



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



09 June 2015

FDA CIRCULAR
No. 2015-009

SUBJECT: Updates and Amendments of the ASEAN Cosmetic Directive (ACD)

In the interest of service, and for the information of all, the Food and Drug Administration (FDA) hereby provides the Reports of the 22nd ASEAN Cosmetic Committee (ACC), 22nd ASEAN Cosmetic Scientific Body (ACSB), and 5th ASEAN Cosmetic Testing Laboratory Committee (ACTLC) Meetings as attachments. The agreed grace period of the updates and amendments of the ACD is presented in the table below:

Amendments	Agreed Grace Period
Limitations and Restrictions of Triclosan	The following grace period will apply to withdraw from the market non-compliant products: For Annex VI – until 31st December 2015 For Annex III – until 31st December 2016 or earlier
Revision of the 'field of application and/or use' and its corresponding 'maximum authorized concentration in finished products' for hydrogen peroxide (Annex III, Part 1, ref #12) in tooth-whitening products	The Meeting agreed that 12 months after adoption (June 2016), only cosmetic products which comply with these labeling requirement shall be placed in the ASEAN market.
Mouthwash labeling requirements for children under 6 years old and Mouthwash containing fluoride and alcohol	The Meeting agreed to the 12 months grace period (June 2016) for the implementation of the labeling requirement in mouthwash containing fluoride or alcohol

The FDA hereby reiterates that companies, as well as individuals who are responsible for placing cosmetic products in the market are responsible for continually checking updates and amendments to the ACD. You are also hereby directed to take note of the abovementioned grace periods.

For updates and amendments, please visit the following websites:

www.fda.gov.ph
aseancosmetics.org
www.asean.org

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines

Trunk Line +63 2 857 1900

Website: www.fda.gov.ph

Fax +63 2 807 0751

Email: info@fda.gov.ph

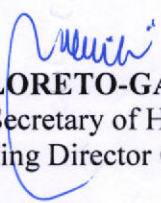


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This order shall take effect immediately.


JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General¹

DTN: 20150609152053

¹ Pursuant to DPO 2015-1845

ANNEX A
HIGHLIGHTS OF THE MEETING

A. 22nd ACSB (Singapore)

1. Amendments to the ASEAN Cosmetic Ingredient Annexes

The summary of the amendments to the ASEAN Cosmetic Ingredient Annexes are presented below:

a. Limitations and Restrictions of Triclosan

- i. The Meeting agreed with ACA recommendation to include 3 additional products (shampoo, hair conditioner and facial cleanser) under column f (part (a) of Annex VI Part 1 Ref. No. 25.
- ii. The Meeting also agreed to remove (+) sign from Annex VI and to include Triclosan under Annex III with the same restrictions.
- iii. Grace period

The following grace period will apply to withdraw from the market non-compliant products:

1. Annex VI as referred in the minutes of 21st ACSB Meeting in November 2014 ie. 31st December 2015
2. Annex III until 31st December 2016 or earlier

b. Revision of the 'field of application and/or use' and its corresponding 'maximum authorized concentration in finished products' for hydrogen peroxide (Annex III, Part 1, ref #12) in tooth-whitening products

- i. The Meeting agreed to add warning "Not to be used under the age of 18" and for the percentage of Hydrogen peroxide to be declared on the label.

ii. Grace Period

The Meeting agreed that 12 months after adoption (June 2016), only cosmetic products which comply with these labeling requirement shall be placed in the ASEAN market.

c. Development of ASEAN references on non-cosmetic regulation list for the entries ref# 21, 293, 323 and 419

The Meeting agreed with Malaysia proposal to replace for entries references as in ref # 21, 293,323 with generic statement as follows:

- i. # 21: Sympathomimetic amines acting on the central nervous system as defined in ASEAN Member States (AMS) local law(s) or regulation(s).
- ii. # 293: Radioactive substances, as defined in ASEAN Member States (AMS) local law(s) or regulation(s).
- iii. # 323: Vaccines, toxins or serums as defined in ASEAN Member States (AMS) local law(s) or regulation(s).

d. Mouthwash labeling requirements for children under 6 years old and Mouthwash containing fluoride and alcohol

- i. The Meeting agreed that Mouthwashes containing fluoride or alcohol should include a warning statement “Do not use in children below 6 years of age”.
- ii. Grace period
The Meeting agreed to the 12 months grace period (June 2016) for the implementation of the labeling requirement in mouthwash containing fluoride or alcohol.

2. Guidance Format of the Safety Assessment Report

The Meeting agreed to accept the Safety Assessment Report documents as a reference to be used by cosmetic safety assessors. The guidance format is uploaded at the FDA website under ASEAN Cosmetic Harmonization.

3. Revision of the ASEAN Sunscreen Labeling Guideline

The Meeting agreed to accept the revision of the ASEAN Sunscreen Labeling Guideline as a reference document. The guideline is uploaded at the FDA website under ASEAN Cosmetic Harmonization.

4. Trace Limit of Cadmium

The Meeting agreed to set a limit of 5 ppm maximum for Cadmium as trace element, recognizing 3 ppm for Thailand.

B. 5th ACTLC (Singapore)

Updated List of Cosmetic Accredited Laboratories

The Meeting noted that ACTLC has to date a total of 65 accredited laboratories which are as follows:

- Indonesia (32)
- Thailand (24)
- Philippines (5)
- Singapore (4)

The lists have been uploaded at ASEAN Secretariat Webpage at <http://www.asean.org/communities/asean-economic-community/category/other-documents-14>.