



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City



MALAYA AT MALUSOG
NA PAMAYANAN

02 May 2008

BUREAU CIRCULAR
No. 2008- 001

SUBJECT: Grace Period for the New 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 adopts the Final report of the ASEAN Cosmetic Scientific Body (ACSB) and ASEAN Cosmetic Committee (ACC) Meeting 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

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


Prof. LETICIA BARBARA B. GUTIERREZ, M.S.
Director

I. HIGHLIGHTS OF THE MEETING

Appendix II ASEAN Labeling Requirements

Adopted December 2006 (ASEAN Cosmetic Committee Meeting (ACC) in Philippines)

1. **Section C.1.c** Full ingredient listing: The ingredients must be declared in descending order of weight at the time they are added. Perfume and aromatic compositions and their raw materials shall be referred to by the word “perfume” or “flavour”. Ingredients in concentrations of less than 1% may be listed in any order after those of concentration of more than 1%. Colouring agents may be listed in any order after the other ingredients, in accordance with the colour index number or denomination adopted in Annex IV.
2. **Section C.1.h** Indication of the durability shall not be mandatory for cosmetic products the minimum durability of which exceeds 30 months.
3. **Appendix A** List of Standard References to be used for Cosmetic Ingredient Nomenclature: Elimination of the 2 Japanese references which do not exist anymore

Adopted September 2007 (Head of Delegation (HOD) Meeting in Indonesia)

1. **Section C.1.c** That the any of the words “perfume”, “flavour”, “aroma” or “fragrance” be allowed to describe perfume and aromatic compositions and their raw materials.
2. **Section C.1.i** That in the final section “...Member countries may require specific warnings based on local needs e.g. declaration of ingredients from animal origin....” the ‘e.g.’ should be replaced by ‘for’. These country-specific warnings will be added to a new appendix (B) to this document.
3. **Section C.4** Country-specific national language needs for this information will also be captured in the new appendix to this document in the interests of transparency and clarity.

Appendix III ASEAN Claim Guideline

Adopted September 2007 (HOD Meeting in Indonesia)

Add the decision making process on claim in Appendix 3 with the inclusion of the acceptable secondary functions and adopt the revised Appendix 3.

ASEAN Microbial Limit

Adopted June 2007 (ACC Meeting in Lao PDR)

Product Categories

Adopted December 2007 (ACC Meeting in Vietnam)

1. Bust creams-Cosmetic (Individual claims should be assessed to ensure that they comply with the cosmetic claim guideline).
2. False eyelashes - Not cosmetic. Not a substance or preparation.
3. Automatic fingernail painting machines -Paints applied to fingernails are cosmetic products
4. Face paints: Cosmetic -• Temporary tattoos:
5. Permanent tattoos:Not cosmetic (Injected under the skin and permanent effect)
6. Denture cleansers: Products applied to dentures outside the mouth are not cosmetic. Dentifrices intended for use in the mouth by denture wearers are cosmetics
7. Moist wipes: The liquid component of wipes making cosmetic claims (e.g. skin cleansing, refreshing, perfuming etc.) is cosmetic.
8. False eyelash glue: Cosmetic

Heavy Metals Limit to be used by regulators for post market surveillance

Adopted December 2007 (ACC Meeting in Vietnam)

- a) Mercury: 1 ppm when tested by the ASEAN Cosmetic Method (ACMTHA05)
- b) Lead: 20 ppm when tested by the ACMTHA05
- c) Arsenic: 5 ppm when tested by the ACMTHA05

ASEAN GMP Training Modules

Adopted December 2007 (ACC Meeting in Vietnam)

Specific Guidance for Soap Industry with five amended GMP training modules

Module 1: Quality Management
Module 2 : Personnel
Module 3-PS: Premises
Module 4-PS: Equipment
Module 5-PS: Sanitation & Hygiene
Module 6-PS : Production
Module 7: Internal Audit
Module 8: Quality Control
Module 9: Documentation
Module 10-PS: Storage
Module 11: Contract Manufacturing & Analysis
Module 12: Product Complaint
Module 13: Product Recall

Updated Annexes of Ingredients see Annex D

Adopted September 2007 (HOD Meeting in Indonesia)

Annex II List of Banned Ingredients

1. Add Diethylene Glycol (Ref. A1137)

Annex VI List of Preservatives

1. To keep the (+) sign in the following reference number in Annex VI until the EU has final decision on this ingredient.
 - 1.1 Ref. No. 8 Zinc Pyrithione
 - 1.2 Ref No. 18 Undec-10-enoic acid and salts
 - 1.3 Ref. No. 25 Triclosan
 - 1.4 Ref. No. 32 (1-(4-Chlorophenoxy)-1-(imidazol-1-yl) 3,3-dimethylbutan-2-one)
 - 1.5 Ref. No. 35 (1-Hydroxy-4-methyl-6(2,4,4-trimethylpentyl)-2-pyridon and its monoethanolamine salt
 - 1.6 Ref. No. 42 (Chlorhexindin (INN) and its digluconate, diacetate and dihydrochloride

1.7 Ref. No. 47 (1,6-Di (4-amidinophenoxy-n-hexane (Hexamidine) and its salts
(including isethionate and p-hydroxy-benzoate

Adopted December 2007 (ACC Meeting in Vietnam)

ASEAN Handbook of Ingredients

Annex II List of Banned Ingredients

1. Add Azelaic Acid
2. Add Bimatoprost (CAS 155206-00-1)

Annex III Part I Restricted Ingredients

Ref #	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warning which must be printed on the label
A5	Tranexamic acid	Leave on products	2%		Keep out of reach of children

Recommended grace period – Products shipped to market from 01/01/2010 must comply (24 months)

Fluoride

Fluoride modification on the entries 26-43 inclusive, 47 and 56 (fluorine compounds for oral hygiene products) as follows:

Add to column f (Conditions of use and warning which must be printed on the labels)

For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. "for adult use only") the following labelling is obligatory:

"Children of 6 years and younger: Use a pea sized ● amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor."

Recommended grace period – Products shipped to market from 01/01/2010 must comply (24 Months)

Annex III Restricted Ingredients

Ref. #	Substance	Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	Conditions of use and warning which must be printed on the label
A6	Thiolactic acid and its salts	Hair waving or straightening products	8.5% ready for use at pH <9.5 Percentage calculated as thiolactic acid.	The directions for use drawn up in the national or official language (s) must obligatorily incorporate the ffg. sentences: • Avoid contact with eyes • In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice. • Wear suitable gloves	<ul style="list-style-type: none"> • Contains thiolactic acid • Follow the instructions • Keep out of reach of children
12	Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	d) Oral hygiene products e) Tooth whitening products for	d) 0.1% of H ₂ O ₂ present or released e) 6% of H ₂ O ₂ present or released	For supply only through a dentist. Not for direct sale to the general public.	Not for direct sale to the general public. For supply only through a dentist. Use only under the supervision of a dentist Read and follow

					<p>the instructions and use the product accordingly</p> <p>Do not use the product within 2 weeks prior to, or immediately after dental restoration</p> <p>Not for use by pregnant women or habitual tobacco and/or alcohol users</p> <p>Stop using immediately if you experience any tooth sensitivity, gum irritation, toothache, defective restorations, gingivitis, nausea etc.</p> <p>Store out of reach of children.</p>
--	--	--	--	--	---

A6 Recommended grace period – Products shipped to market from 01/01/2009 must comply (12 months)

A12 Recommended grace period – Products shipped to market from 01/07/2008 must comply (6 Months)

Annex IV List of Colorants

1. Add Henna CI 75480

Annex VII List of UV Filters

1. Deleted Ethyl-4-bis hydroxypropyl aminobenzoate as sunscreen agent
2. Adopted the “European Commission Recommendation 2006/647/EC on the Efficacy of Sunscreen Products” as a guideline for ASEAN regulators and industry.

Use of the mandatory statement to be added:

“Do not stay too long in the sun, even while using a sunscreen product”

Recommended grace period – Products shipped to market from 01/01/2010 must comply (24 Months)

II. AGREEMENT

Grace Period

a) ACSB proposals approved before 14 June 2007

These will become effective with implementation of the ACD on 1 January 2008. Grace period for existing cosmetic products not fully compliant with ACD and its Annexes shall be subjected to NRAs decision.

b) ACSB proposals approved between 14 June 2007 and 9 December 2007

Additions to Annex II will become effective with the implementation of the ACD on 1 January 2008. All other changes will become effective no later than 1 January 2010.

c) ACSB proposals approved after 9 December 2007

All ACSB proposals will be delivered to ACC with a recommended grace period based upon the assessed balance of risk to consumer health and the ability of industry to comply.