GENERAL INFORMATION BOOKLET ON ASEAN HARMONIZED COSMETIC REGULATORY SCHEME

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GENERAL INFORMATION BOOKLET ON ASEAN HARMONIZED COSMETIC REGULATORY SCHEME

I. Background

ASEAN is a very important player in the global trade, regardless of product category, with a market of >500 million people as compared to EU's only >300 million. ASEAN with its 10 member countries namely; Brunei Darussalam, Cambodia, Indonesia, Malaysia, Myanmar, Lao PDR, Philippines, Singapore, Thailand and Vietnam, has always been focused on its economic and social growth. The region has a very strong economic alliance with ASEAN secretariat in Jakarta, Indonesia that has been working to meet its key goals of economic growth in its Member Countries. As you may know, there is the creation of the ASEAN Free Trade Area (AFTA) as embodied in the Singapore Declaration 1992 signed by the ASEAN Heads of Government in 1992 and that they agreed to implement by year 2002. The vision of AFTA was conceptualized in recognition of the importance and potential of trade liberalization and in desiring to increase regional competitiveness. Most recently, ASEAN began looking at technical regulations as the economic leaders are convinced that these could pose technical barriers to trade.

ASEAN supports the vision of harmonization of cosmetic regulations in the region as it will benefit all sectors of the industry: the consumers (a wider choice of cosmetic products), the regulatory bodies (one simplified regulatory system) and the cosmetic industry (open ASEAN as one single market for manufacturers, with 500M consumers); the individual countries and the region as a whole (eliminate technical barriers to trade in the establishment of AFTA by year 2002 and facilitate flow of products across ASEAN Member Countries to boost economic growth).

A. Coverage

Phase I: MUTUAL RECOGNITION OF PRODUCT REGISTRATION APPROVAL (schedule A) "where the regulatory authority approval in any of the ASEAN countries is recognized in the rest of the Member Countries."

Phase II: THE ASEAN COSMETIC DIRECTIVE: (Product Notification){ schedule B)
The manufacturer or the person responsible for placing cosmetic products on the ASEAN market, shall notify the cosmetic authority of the Member Country the place of manufacturer or of the initial importation of the cosmetic product before it is placed on the ASEAN market. In most ASEAN countries, this is a transition from a pre-market approval (registration) to post -market surveillance.

B. Technical Documents

The following are the highlights of the ASEAN harmonized Cosmetic regulatory Scheme Common Technical Documents. These have been worked both by the ASEAN governments and the cosmetic industry with the objective to harmonize cosmetic

technical requirements among ASEAN Member Countries for the marketing of safe and quality cosmetic products.

i. Illustrative List By Categories of Cosmetics

The current EU's illustrative List has been adopted with emphasis that this list is not exhaustive. Products satisfying the definition of cosmetic (EU definition) shall be allowed as a cosmetic.

ii. Cosmetic Ingredient Lists

The ASEAN Cosmetic Directive has in its annexes II; III; IV; V and VI respectively the list of substances which must not form part of the composition of cosmetic products, which cosmetic products must not contain except subject to restriction and conditions laid down, the list of colouring agents allowed for use, the list of excluded from the scope, the list of preservatives which cosmetic products may contain and the list of permitted UV filters.

Additionally the Directive contains an ASEAN Handbook which helps manage the differences between current practices and the implementation of the Cosmetic Directive. The ASEAN Cosmetic Scientific Body (ACSB) is tasked with making a decision as to the ingredients contained in the Handbook no later than January 2011.

iii. ASEAN Guidelines for Cosmetic GMP

This document has been the result of close collaboration of both the regulatory authorities and the cosmetic industry with the objective to provide a simple guideline on Cosmetic GMP that addresses the needs of both the industry and government.

iv. ASEAN Cosmetic Labeling Requirements

Full Ingredient Listing will be required using International Nomenclature of Cosmetic Ingredients names (INCI) would be the primary reference for ingredient names on the label. Please refer to the ASEAN labeling requirements for details.

v. ASEAN Cosmetic Claims Guidelines

There will be no negative or positive list of claims. Claims will be subject to country control because of difference in languages, interpretations and culture/religion. The cosmetic definition, Ingredient Lists and Illustrative List and the ASEAN Cosmetic Claims Guideline shall be the technical documents that will guide the countries in the review and acceptability of a cosmetic claim.

vi. ASEAN Cosmetic Product Registration Requirements/Procedure

This is for Phase I only and applies to all cosmetic products that are currently required to be registered in the respective ASEAN countries. Target registration processing period is 30 days maximum.

vii. ASEAN Requirements for Import/Export of Cosmetic Products

Overall, the products that will be imported/exported within ASEAN shall comply with the other ASEAN Harmonized Cosmetic Regulatory Scheme and its technical documents. Licensing and its requirements shall be controlled by each country's regulatory authority.

II. ASEAN Cosmetic Regulatory Harmonization : Frequently Asked Questions

General

1.What is the ASEAN Harmonized Cosmetic Regulatory Scheme? Who shall need to comply with it and when?

A. The ASEAN Harmonized Cosmetic Regulatory Scheme is the agreed one standard scheme for regulating cosmetic products among the ASEAN countries. It is composed of (i) Schedule A – The Mutual Recognition of Product Registration Approval (MRA) where a product registration processed and issued by one country is recognized by the ASEAN countries, who have signed the MRA and
(ii) Schedule B – The ASEAN Cosmetic Directive which requires Product Notification (no registration) before the product is placed in the market . This is a shift from pre-market approval to post marketing surveillance.

ASEAN countries who accede to Schedule A can implement MRA between now and January 2008. The cosmetic products marketed in these countries need to comply with the Schedule A – MRA requirements.

All ASEAN countries are committed to implement Schedule B – The ASEAN Cosmetic Directive by January 2008. Therefore, all cosmetic products marketed in the 10 ASEAN countries need to comply with the Directive requirements by January 2008.

2. **Why is ASEAN moving to this scheme? What are the benefits we can derive from this?**

A. ASEAN is moving to one harmonized cosmetic regulatory scheme to remove technical barriers to trade and facilitate the flow of cosmetic products across ASEAN Member Countries. This is in line with the vision of AFTA (ASEAN Free Trade Area) signed by the ASEAN Heads of Government in 1992. The AFTA was conceptualized in recognition of the importance and potential of trade liberalization and in desiring to increase regional competitiveness.

ASEAN supports the vision of harmonization of cosmetic regulations in the region as it will benefit all sectors of the industry :
i. the consumers (a wider choice of cosmetic products),
ii. the regulatory authorities (one simplified regulatory system)
iii. the cosmetic industry (open ASEAN as one single market for manufacturers; ASEAN would be one market with 500M consumers.)
iv. The individual countries and the region as a whole (by eliminating the technical barriers to trade in the establishment of AFTA by year 2002 and facilitate flow of products across ASEAN Member Countries to boost economic growth.)

3. **How can I make ASEAN Harmonized Cosmetic Regulatory Scheme work for me? Who can I contact if I have questions? Where can I get help?**

A. It is encouraged that the company/industry actively participates in all information dissemination campaigns and activities eg training, seminars, workshops, etc.for awareness and understanding of the scheme. Preparations for compliance with the regulatory scheme should start now and any concerns/ difficulty should be raised so it can be properly addressed. The companies should also start to look for opportunities to expand marketing of products within the ASEAN region. Seek the help of your regulatory authorities and industry associations if you have queries or concerns on the scheme.

ASEAN Common Technical Documents

Product Registration for schedule A

4. **When do I need to comply with the ASEAN Cosmetic Product Registration Requirements? What will happen with the local registration requirements/timing?**
    a. If the country accedes to Schedule A – MRA, the cosmetic products marketed in these countries will need to comply with the ASEAN requirements when the country starts implementing the scheme. When this happens, the existing local requirements/timing will be superseded by the ASEAN requirements.

5. **If my country implements Schedule A, what do I need to comply with? What do I need to do to ensure that I can comply with the requirements?**

    A. When Schedule A is implemented, the cosmetic product will need to comply with the ASEAN Common Product Registration Requirements (pls see the ASEAN Common Product Registration Requirements/Procedure Technical Document.) The product should also need to comply with the ASEAN Common Technical Documents specifically Common Labeling Requirements and CGMP as required by the country of registration and/or importing country.

    The company should be aware and understand the ASEAN Common Technical Documents. The company's representative, system and technical documentations would also need to be aligned with the MRA requirements. Seminars, trainings and workshops will be conducted and will be made available to the industry so we encourage that you actively participate in these activities.

6. **If my country implements Schedule A, what do I need to comply with? What do I need to do to ensure that I can comply with the requirements?**

    A. When Schedule A is implemented, the cosmetic product will need to comply with the ASEAN Cosmetic Product Registration Requirements The product should also need to comply with the ASEAN Common Technical Documents specifically ASEAN Cosmetics Labeling Requirements and ASEAN Guidelines for Cosmetic GMP as required by the country of registration and/or importing country.

    The company should be aware and understand the ASEAN Common Technical Documents. The company's representative, system and technical document would also need to be aligned with the MRA requirements. Seminars, trainings and workshops will be conducted and will be made available to the industry for their active participation.

7. **Does change of any packaging materials of an existing product in the market requires new product registration?**

    A. No

8. Does change of brand name of an existing product in the market requires new product registration?

A. No. Only notification. However, products that incur changes in the formulation which affect the product function and/or claims should require new registration.

9. How does the ASEAN Cosmetic Product Registration Requirement impact the current Product Listing/Notification system existing in some countries?

A. The ASEAN Cosmetic Product Registration Requirements shall only apply to all cosmetic products that are currently required to be registered in the respective ASEAN

countries. Products which are currently required to be listed or notified in the ASEAN countries are not covered by this Technical Document.

Labeling

10. What are the ASEAN Cosmetic Labeling Requirements? What do I need to do to comply with the requirements and when?

A. The ASEAN Cosmetic Labeling Requirements define what are needed to appear on the label that will be accepted by all ASEAN Member Countries. Please see the ASEAN Cosmetic Labeling Requirements Technical Document for particulars.

If an ASEAN member country chooses to implement the ASEAN Cosmetic Labeling Requirements before January 2008, the cosmetic product marketed in this country should comply with the requirements. By January 2008 when the ASEAN Cosmetic Directive will be implemented, all cosmetic products marketed in ASEAN should comply with the ASEAN Cosmetic Labeling Requirements. The company/industry should start revising the labels to comply with the ASEAN requirements and work on the transition so existing inventory can be exhausted and compliant labels will be marketed by Year 2008.

11. Does ASEAN Cosmetic Labeling Requirements require ingredients to be reflected in packaging?

A. Yes. Full Ingredient Listing using INCI names needs to be reflected in packaging/label of cosmetic products under the ASEAN Cosmetic Product Labeling Requirements. However, for botanicals and extracts of botanicals, it should be identified by genus and species. The genus may be abbreviated.

12. Is Expiry Date a mandatory labeling requirement under ASEAN?

A. The cosmetic product can reflect either the Expiry Date or the Manufacturing Date on the label under the ASEAN Cosmetic Labeling Requirements.

13. As Per the ASEAN Cosmetic Labeling Requirement, we need to reflect either Manufacturing Date OR Expiry Date of the product in clear terms (eg month/year). Please clarify how it should be presented – eg Mfg Date: Sep 2000 or Mfg Date : 09/00. Is there a standard format to be followed?

A. No, the common technical document does not dictate any standard format for Exp Date or Mfg Date. Any format can be used, whichever you choose to reflect on the label, as long as it is presented clearly and will not cause any confusion among consumers.

14. **Do we need to reflect the Manufacturer's name and address per the ASEAN Cosmetic Labeling requirement?**
A. The ASEAN Cosmetic Labeling Requirement requires the name and address of the company or person responsible for placing the product in the local market on the label. Therefore, if the manufacturer is the one responsible for placing the product on the local market, then its name and address should be reflected on the label. However, the country of manufacture should be reflected at all times.

15. I have existing inventory of old labels/packaging? What will I do with this inventory?

A. You would need to work with your regulatory authorities/cosmetic industry on the transition to the ASEAN compliant labels. It is ideal that exhaustion of old labels be worked out to avoid scrapping. Meanwhile, you would need to plan how to ensure that your product labels comply with the ASEAN Cosmetic Labeling requirements by January 2008.

Claims

16. How do I determine if my claim is acceptable as cosmetic?

A. Check your claim if it is promising cosmetic benefit and not medicinal or therapeutic benefit. Any cosmetic claimed benefits made shall be aligned with what is accepted internationally and shall be justified either by technical data and/or cosmetic formulation or preparation itself. Refer to the ASEAN Cosmetic Claims for Guidelines.

17. Is there a harmonized list of allowed/not allowed claims in ASEAN?

A. No. ASEAN does not have a harmonized list of claims. Claims/claims assessment will be subjected to national control.

Ingredient Listings

18. What are the ASEAN Ingredient Listings? How do I use them? What is a Restricted List? What is a Negative List? What is a Positive List?

A. The ASEAN Ingredient Listings would be the reference document by all ASEAN Member Countries in the review of formulations of cosmetic products. It will provide the list of ingredients that are banned for use or restricted for use and list of colorants, preservatives and UV filters that are allowed for use in cosmetic products marketed in ASEAN. Refer to these listings during product formulation to ensure your products comply with the ASEAN Ingredient Requirements.

The Restricted List will indicate ingredients that are allowed for use in cosmetic products but subject to restrictions and conditions. It will define the restrictions on the field of application and/or use, the maximum authorized concentration in the finished product, other limitations and requirements and conditions of use and warning which must be printed on the labels.

19. What are the ASEAN Cosmetic Ingredient Listings? How do I use them? What is a Restricted List? What is a Negative List? What is a Positive List?

A. The ASEAN Cosmetic Ingredient Listings would be the reference document by all ASEAN Member Countries in the review of formulations of cosmetic products. It will provide the list of ingredients that are banned for use or restricted for use and list of colorants, preservatives and UV filters that are allowed for use in cosmetic products marketed in ASEAN. Refer to these listings during product formulation to ensure your products comply with the requirements of the ASEAN Ingredient listings.

The Restricted List will indicate ingredients that are allowed for use in cosmetic products but subject to restrictions and conditions. It will define the following restrictions on the field of application and/or use, the corresponding maximum

authorized concentration in the finished product, other limitations and requirements and conditions of use and warning which must be printed on the labels.

The Negative List will indicate ingredients that are NOT allowed for use in cosmetic products. It is usually referred to as the Banned List or defined as the List of Ingredients which must NOT form part of the cosmetic products.

The Positive List will indicate ingredients that are allowed for use in cosmetic products. Ingredients outside this list will not be allowed. For ASEAN, we have positive lists for colorants, preservatives and UV filters for cosmetic products.

20. What is the ASEAN Handbook of Cosmetic Ingredients?

A. The ASEAN Handbook of Ingredients captures ingredients currently allowed or banned or restricted for cosmetic products in specific ASEAN country/ies and deviating from the ASEAN Common Ingredient Listings. ASEAN Cosmetic Committee created the ACSB (ASEAN Cosmetic Scientific Body) with primary task to review each ingredient in the Handbook and check whether the current status of the ingredient in the country/ies should be dropped or adopted by ASEAN. Until such assessment is made, the countries are allowed to continue implementing the local regulations on the ingredients.

21. What do I need to follow if my country has existing local Cosmetic ingredient listings?

A. When the country starts implementing the ASEAN Cosmetic Ingredient Listings, these supersede the local ingredient listings. The ASEAN Handbook of Cosmetic Ingredients will be superseded once the ACSB completed the review of the Handbook and makes an assessment for its adoption or deletion by ASEAN Cosmetics Committee.

22. What if my ingredient is not found in any of the ASEAN Ingredient Listings?

A. If the ingredient is not in the Banned List or Restricted List, the ingredient is allowed for use without any restrictions or special conditions. However, if the ingredient is functioning as a colorant or preservative or UV filter and is not in the ASEAN ASEAN List of allowed Colorants, Preservatives or UV filters, the ingredient will not be allowed for use.

23. What if my ingredient exceeds the allowable maximum level per ASEAN and I have extensive safety data to support my ingredient level?

The ingredient is not allowed beyond the maximum limit. One can present the safety data to the ACSB through the ACC for modification of the limit. Until a positive recommendation is made by the ACSB and adopted by the ACC, the limit is to be respected.

24. What is the ASEAN Cosmetic Scientific Body (ACSB)? How does it work?

A. The ACSB has been established to assist ACC in reviewing the ingredient lists, technical and safety issues. The ACSB consists of representatives from the regulatory authorities, the industry and the academe. The ACSB reviews all the data available to make an assessment on ingredient lists and on technical/safety issues and make a recommendation for adoption by the ASEAN Cosmetic Committee (ACC). At present, the ACSB is reviewing the ASEAN Handbook of Cosmetic Ingredients as well as additions to the annexes of the Directive.

25. Who do I contact if I have queries/concerns on Ingredient Listings?

A. You can contact your cosmetic regulatory authorities or industry associations. You can also access the following websites: (indicate ASEAN website, ACA website, industry associations' websites.)

26. What is the Illustrative List? Is this a restricted list?

A. The Illustrative List of Cosmetics By Categories identifies common product categories that are classified as cosmetics in ASEAN. It is NOT a restricted list and currently unimagined product forms and types should be considered against the definition of a cosmetic and not the list.

27. Is the Illustrative List my basis for determining whether my product is cosmetic or not?

Answer:

A. The Illustrative List is a basis for determining whether the product is classified as cosmetic. However, it is not the sole basis. Together with the Illustrative List, you would need to refer to the ASEAN Cosmetic Definition, the ASEAN Cosmetic Ingredient Listings and the ASEAN Cosmetic Claims Guidelines to fully assess whether your product will be classified as cosmetic.

GMP

28. What is the ASEAN Cosmetic GMP? How is it different from the existing/local GMP?

A. The ASEAN Cosmetic GMP is a set of guidelines which is consistent with accepted international practices that cosmetic manufacturers have to follow in order to ensure Quality and Compliance of the products put on the ASEAN market.

29. **What will happen if I am a small company and I can't comply with GMP?**

A. The Directive does not make any difference between small, medium or big companies. All cosmetic products put on the ASEAN market must be manufactured according to the ASEAN GMP by January 2008.

30. **How can I comply with the ASEAN Cosmetic GMP? What Should I do ?**
A. The ASEAN cosmetic GMP has 13 training modules to guide you to implement GMP in your factory. This information is available with your local NRA and the following websites www.aseansec.org/4951.htm , www.ecasean.com and www.aca.org. You may also contact your local cosmetic association for the training of the 13 modules.

Schedule B - ASEAN Cosmetic Directive

31. What is Schedule B - the ASEAN Cosmetic Directive? How is it related/different from the Schedule A – Product Registration?

A. Schedule B or the ASEAN Cosmetic Directive will be the ASEAN Harmonized Cosmetic Regulatory Scheme that will be implemented by all ASEAN Member Countries by January 2008 or earlier. This is the Product Notification Scheme with the basic principle that the company or person responsible for placing the cosmetic products in the market, shall notify the cosmetic regulatory authority responsible for cosmetics of each

Member State where the product will be marketed of the place of manufacture or of initial importation before the product is placed in the market.

The Directive does not require Product Registration. It is a shift from pre-market approval (product registration) to post marketing surveillance.

32. What are the benefits we can derive from the implementation of the Directive?

A. As the Directive requires product notification, the product to trade cycle will be short. Research breakthroughs and new product technologies shall be made available to consumers faster. Consumers will have a wider choice of cosmetic products and this widens cosmetic/ingredient safety database.

33. How will the Directive affect my company? How do I prepare for the implementation of the Directive?

A. The Directive identifies the company or person placing the cosmetic products in the market to be ultimately responsible for the safety and quality of cosmetic products. The company shall take all necessary precautions to ensure that the product fully complies with the technical requirements of the Directive. You should work with your cosmetic regulatory authorities and industry associations to help you prepare on the implementation of the Directive.

34. What are my responsibilities under the ASEAN Cosmetic directive after it has been implemented?

A. You and your company will be responsible for the cosmetic products you placed in the market. You will need to do the following when you intend to market a cosmetic product in the ASEAN Member Country (ies) :

i. File Notification with the cosmetic regulatory authority in the country where you intend to market the product. Pay the necessary notification fee as required.

ii. Check compliance of your product against the Directive requirements/technical documents

iii. Ensure that the Product Information File (PIF) is ready anytime for inspection by the cosmetic regulatory agency. Please refer to Article 8 of the Directive for details of the PIF.

iv. Monitor products in the market for product quality or adverse cosmetic event. Report any serious adverse cosmetic event to the regulatory authority.

35. What is Post Marketing Surveillance (PMS)? How will the PMS be conducted by the regulatory authority?

A. Post Marketing Surveillance is the responsibility of the Regulatory Authorities to, at any time, review and audit the Product Information File for compliance with the regulations, in particular, but not exclusively, on product safety and product efficacy (as claimed). The Regulatory Authorities can, at any point in time, take products samples from the market or the warehouses to analyze them for conformance.

36. I understand there is no more registration requirement when the Directive is implemented? Does my label need to reflect any registration number?

A. No. Product label will no longer be required to reflect registration numbers.

37. What if I change formulation or packaging or claims of an existing product in the market? What do I need to do under the Directive?

A. Check if your formula changes comply with the ASEAN Cosmetic Ingredient Listings and with the Directive. Check your packaging changes if it complies with the ASEAN Cosmetic Labeling Requirements. Check if your claims comply with the ASEAN Cosmetic Claims Guidelines.

Product Notification will need to be filed.

38. What is the role of the cosmetic regulatory agency under the Directive?

A. Member States shall undertake all necessary measures to ensure that only cosmetic products, which conform to the provisions of this Directive, its Annexes and Appendices, may be placed in the market. The cosmetic regulatory authority has the authority to enforce post-marketing surveillance to ensure compliance with the ASEAN Cosmetic Directive. They can also visit the company anytime and audit or review the Product Information File. In the event that the product has been found to be violating the ASEAN Cosmetic Directive/requirements, the regulatory authority has the authority to issue a product recall and impose sanctions for the violation as defined in the local laws.

39. Where to get information about the Asean Harmonized Cosmetic Regulatory Scheme?

1. Information about the Asean Harmonized Cosmetic Regulatory Scheme can be obtained from the following websites:

   a. ASEAN Secretariat (http://www.aseansec.org/4951.htm)
   b. EC-ASEAN (www.ecasean.com)
   c. ASEAN Cosmetics Association (www.ASEANcosmetics.org)

2. Information could also be obtained from the contact person in each Member Countries (Appendix 3)

E. Guidance on Product Notification Procedures

Questions on Notification procedures

1. What should I do if I intend to import or manufacture a cosmetic product for local sale?

The company or person responsible for placing the cosmetic products in the market must notify the regulatory authority responsible for cosmetics of each Member State where the product will be marketed, of the place of manufacture or of initial importation before the product is placed in the market, using the Product Notification Form prescribed by the regulatory authority. *The product can be marketed after the product notification.has been sent to the regulatory authority.*

2. After filing a product notification and receiving a notification number from the regulatory authority, does it mean that the product has been approved for sale by the authority?

Acceptance of a product notification does not constitute, in any way, an agreement that the product meets all the regulatory requirements. The company or person responsible for placing the product in the market has to ensure that each consignment of the product meets the requirements of the Directive and will not cause damage to human health under normal or reasonably foreseeable conditions of use. The ASEAN Cosmetic Directive shifts from a pre-market approval system, to a post-marketing surveillance system. The Regulatory Authority will carry out a range of post-marketing monitoring and surveillance activities to ensure compliance with the Directive.

3. If my product has been notified to an ASEAN Member Country, is it exempted from notification of another ASEAN country in which I intend to market the product too?

No, *as the authority of each country where the product is going to be marketed has to be informed individually*. If you intend to market the product in 3 ASEAN Member countries, you will have to notify the regulatory authority of the 3 ASEAN Member Countries.

4. If the cosmetic product is meant <u>solely</u> for re-export, must notification be filed with the regulatory authority?

Cosmetic products that are imported or locally manufactured *solely* for direct re-export can be exempted from product notification requirement, as they will not impact the safety of local consumers, but the company should maintain proper records and documents. These records should be open to inspection by the regulatory authorities at any time when required. However, if you export the products to market in an ASEAN Country, notification in that ASEAN Country is required.

5. Does each individual shade of a range of a cosmetic product or a palette of colours require a separate product notification?

No. A single notification can be made for a range of cosmetic products or a palette of colours. However, full ingredient listing (one can use “may contain” to list the colorants used in each product form the palette) and the percentage of restricted substances will have to be declared for each colour in the range or palette. Please refer to the Guidelines on filing a notification to the regulatory authority.

Please note that you will have to file a new notification for colours added to an existing range or palette that are not included in the initial notification.

6. Can a foreign company that is not registered to operate business in the country where the product will be marketed, file the product notification?

No. A company registered to operate business in the country where the product will be marketed should file a product notification.

7. [1]What are the supporting documents to be submitted with a product notification?

The following documents should be submitted with the notification:

[1] The answer will be revised according to the final product notification template endorsed by the Asean Cosmetic Committee.

- *Full ingredient listing (as per labeling requirements) and the percentage of restricted ingredients appearing in the annexes of the Directive;*
- *Clear & legible colour photographs or draft drawing/artwork of the product labels, package inserts, inner and outer cartons.*
- *Business Licence of the registrant or company responsible for placing the product in the market (To be submitted once if applicable).*

8. If there are any changes in the information submitted in a product notification[1], do I have to file a new product notification?

It will depend on the types of changes involved, as indicated below:

a) New product notification is required for changes in:

- Manufacturer or assembler (?)
- Product types
- Intended use
- Product presentation
- Formula (?)
- Manufacturer (?)

b) An amendment notification can be submitted in an amendment form as prescribed by the regulatory authority for changes involving the following particulars:

- Brand and product name
- Company responsible for placing the product in the market
- Person representing the local company
- Pack sizes, packaging material, labels (?)
- Formula (?)
- Change of assembler (?)

<u>Guidelines on filing a notification to the regulatory authority</u>

Particulars of a product

9. Name of brand and product

The complete name of the product should be given, in the following sequence: brand name, line name (if applicable), product name, if a single shade is notified, the shade name/number .

10. Product types

The illustrative list is not exhaustive and you can include other types of cosmetic products not in the list by selecting others and specifying what it is. More than one category can be selected, e.g. 'Bath or shower preparations' and 'Hair-care products' can be selected if your product is both a shower gel and hair shampoo

11. Intended use

This refers to the function or use of the product and not the directions for use e.g. to moisturize the face, hand, etc.

[1] Please refer to the Template For Notification for a Cosmetic Product. The answer will be revised according to the final product notification template endorsed by the Asean Cosmetic Committee.

12. Pack size
It should be given by weight or volume, in either metric or *both* metric and imperial system.

13. Product presentation(s)
Please select only one out of the 4 choices that best fit the presentation type of the product. The following is an explanation of the presentation types:

- '*A single product'* exists in a single presentation form.
- [2]'*A range of colours'* is a range of cosmetic products, which are similar in composition and produced by the same manufacturer, and are intended for the same use but are available in different shades of colour (e.g. lipsticks, eye shadows or nail polish but not composite packs of different types).
- '*Single palette(s) in a range'* refers to a range of colours as defined above, which are presented in a range of single palettes.
- '*Combination products in a single kit'* refer to similar and/ or different product types packed and sold in a single kit. They cannot be sold separately. (e.g. a make-up kit of eye and lip colours; a set of skin-care products sold in a single kit).

14. Particulars of the manufacturer(s)/ Assembler(s) There may be more than one manufacturer and/or assembler for one product. The full names and contact details of each of them must be submitted.

15. Particulars of company
It refers to the local company responsible for placing the cosmetic products in the market, which may be a local manufacturer, an agent appointed by a manufacturer to market the product or the company that *is responsible for bringing in the product for sale in the country.* The business registration number or its equivalent should be indicated in the notification form, if applicable.

16. Particulars of the person representing the local company
The person who represents the company to submit the product notification must possess adequate knowledge or experience in accordance with the legislation and practice of the Member Country.

Product Ingredient list

17. [4]Full ingredient listing and nomenclature

a) All the ingredients in the product must be specified by using the nomenclature from the latest edition of standard references (Refer to appendix A). Botanicals and extract of botanicals should be identified by its genus and species. The genus may be abbreviated. The following are not regarded as ingredients:

   - Impurities in the raw materials used;

[2] For these presentation types, only one notification needs to be submitted.
[4] The answer will be revised according to the final product notification template endorsed by the Asean Cosmetic Committee.

- Subsidiary technical materials used in the preparation but not present in the final product;
- Materials used in strictly necessary quantities as solvents, or as carriers for perfume and aromatic compositions.

b) The percentage of ingredients must be declared if they are substances with restrictions for use as specified in the annexes of the ASEAN Cosmetic Directive.

F. GUIDELINES FOR INDUSTRY ON ADVERSE EVENT REPORTING OF COSMETIC PRODUCTS.

1. Introduction:

Pursuant to the ASEAN Cosmetic Directive, Article 3 (1) and the Discussion Paper on Post Marketing Surveillance/Product Safety, adopted by the ASEAN Cosmetic Committee in its second meeting held in Bangkok June 7-8, 2004, it is important to harmonize the mechanism to gather and, if necessary, take action on important safety information arising from post marketing surveillance of cosmetic products.

Thus, agreed definitions and terminology, as well as procedures, will not only ensure uniform standards in the adverse event reporting process but will also facilitate product safety information sharing among ASEAN Regulatory Bodies.

There are two issues within the broad subject of safety data management that are appropriate for harmonization at this time:

- The development of standard definitions and terminology for key aspects of adverse event reporting, and
- The appropriate mechanism for handling adverse event reporting

This Guideline shall be revised as necessary, to take into account technical progress and regulatory developments.

2. Definitions and terminologies

2.1 Adverse Event:

Any genuine harmful or unintended event reasonably attributable to the normal or foreseeable use of a given cosmetic product.

2.2 Serious Adverse Event:

A serious event is any untoward medical occurrence that:

- Results *in death,*
- Is life threatening *(*the term life threatening refers to an event in which the person was at risk of death at the time of the event;
- Requires in-patient hospitalization*, or*
- Results in persistent or significant disability/incapacity

3 Who should the industry report to?

The company or person responsible for placing the cosmetic product in the market shall report to the regulatory authority of the ASEAN Member State where the adverse event occurred, regardless of the source of the report (consumer, healthcare professional, etc).

4 What should be reported?

4.1 Every case~~s~~ of serious adverse event:

All serious adverse events should be reported. Non-serious adverse events are not required to be reported.

> Whenever there is reasonable suspicion that the cosmetic product might be the cause of the reaction, reporting is necessary for all serious adverse events as defined in section 2.2 The expression "reasonable suspicion" is meant to convey in general that there are evidences to suggest a causal relationship or an association.

4.2 High incidence of adverse event (Non-serious/severe reactions)

There are "non-serious" adverse events that occur at a high incidence (as defined by the ratio of events to units sold) of a single "severe" reaction type that may necessitate rapid communication to the regulatory authority. However, appropriate medical and scientific judgment should be applied for each situation of non-serious, single "severe"[3] adverse event that has a high incidence before reporting to the regulatory authority.

5. When to report an adverse event?

5.1 Fatal or life threatening adverse events

Fatal or life threatening adverse event qualify for very rapid reporting to the regulatory authority, which shall be notified (e.g. by telephone, facsimile transmission, email or in

writing) as soon as possible but no later than 7 calendar days after first knowledge, followed by completing the Adverse Cosmetic Event Report Form (Appendix I) within an additional 8

[3] **To ensure no confusion or misunderstanding between the terms "serious" and "severe", which are not synonymous, the following note of clarification is provided:**
The term "severe" is often used to describe the intensity (severity) of a specific event (as in mild, moderate, severe reaction); the event itself, however, may be of relatively minor significance (such as skin irritation, headache). Seriousness, not severity, serves as a guide for defining regulatory reporting obligations.

calendar days and providing any other information as may be requested by the regulatory authority.

5.2 Other serious adverse events

All other serious **adverse events** (as defined in section 2.2) that are not fatal or life threatening must be reported as soon as possible, but no later than 15 calendar days after first knowledge.

G. APPENDICES

Appendix A

List of Standard References to be use for Cosmetic Ingredient Nomenclature

1. International Cosmetic Ingredient Dictionary
2. British Pharmacopoeia
3. United States Pharmacopoeia
4. Chemical Abstract Services
5. Japanese Standard Cosmetic Ingredient
6. Japanese Cosmetic Ingredients Codex

COSMETIC PRODUCT [CONFIDENTIAL] **APPENDIX 1**

To:
Name & Address of the Regulatory Authority
Department
Telephone no,
Fax no.
Email address

FOR OFFICIAL USE ONLY
Date received:
Product Notification No.

REPORT FORM FOR ADVERSE COSMETIC EVENT

I. Company Particulars

Name and address of Company		
Name & designation of person reporting		
Tel No.:	Fax No.:	Email:

II. Product Particulars

Product Name (as in product notification)	
Ingredient listing & pack size	(Please attach a separate list)
Product Type/Intended use	
Name of Manufacturer & country of manufacture	
Expiry or manufacturing date	
Batch No.	

III. Details of Adverse Event

Name/ Initials of person			
Identification or Passport no.			
Age		Sex	
Ethnic group / Nationality			
Date of onset of adverse event			
Description of adverse event (please use and attach a separate report if necessary) Delay between last application of the product and onset of symptoms: ___ min(s) ___hour(s)____day(s) How was the product used:			
Is the person hospitalised due to the adverse reaction?		□ Yes	□ No
Did person seek medical attention?		□ Yes	□ No
Outcome	□ Recovered (Date:_____) □ Not yet recovered	□ Death (Date: _____) □ Unknown	
Source of report	□ Healthcare professional	□ Consumer	□ Others (specify)

[Signature of person making report & date of report]

APPENDIX 2

Schedule B: ASEAN Cosmetic Directive

FOR OFFICIAL USE
Date received:

Product Notification No.**:**

TEMPLATE FOR NOTIFICATION FOR A COSMETIC PRODUCT

☑*Tick where applicable*

PARTICULARS OF PRODUCT

1. Name of brand & product:

1.1 Brand

1.2 Product Name

1.3 List of Variants or Shades.

_____

_____

_____

2. Product type(s)

- ☐ Creams, emulsions, lotions, gels and oils for skin (hands, face, feet, etc.)
- ☐ Face masks (with the exception of chemical peeling products)
- ☐ Tinted bases (liquids, pastes, powders)
- ☐ Make-up powders, after-bath powder, hygienic powders, etc.
- ☐ Toilet soaps, deodorant soaps, etc
- ☐ Perfumes, toilet waters and eau de Cologne
- ☐ Bath or shower preparations (salts, foams, oils. gels, etc.)
- ☐ Depilatories
- ☐ Deodorants and anti-perspirants
- ☐ Hair care products
  - hair tints and bleaches.
  - products for waving, straightening and fixing,
  - setting products,
  - cleansing products (lotions, powders, shampoos),
  - conditioning products (lotions, creams, oils),
  - hairdressing products (lotions, lacquers, brilliantines)
- ☐ Shaving product (creams, foams, lotions, etc.)
- ☐ Products for making-up and removing make-up from the face and the eyes

- ☐ Products intended for application to the lips
- ☐ Products for care of the teeth and the mouth

- ☐ Products for nail care and make-up.
- ☐ Products for external intimate hygiene
- ☐ Sunbathing products
- ☐ Products for tanning without sun.
- ☐ Skin whitening products
- ☐ Anti-wrinkle products
- ☐ Others (please specify) -

  _____

3. Intended use

   _____
   _____
   _____

4. Product presentation(s)

   - ☐ Single product
   - ☐ A range of colours
   - ☐ Palette(s) in range
   - ☐ Combination products in a single kit

PARTICULARS OF MANUFACTURER (S)/ASSEMBLER(S)

[Please attach in a separate sheet if there are more than one manufacturer/assembler]

5. Name of manufacturer:

   Address of manufacturer (state country):

C o u n t r y																								

   Tel**:** | | | | | | | | | | | | | | | | Fax**:** | | | | | | | | | | | | | |

6. Name of assembler:

   Address of assembler (state country):

C o u n t r y																								

   Tel**:** | | | | | | | | | | | | | | | Fax**:** | | | | | | | | | | | | | | |

PARTICULARS OF LOCAL COMPANY RESPONSIBLE FOR PLACING THE COSMETIC PRODUCT IN THE MARKET (Please submit a Letter of Authorisation from the product owner or manufacturer. Need to submit once only)

7. Name of company:

Address of company:

Tel: Fax:

Business Registration Number (if applicable):

PARTICULARS OF PERSON REPRESENTING THE LOCAL COMPANY

8. Name of person:

Tel: Email:

Designation in the company:

PRODUCT INGREDIENT LIST

9. Please check the relevant boxes

☐ I have examined the Annexes II to VIII of the ASEAN Cosmetic Ingredient Listing and confirmed that the product in this notification does not contain any prohibited substances and is in compliance with the restrictions and conditions stipulated in the Annexes.

☐ I undertake to respond to and cooperate fully with the regulatory authority with regard to any subsequent post-marketing activity initiated by the authority.

No	Full Ingredient name (use INCI or approved nomenclature in standard references)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	

DECLARATION

1. I hereby declare on behalf of my company that the product in the notification meets all the requirements of the ASEAN Cosmetic Directive, its Annexes and Appendices.

2. I undertake to abide by the following conditions:

   i. Ensure that the product's technical and safety information is made readily available to the regulatory authority concerned ("the Authority") and to keep records of the distribution of the products for product recall purposes;
   ii. Notify the Authority of fatal or life threatening serious adverse event[4] as soon as possible by telephone, facsimile transmission, email or in writing, and in any case, no later than 7 calendar days after first knowledge;
   iii. Complete the Adverse Cosmetic Event Report Form[5] within 8 calendar days from the date of my notification to the Authority in para 2ii. above, and to provide any other information as may be requested by the Authority;
   iv. Report to the Authority of all other serious adverse events that are not fatal or life threatening as soon as possible, and in any case, no later than 15 calendar days after first knowledge, using the Adverse Cosmetic Event Report Form[2];
   v. Notify the Authority of any change in the particulars submitted in this notification;

3. I declare that the particulars given in this notification are true, all data, and information of relevance in relation to the notification have been supplied and that the documents enclosed are authentic or true copies.

4. I understand that I shall be responsible for ensuring that each consignment of my product continues to meet all the legal requirements, and conforms to all the standards and specifications of the product that I have declared to the Authority.

5. I understand that I cannot place reliance on the notification of my product to the authority in any legal proceedings concerning my product, in the event that my product has failed to conform to any of the standards or specifications that I had previously declared to the Authority.

_____
[Name and Signature of person making application on behalf of company]

_____ _____
[Company stamp] [Date]

[4] As defined in the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products
[5] Set out in Appendix I to the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products

APPENDIX 3

CONTACTS: LIST OF ACC MEMBERS , ASEAN Secretariat, CEN Team

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