discussed that there might be different understanding and interpretation among ASEAN regulators and consumers on the condition of usage of M-N-MA in ASEAN for the use in day care products (with sun protection claims). Hence, it was agreed to insert a footnote entry for this substance to provide guidance in its condition of use and stated herewith as "***This restriction does not apply to products with secondary UV protection claims, such as moisturizing and skin lightening products as described in the preamble of ASEAN Sunscreen Labeling Guidelines"***. As such, the AMS agreed to adopt the EU Annex III, entry 323, M-N-MA into the ACD Annex III with a grace period of **24 months** - Effective **08 May 2025**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

The AMS also agreed to apply the same footnote entry for M-N-MA to the following ACD Annex III entries: (a) Ref# 324 (Tagetes minuta flower extract, Tagetes minuta flower oil), (b) Ref# 325 (Tagetes patula flower extract, Tagetes patula flower oil) and; (c) Ref# 327 (Tagetes erecta flower extract, Tagetes eracta flower oil), which have the same conditions of use as M-N-MA as well.

3. **Octocrylene (Annex VII - List of UV filters which cosmetic products may contain, Ref. No. 10) (EU 2022/1176: Amending Regulation (EC) No. 1223/2009 the use of certain UV Filters in Cosmetic Products)**

ACA presented the safety review of Octocrylene in cosmetic products. As specified in Annex VI of EU Cosmetic Regulation, Octocrylene is considered safe following the conditions and corresponding maximum concentrations in ready for use preparation. Based on the safety assessment of Octocrylene, the AMS agreed to adopt its conditions of use under EU Annex VI into the ACD Annex VII, with a grace period of **24 months**- Effective **08 May 2025**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

4. **Sodium N-(hydroxymethyl) glycinate (Sodium Hydroxymethylglycinate) (EU 2022/1531: Amending Regulation (EC) No. 1223/2009 as regards the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction and correcting that Regulation)**

ACSB Secretary also informed the AMS that Sodium N-(hydroxymethyl) glycinate (SHMG) was removed from EU Annex II (EU 2022/1531). SHMG was classified as carcinogenic-category 1B and mutagenic-category 2 by EU Commission Delegated Regulation (EU) 2020/1182 (based on the classification of formaldehyde). SHMG, which was previously banned in Annex II as Ref #1669, is now deleted from Annex II; it was erroneously listed in both Annexes II and V, hence, the correct entry for SHMG, that is, in Annex V (Ref #51) of the EU Cosmetics Regulation have been reflected.

Article 15 and the restrictions based on its conditional CMR classification states that whereby a substance can only be used as a preservative in cosmetic products, if it can be shown that the concentration of releasable formaldehyde, irrespective of source, in the mixture as placed on the market is less than 0.1 % w/w.

Based on the correction of the EU regulation and the safety assessment review on SHMG, the AMS agreed to follow the EU amendment by removing Ref #1669 from the ASEAN Consolidated List of Banned Ingredients and adopt SHMG conditions of use under EU regulation Annex V, Ref #51 into ACD Annex VI with **24 months** grace period - Effective **08 May 2025**, only compliant products shall be made available in the market and non-compliant products shall be withdrawn from the market.

5. **Amendment of Annex II - List of substances which must not form part of the composition of cosmetic products**

a. Singapore and ACA proposed to delete CAS No. 30399-84-9 in the entry under Ref# 631 which belongs to the substance ISOSTEARIC ACID and is not included under the substance of concern under the said item.

The AMS agreed to the proposal of Singapore and ACA. The ACD Annex II, Ref# 631 will be revised to reflect the ACSB decision.

b. The AMS agreed to the proposal of Singapore to correct typographical error under the Ref. No. 1404 of the ACD Annex II. The ACD Annex II entry for Ref# 1404 will be corrected to reflect the comment from Singapore, accordingly.

c. It was agreed during the meeting to correct the typographical error on the CAS number under Ref# 30 of ACD Annex VII. The ACD Annex VII will be revised to reflect the correct CAS number.

B. Amendment of ACSB Terms of Reference (TOR)

1. Change of Article 2 in the Terms of Reference (TOR) of ACSB

Malaysia and ACA informed their alignment with ACSB agreement made at the 36th ACSB Meeting to maintain Article 2(c) of the TOR with the additional statement of "*Scientific opinions from other regions and countries could also be considered for amendments to the annexes*." The AMS adopted the revised TOR of ACSB for circulation.

2. Revision to consider ACTLC representatives' participation in the ACSB Meeting

The AMS agreed to the proposal from the 36th ACC Meeting to amend the ACSB TOR to consider ACTLC representatives' participation in the ACSB Meeting

The revised ACSB TOR is attached as **Annex B**.

C. Completion of Development of Information Sharing Paper on Cosmetic Refilling and Cosmetic Forms

1. Information Sharing Paper for National Regulatory Authorities (NRAs) on the Refilling of Cosmetic Products

Singapore informed the AMS on her adoption of the Option 1 of Cosmetic Refilling Information Sharing Paper. Malaysia and Singapore provided their comments for consideration of the AMS. The Meeting agreed to adopt the aligned document for dissemination.

The final information sharing paper of Cosmetics Refilling is attached as **Annex C.**

2. Cosmetic Products Packaged in Vials/Ampoules/Syringes: An Information Sharing Paper

Thailand representing the TWG (TH, ID, MY, ACA) presented the revised draft information sharing paper reflecting the final comments from Singapore. The Meeting agreed to adopt the aligned document for dissemination.

The final information sharing paper of Cosmetics in vials and ampoules is attached as **Annex D.**

3. Information Sharing Paper on Personalised Cosmetics

Malaysia representing the TWG (MY, PH, ID, ACA) presented the revised draft information sharing paper reflecting the final comments from Singapore. The Meeting agreed to adopt the aligned document for dissemination.

The final information sharing paper of Personalised Cosmetics is attached as **Annex E.**

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.