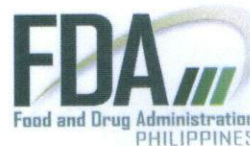




Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



11 December 2014

FDA Memorandum Circular

No.: **2014-017**

TO : All Cosmetic Manufacturers, Traders, Distributors & other Concerned Parties


FROM : Center for Cosmetics Regulation and Research

SUBJECT : Correction on Annex III/Part I Ref. No. 1a: Boric acid, borates and tetraborates with the exception of substance No. 1184 in Annex II

In the interest of service, and for the information of all, the Food and Drug Administration (FDA) hereby adopts the Final Report of the 21st ASEAN Cosmetic Scientific Body (ACSB) and 21st ASEAN Cosmetic Committee (ACC) correction in Annex III – Part 1 Ref. No. 1a, column C point (b) “**Products for all hygiene**” to “**Products for oral hygiene**”.

All company/ies or person/s responsible for placing the cosmetic product/s in the market are hereby advised to comply with this directive.

This order shall take effect immediately.


ATTY. NICOLAS B. LUTERO III, CESO III
Assistant Secretary of Health
OIC, Food and Drug Administration





**The Report of the Twenty first Meeting of the
ASEAN Consultative Committee for Standards and Quality (ACCSQ)
The ASEAN Cosmetic Committee (ACC)
The ASEAN Cosmetic Scientific Body (ACSB)
25-26 November 2014
Manila - Philippines**

INTRODUCTION

1. The Twenty first Meeting of the ASEAN Cosmetic Scientific Body (ACSB) was held on 25-26 November 2014 in Manila, Philippines.
 2. The Meeting was chaired by Alternate Chair Mrs. Narupa Wongpiyaratnakul (Head of Cosmetic Standard Establishment) from Food and Drug Administration, Thailand. The Chair, Mr. Hary Wahyu T (Director of Standardization of Traditional Medicine, Cosmetic and Health Supplement) from the National Agency of Drug and Food Control, Republic of Indonesia requested Alternate Chair to lead the discussion.
 3. The Meeting was attended by the representatives from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Vietnam, the ASEAN Secretariat representatives and the ASEAN Cosmetic Association. The list of delegates appears as Appendix 1.
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1. Welcome, introduction of chair, alternate chair, and ACSB Members & adoption of the agenda

The Chair extended her warm welcome to all delegates and expressed her gratitude to Philippines FDA in arranging and hosting the ACSB Meeting. The agenda was adopted, as appears in Appendix 2.

2. Update information following the new issuance of EU Regulations – Secretary

- The Meeting agreed to adopt EU Regulation 866/2014, which impacts Annex III, Annex VI and Annex VII.

The Meeting agreed to a grace period for Annex III ref # 286 and # 287 until July 1st 2015 or earlier for products to be placed in the market and December 1st, 2015 for existing products in the market. The Meeting agreed to delete the word “leave on” on ref # 286 and # 287 point c under column “f” (product type). Changes to Annex VI # 59 and VII # 29 from the EU 866/2014 were adopted with immediate effect. The Meeting noted that Thailand and Philippines request for a grace period for this adoption

- Ref # 39 for MCI + MIT (5-Chloro- 2-methyl-isothiazol-3 (2H)-one and 2-methylisothiazol-3(2H)-one) and Ref # 57 for MIT (2-Methyl-2H-isothiazol- 3-one)

The Meeting agreed to adopt EU Regulation 1003/2014. Footnotes to ref # 39 and # 57 in Annex VI will be added.

- Ref # 12a Butyl 4-hydroxybenzoate and its salts Propyl 4-hydroxybenzoate and its salts

The Meeting agreed to adopt EU Regulation 1004/2014 impacting Annex VI ref # 12 and to add ref # 12a

The Meeting agreed to a grace period for product to be placed in the market until end of December 2015, and for existing product in the market will be end of June 2016

The EU Regulation No. 866/2014, No. 1003/2014, No. 1004/2014 and the presentation appear as Appendixes 3, 3(1), 3(2), and 3(3)

- The Meeting still needs time to review EU Regulation No. 344/2013; EU No. 483/2013; EU No. 658/2013; EU No. 1197/2013

The presentation on EU Regulation No. No. 344/2013; EU No. 483/2013; EU No. 658/2013; EU No. 1197/2013 appears as Appendix 4

Action – Secretary to revise those Annexes accordingly

EU Regulation No. 344/2013, No. 483/2013; No.658/2013; and No. 1197/2013 will be discussed on the next ACSB meeting

3. Confirmation to include 5 Paraben derivatives (#1374 – 1378) on Annex II

The Meeting noted and agreed to include (5) five parabens derivatives on the Annex II of ACD as entries Ref # 1374 – 1378. The presentation on 5 (five) paraben derivatives appears as Appendix 5

The Meeting noted that most ASEAN Member States agreed that existing product can be in the market until 30 July 2015, except Thailand and Philippines who proposed for a longer grace period until December 31st, 2015

4. Proposal from ACA to correct a mistake in Annex III #1a – Boric acid

The meeting agreed with ACA's proposal to correct Annex III #1a – Boric acid by changing under column C point (b) the word "all hygiene" into "oral hygiene". The proposal appears as Appendix 6

Action – Secretary to update Annex III # 1a accordingly

5. Proposal from Philippines to review the "maximum authorized concentration" and "limitations and requirements" of triclosan (Annex VI Part 1 Ref. No. 25) in light of the changes in the EU Cosmetic Regulation as amended by Commission Regulation (EU) No 358/2014

- The Meeting agreed to adopt Annex VI part 1 # 25 as in EU Regulation No. 358/2014 appears as Appendix 7
- The Meeting noted ACA presentation on Safety data for the use of Triclosan in Shampoo, but the Meeting needs time to review it. ACA presentation appears as Appendix 8
- The grace period will be end December 2015 but subject to review at the next meeting

Action – Secretary will revise Annex VI ref # 25 accordingly and the use of Triclosan in Shampoo and other applications will be discussed on the next meeting, and ACA need to check with EU on why shampoo is not stated on Annex V #25 under column f of EU. Grace period will be reviewed at the next Meeting

6. Confirmation on the rationale of previously recorded decisions on Borderline Products in instances that had not been reflected in the final report

The Meeting noted Malaysia comment on Perineal massage products, and questions from Singapore on Leave on antimicrobial product and other similar claims ie. Antibacterial, Products with antiseptic claims; Products with antibacterial claims; Products with germicidal claims. The List of Borderline product appears as Appendix 9

The Meeting noted that Malaysia and Thailand consider this Perineal massage products to be not cosmetic

The meeting agreed to discuss those 6 borderline products on the next meeting

Action – The 6 borderline products (Perineal massage products, Leave on antimicrobial, antibacterial, Products with antiseptic claims; Products with antibacterial claims; Products with germicidal claims) will be discussed at the next meeting

7. ACA presentation on a simple format of the Safety Assessment Report

The Meeting noted the comments from Malaysia on ACA proposal appears as Appendix 10

ACA agreed to revise the Safety Assessment Report and the Summary to consider inputs from Malaysia. This will be discussed during the next meeting

The Meeting noted the clarification from ACA regarding the qualifications of the Safety Assessor which may be found in ASEAN Safety Assessment Guidelines

Action – The revision of Safety Assessment Report and the Summary will be presented by ACA at the next meeting

8. Malaysia's Proposal to review the use of Methylisothiazolinone (MIT) on leave-on cosmetic products

The Meeting agreed to amend 20th ACSB Meeting Report Agenda item 3, to change the word discontinue into review in the sentence of *"The Meeting noted the request to discontinue the use of Methylisothiazolinone (MIT) in skin leave-on cosmetic products and wipes"*.

The Meeting noted of Malaysia comment to wait for EU Decision for the use of MIT as single preservative on leave on product. Malaysia's proposal appears as Appendix 11

Action – Monitor EU Decision on the use of single MIT on the leave on product and will discuss this EU Decision at the next Meeting (if any progress)

9. Discussion on ASEAN Sunscreen Labeling Guideline as proposed by Malaysia, additional warning (as strongly recommended) and prohibited claim for Sunscreen :

The Meeting agreed with proposal from Malaysia on strongly recommended warning for primary sunscreen. The proposal appears as Appendix 12

The Meeting noted that Thailand expressed that for mandatory warning and strongly recommended warning, she has different expression in Thailand but having the same meaning

The Meeting noted ACA presentation which appears as Appendix 13 and upon the proposal:

- All Member can accept Sunblock claim, except Malaysia who deems this claim to be misleading

- All Member States can accept Water resistant
- Most Member States can accept claim of water proof and sweat proof, except Thailand and Malaysia
- The use of the terms shall be guided by the principles as appearing in ACA's proposal

Action – Secretary to revise ASEAN Sunscreen Labeling Guideline to include strongly recommended warning as proposed by Malaysia. For the prohibited claim, there will be country specific as there is no consensus

10. Comparison on ACD, EU Directive and EU Regulation

a) Thailand presented the comparison of Annex VI

The Meeting agreed to maintain the Preamble of Annex VI of ACD and agreed to revise ref # 12 to be in-line with EU Regulation. The presentation appears as Appendix 14

b) Philippines presented the comparison of ACD vs EU Directive vs EU Regulation

The Meeting noted Philippines presentation on comparison of ACD, EU Directive and EU Regulation which appears as Appendix 15

The Meeting noted the differences between ACD and EU Regulation

ACA and Philippines will present the recommendations to be considered at the next meeting

c) Vietnam presented the comparison of Annex IV

The Meeting noted Vietnam presentation on Annex IV – List of Colorant, appears as Appendix 16

The Meeting agreed to maintain current format of ACD, and for CI 77510 to amend the word chromate ion to cyanide ions

ACA was requested to establish Task Force to set purity Criteria for some Colorants

d) Singapore presented the comparison of Annex VII

The Meeting noted that format Annex VII of EU is different to the ACD, and the Meeting agreed to maintain ACD format.

The presentation appears as Appendix 17

Action – Secretary to distribute updated Annex II, III, IV, VI and VII of ACD by end of January 2015

11. Presentation and discussion of the revised draft of Pilot risk assessment of botanical ingredients:

The Meeting noted final revision of Pilot risk assessment of botanical ingredients presented by ACA. The final revision of Pilot risk assessment of botanical ingredient appears as Appendix 18

The Meeting agreed to adopt the Final revision of the Guideline

- **Proposal from Malaysia to review and comment on the use of :**
 - a) nonoxynols in cosmetic product, appears as Appendix 19
 - b) *Papaver rhoeas* in cosmetic product, appears as Appendix 20
 - c) *Pueraria mirifica* which contains phytoestrogens that had been used in cosmetic products particularly for product meant to be applied on breast (including presentation from Thailand's expert on *Pueraria mirifica*). The proposal and presentation appears as Appendix 21
- **Proposal to revise 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**
 - a) Differences Regulation of three concentration categories
 - b) proposal to add the warning "Not to be used under the age of 18" - Thailand and Indonesia
 - c) proposal to put the percentage of Hydrogen peroxide on the label – Thailand

The documents appear as Appendix 22
- **Presentation on development of ASEAN references on non-cosmetic regulation list for the entries ref# 21, 293, 323 and 419**
 - o ACA and Singapore to extract relevant information from the EU references and put them as attachment/reference in the ACD (option 3), appears as Appendix 23
- **Malaysia's proposal to review Mouthwash labeling requirements for children under 6 years old and Mouthwash containing alcohol**
 - a) Pending input from Philippines regarding labeling requirements of Mouthwash containing fluoride for children below 6 years-old
 - b) ACA presentation on Safety Assessment for mouthwash containing alcohol as well as fluoride for children below 6 years-old

The document appear as Appendix 24
- **Proposal from Indonesia about Trace Limit of Cadmium**
 - o ACA will present Cadmium as trace limit which appears as Appendix 25

13. AOB

In memory of Ms. Zenaida Soriano, the meeting expressed its sincere appreciation and recognized Ms. Soriano's valuable services and contributions to ACSB. Ms. Soriano has been a pioneer member of ACSB from the Philippines and industry

14. Meeting Close

The Chair of ACSB thanked all Member States delegates and ACA on their valuable inputs, comments and attention during the meeting.

Acknowledgement

The delegates from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Singapore, Thailand, Vietnam, ASEAN Secretariat representatives and ASEAN Cosmetic Association expressed their appreciation to the Food and Drug Administration, Department of Health, Philippines for the excellent arrangements made for the meeting and for the warm hospitality extended to the members.

The Meeting was held in the traditional spirit of ASEAN cordiality and solidarity

AGENDA 15 – PROPOSAL FROM ACA

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
A	B	C	D	E	F
1a	Boric acid, borates and tetraborates with the exception of substance No 1184 in Annex II	<p>(a) Talc</p> <p>(b) Products for <u>all oral</u> hygiene</p> <p>(c) Other products (excluding bath products and hair waving products)</p>	<p>(a) 5% (by mass/mass as boric acid)</p> <p>(b) 0.1% (by mass/mass as boric acid)</p> <p>(c) 3% (by mass/mass as boric acid)</p>	<p>(a) 1. Not to be used in products for children under 3 years of age</p> <p>2. Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1.5% (by mass/mass as boric acid)</p> <p>(b) Not to be used in products for children under 3 years of age</p> <p>(c) 1. Not to be used in products for children under 3 years of age</p> <p>2. Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1.5% (by mass/mass as boric acid)</p> <p>As a preservative, see Annexe VI, Part 1, No 58</p>	<p>(a) 1. Not to be used in products for children under 3 years of age</p> <p>2. Not to be used on peeling or irritated skin</p> <p>(b) 1. Not to be swallowed</p> <p>2. Not to be used in products for children under 3 years of age</p> <p>(c) 1. Not to be used in products for children under 3 years of age</p> <p>2. Not to be used on peeling or irritated skin</p>

Revised based on agreement of 12th ACSB Meeting

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