



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS

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MALAYA AT MALUSOG
NA PAMAYANAN

02 July 2009

BUREAU CIRCULAR
No. 2009- 003

SUBJECT: Grace Period for the 4th Updates and Amendments of the ASEAN Cosmetic Directive (ACD)

In the interest of service, and for the information of all, the Bureau of Food and Drugs (BFAD) hereby provides the Final report of the 10th ASEAN Cosmetic Scientific Body (ACSB) and 11th ASEAN Cosmetic Committee (ACC) Meetings as attachments.

Company/s or person/s responsible for placing the cosmetic product/s in the market are responsible for continually checking any **updates and amendments** to the ACD for proper guidance and compliance through the following websites:

www.bfad.gov.ph (under ASEAN Cosmetic Harmonization)

www.aseancosmetic.org

www.asean.org

You are hereby directed to take note of the cited grace period as agreed during the 12th ACC Meeting.

This order shall take effect immediately after its posting at the BFAD website.


NAZARITA T. TACANDONG, RPh,MPA
Acting Director

Progress of the ASEAN Cosmetic Scientific Body (ACSB)

The Meeting agreed to the following proposal from ACSB:

EU Annex Update

Incorporation of changes made to the EU Annexes 2008/123/EC and 2009/36/EC

Annex II (List of substances which must not form part of the composition of cosmetic products):

1. Amend - Diethylene glycol (DEG), for trace level see Annex III CAS No. 111-46-6 EC No. 203-872-2 Ref No. 1370
2. Inclusion of Phytomenadione (INCI), phytomenadione (INN) CAS No. 84-80-0/81818-54-4; EC No. 201-564-2 Ref. No. 1371

Date of Implementation: 05 August 2009

Annex III Part 1 (List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down):

Addition (date of implementation):

- Ref.Nos. 185 Toluene (05 February 2010)
186 Diethylene glycol (DEG) (05 August 2009)
187 Butoxydiglycol (05 August 2009)
188 Butoxyethanol (05 August 2009)
189-205 hair dye ingredients (15 May 2010)

Amended:

- Ref. Nos. A1 Tranexamic acid (20 November 2009)

Annex III Part 2 (List of substances provisionally allowed):

Extended the allowed use of substances under this annex until **12-31-09**

Deletion:

- Ref. Nos. 7, 8, 9, 13, 14, 15, 24, 28, 30, 41, 43, 45, 46, 47, 51, 52, 53, 54, 58

Annex VII (List of UV filters which cosmetic products may contain):

Deletion:

- Ref No. 1 4-aminobenzoic acid (08 October 2009)

Implementation date tracking

The ACSB had developed a template to keep track of the decisions made by the ACC with regards to the ACD Annexes of ingredients. The template for tracking and publication of decisions made on cosmetic together with the implementation dates will be uploaded in the ASEAN and ACA websites for public reference.

AHA Labeling

The following wording when mandatory sunburn alert labeling is required for products containing AHAs:

"Labeling mandatory for products containing Glycolic and/or Lactic acids at a concentration \geq 2.5% and do not contain a sunscreen. Not required for products that are intended to be applied to non sun exposed areas of the body, contain a sunscreen or a lower concentration of AHA"

Botanical Ingredients

Member States requested to review the lists of cosmetic ingredients/products notified in their own markets against the Chinese Cosmetic Banned Botanical List and UK topical Traditional Chinese Medicine banned list in order to establish review priorities. To send the results of this review to Indonesia by **01 October 2009**

Methanol

Thailand reported that they had concluded their process to consider and amend control of methanol in ethanol specifically for use in refreshing tissues and product use around the eyes. Since data from the US Cosmetic Ingredient Review demonstrated that the toxicity of methanol is reduced when used as a denaturant in ethanol to the point where a safe level of 5% is possible. Thailand have agreed to follow the ACD and no further action is required.

Tranexamic acid

Tranexamic should be regulated in rinse-off products at the same level as for leave-on and both uses transferred to Part 1 in Annex III, at up to 3% in skin products not intended to be placed in contact with the mucous membranes.

Preamble to Preservatives Annexe

The Meeting accepted the following wording, as new wording to clarify the preamble and to reflect the fact that all non-preservative uses of ingredients in the preservatives positive list will be specified by entries in Annexe III.

"The substances marked with the symbol (+) may also be added to cosmetic products in concentration other than those laid down in this ANNEX for other purposes as specified in Annexe III (List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down)"

The Meeting noted that Malaysia and ACA will compile and circulate the list of impacted ingredients and Annex III proposals to ACSB members by **31 October 2009**.

The ACSB Secretary will provide a review of the borderline between the EU Cosmetics Directive and Biocidal Products Directive with particular reference to the impact of this borderline on continued use of substances currently in Annex 6 of the ACD by the next ACSB meeting.

Cosmetic with medicine-like packaging

With regards to the cosmetics which had medicine-like packaging, the Meeting agreed that regulators will exchange information on PMS priorities, experience, examples and outcomes with each other before next ACSB Meeting in order to scope opportunities for consistent priorities, positions and data sharing.

Thiolactic acid

Malaysia and ACA will draft a proposal on the extension of scope of use as per thioglycolic acid, including a limit for total thioacids by **30 August 2009** for consideration at the next ACSB meeting.

"Antiseptic" in claim

The Meeting agreed as follows for the claims of "antiseptic" in cosmetic products:

- (i) antiseptic is an acceptable secondary claim for a cosmetic product;
- (ii) antibacterial is an acceptable secondary claim for a cosmetic product; and
- (iii) germicidal is an acceptable secondary claim for a cosmetic product.

The Meeting also agreed that the claims of disease treatment are not acceptable for cosmetic products.

Annex II restriction

The Meeting agreed to the recommendation that the ACSB Secretary propose options and implications for revisions to the Annex II and III structure and function at the next ACSB meeting.