

**GENERAL INFORMATION BOOKLET
ON
ASEAN HARMONIZED COSMETIC REGULATORY SCHEME**

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**GENERAL INFORMATION BOOKLET
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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 integration in the region. The vision of regional economic integration was conceptualized in recognition of the importance and potential of trade liberalization and facilitation and in desiring to increase regional competitiveness.

However, market integration is not just about cutting or removing tariffs on trade. ASEAN countries have to make sure that non-tariff barriers including technical barriers created by standards, technical regulations and conformity assessment are removed. ASEAN has recognized the need to conclude Mutual Recognition Arrangements and harmonize standards and technical regulations in order to facilitate the movement of goods within the region.

In December 1998, ASEAN decided to meet this problem head-on by signing the Framework Agreement on Mutual Recognition Arrangements and the ASEAN Cosmetic Association was the driving force for this. In July 1997, the ASEAN Cosmetic Association officially asked the ASEAN Secretariat and the ASEAN Consultative Committee on Standards and Quality for help in removing barriers to cosmetics, specifically by harmonizing technical regulations governing the cosmetic industry in ASEAN. Since then ASEAN cosmetic regulators and the cosmetic industry in the ASEAN region have been working together to address the issues associated with barriers.

As a result of this collaboration, the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS) was signed on 2 September 2003. The AHCRS lays down the requirements for cosmetic products for all signatory ASEAN Member Countries starting from 1 January 2008. A product produced or marketed in any signatory country and meeting the requirements of AHCRS would be able to enter other signatory countries. The most significant aspect of this harmonized scheme is that all ASEAN Member Countries will move from the traditional and preferred approach of "pre-market approval" to the new approach of "post-market surveillance" for cosmetic products, considered being more effective.

The harmonization of cosmetic regulations in the region will benefit all stakeholders: the consumers (a wider choice of safe cosmetic products), the regulatory bodies (one simplified regulatory system) and the cosmetic industry (open ASEAN as one single market for manufacturers, with more than 500M consumers).

A. Coverage

SCHEDULE A: MUTUAL RECOGNITION ARRANGEMENT OF PRODUCT REGISTRATION APPROVAL. The product registration approval in an Asean country is recognized in Member Countries, where a mutual recognition arrangement has been agreed

upon.” Schedule A is a preparatory stage for Member Countries to proceed to Schedule B but a Member Country can opt to proceed directly to Schedule B.

SCHEDULE B: THE ASEAN COSMETIC DIRECTIVE: Product Notification The manufacturer or the person responsible for placing cosmetic products on the ASEAN market, shall notify the cosmetic regulatory authority of each Member State where the product will be marketed of the place of manufacture 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) system to post -market surveillance. All ASEAN countries are committed to implement Schedule B – The ASEAN Cosmetic Directive by January 2008.

B. Technical Documents

The following are the highlights of the ASEAN Harmonized Cosmetic Regulatory Scheme Common Technical Documents. These have been the result of close collaboration between 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 in the ASEAN Directive (similar to the EU definition) shall be allowed as a cosmetic.

ii. Cosmetic Ingredient Lists

The ASEAN Cosmetic Directive has the following Annexes:

Annex II: List of Substances which must not form part of the composition of cosmetic products

Annex III: List of Substances which cosmetic products must not contain except subject to restriction and conditions laid down

Annex IV: List of Colouring Agents allowed for use in cosmetic products

Annex V: List of Excluded from the scope of the Directive

Annex VI: List of Preservatives which cosmetic products may contain

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

Additionally the Directive contains an ASEAN Handbook of Ingredients which lists the differences between current regulations and the Cosmetic Directive. The ASEAN Cosmetic Scientific Body (ACSB) is tasked with making a decision as to the status of 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 between 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 become mandatory. The 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 local country control because of difference in languages, interpretations, culture and religions. The definition of a cosmetic product, Illustrative List by Category of Cosmetic Products, Ingredient Lists and and the ASEAN Cosmetic Claims Guideline shall be the technical documents that will guide the countries in the review of the acceptability of a cosmetic claim.

vi. ASEAN Cosmetic Product Registration Requirements/Procedure (Schedule A)

This applies to all cosmetic products that are currently required to be registered in the respective ASEAN countries that have entered into mutual recognition arrangement with another ASEAN country. Target registration processing period is 30 days maximum.

vii. ASEAN Requirements for Import/Export of Cosmetic Products

All cosmetic products manufactured in or imported from non-ASEAN Member countries or ASEAN Member Countries have to comply with the ASEAN Harmonized Cosmetic Regulatory Scheme and its technical documents. Licensing and its requirements shall be regulated 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 are affected by this Scheme and when is it effective?

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 Arrangement 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 is Product Notification scheme does not require registration. The company shall file the Product Notification with the regulatory agency in the country prior to placing the cosmetic product in the market.

ASEAN countries who accede to Schedule A can implement MRA between now and January 1, 2008. The cosmetic products marketed in these countries need to comply with the Schedule A – MRA requirements.

ASEAN Member 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 1, 2008.

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

A. The Scheme aims to remove technical barriers to trade by harmonizing regulatory and technical requirements across ASEAN without compromising product safety and quality. This would facilitate the flow of cosmetic products across ASEAN Member Countries to increase ASEAN 's competitiveness in the region

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. to promote awareness and understanding of the scheme. Preparations for compliance with the regulatory scheme should start now and any concerns/ difficulties should be raised so that they 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 local regulatory authorities and industry associations if you have queries or concerns on the scheme. (Please refer to Appendix 2)

4. Where can I get more 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)
- d. Please refer to Appendix 2.

2. Information could also be obtained from the contact person in each Member Countries and local cosmetics associations. (Appendix 2)

SCHEDULE A - Mutual Recognition of Product Registration Approval

5. 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 Cosmetic Product Registration Requirements when the country starts implementing the scheme. When this happens, the existing local requirements/timing will be superseded by the ASEAN requirements.

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 all the ASEAN Technical Documents on Cosmetic Product Registration Requirements, the ASEAN

Cosmetic Labeling Requirements, the ASEAN Cosmetic Claims Guidelines and Cosmetic GMP and Annexes of prohibited and restricted ingredients.

The company should be aware and understand the ASEAN Common Technical Documents. The company's 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.

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

A. For those in Schedule A, No. For those not in Schedule A, please refer to the regulations on registration of your country and/or the country where you wish to market the product.

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

A. For those countries that accede to Schedule A, a change in brand name requires an amendment application. However, products that incur changes in the formulation which affect the product function and/or claims require new registration. For countries not implementing Schedule A, please refer to the regulations on registration of the country where you wish to market the product.

9. How does the ASEAN Cosmetic Product Registration Requirements impact the current Product Notification or registration system existing in some countries?

A. In the country that choose to implement Schedule A, the ASEAN Cosmetic Product Registration Requirements shall only apply to all the cosmetic products to be marketed in the country. For countries that choose to proceed directly to Schedule B but have not yet implemented the ASEAN Cosmetic Directive (Schedule B) the existing regulatory requirements applies. But once the ASEAN Cosmetic Directive is implemented, notification of product will apply.

Schedule B - ASEAN Cosmetic Directive

10. What is Schedule B - the ASEAN Cosmetic Directive?

A. Schedule B or the ASEAN Cosmetic Directive shifts from a pre-market approval system (product registration) to a post marketing surveillance system, that will be implemented by all ASEAN Member Countries by January 2008 or earlier. 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 Country where the product will be marketed of the place of manufacture or of initial importation before the product is placed in the market. The existing Product Registration system will be replaced by a Product Notification System where it involves an upfront declaration of compliance by the company responsible for the product. As the intention of the Directive is to place the responsibility of ensuring product safety on the company that markets the product, self regulation by the cosmetic industry to ensure compliance with the safety and quality criteria, becomes an important part of the regulatory scheme.

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

A. As the Directive requires only product notification, the product to trade cycle will be shortened. Research breakthroughs and new product technologies can be made available to consumers faster. This will provide consumers with a wider choice of cosmetic products as well as help build cosmetic/ingredient safety database for the industry.

12. 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 should take all necessary steps to understand fully and comply with all the requirements of the Directive. You should work with your cosmetic regulatory authority and industry associations to help prepare for the implementation of the Directive.

13. What are my responsibilities under the ASEAN Cosmetic Directive after it has been implemented?

A. You and your company will be fully responsible for the safety and quality of cosmetic products placed in the market. The following is a guide of what you will need to do when you intend to market a cosmetic product in ASEAN:

- i. Be conversant with the all requirements of the Directive and the Annexes of ingredient listings (i.e banned, restricted and permitted substances). Seek the help of the local regulatory authority and industry association.
- ii. Take steps to ensure full compliance with the Directive 's requirements and technical documents, particularly the requirement on the safety and quality of the cosmetic product.
- iii. File Notification with the cosmetic regulatory authority in the country where you intend to market the product. Pay the necessary notification fee as required.
- iv. Ensure that the technical and safety information required in Article 8 of the Directive (Product Information File) is ready anytime for inspection by the cosmetic regulatory authority.
- v. Monitor products in the market for product quality or adverse cosmetic event. Report any serious adverse cosmetic event to the regulatory authority.

14. What is Post Marketing Surveillance (PMS)?

A. The Regulatory Authorities will conduct an on-going post-market surveillance programme on cosmetic products to ensure that they comply with the Directive 's requirements. This may involve any or all of the following activities:

- Audit of Product Information File for compliance with the regulations, in particular, but not exclusively, on product safety.
- The Regulatory Authorities may, take products samples from manufacturers, importers and distributors to analyze them for compliance.
- The Regulatory Authorities may request for laboratory test reports from the company as and when necessary.

15. When the Directive is implemented, will the industry still need to label registration numbers on the product?

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

16. 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, the ASEAN Cosmetic Labeling Requirements, the ASEAN Cosmetic Claims Guidelines. You will also need to check if the change would require a new notification or amendment and file for the change accordingly.

17. What is the role of the cosmetic regulatory authority under the Directive?

A. The cosmetic regulatory authority has the authority to enforce post-marketing surveillance to ensure compliance with the ASEAN Cosmetic Directive. They can visit the company anytime, with or without prior notice, to audit the Product Information File as well as take samples for analytical testings. In the event of non-compliance with requirements of the ASEAN Cosmetic Directive, the regulatory authority can impose sanctions for the violation as defined in the local laws and issue a product recall if deemed necessary to protect public health.

B. ILLUSTRATIVE LIST

18. 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 product forms and types currently not in the list should be considered against the definition of a cosmetic and not the list.

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

A. The Illustrative List is one of the 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.

C. COSMETIC INGREDIENT LISTS

20. 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 of all ASEAN Member Countries in the review of formulations of cosmetic products. It will provide the list of ingredients that are banned or restricted for use, the positive 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.

The Negative List indicates 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 the positive lists for colorants, preservatives and UV filters for cosmetic products.

21. What is the ASEAN Handbook of Cosmetic Ingredients?

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

22. 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 will supersede the local ingredient listings. The ASEAN Handbook of Cosmetic Ingredients will be superseded by the recommendations of the ACSB adopted by the ASEAN Cosmetics Committee.

23. 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 List of allowed Colorants, Preservatives or UV filters, the ingredient will not be allowed for use.

24. What if my ingredient exceeds the allowable maximum level in the ASEAN Ingredient Listings and I have extensive safety data to support my ingredient level?

A. The ingredient is not allowed beyond the maximum limit. The safety data can be presented 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 complied with.

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

A. The ACSB has been established to assist ACC in reviewing the safety and technical data of ingredients and making recommendations on other technical and safety issues for adoption by the ACC. The ACSB consists of representatives from the regulatory authorities, the industry and the academe. At present, the ACSB is reviewing the ASEAN Handbook of Cosmetic Ingredients as well as additions to the annexes of the Directive.

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

A. You can contact your local cosmetic regulatory authorities or industry associations. You can also access the following websites: (ASEAN website: www.ecasean.com, ACA Website: www.ASEANcosmetics.org (Please refer to Appendix 2)

D. GMP

27. What is the ASEAN Cosmetic GMP?

A. The ASEAN Cosmetic GMP is a set of guidelines published in accordance with the ASEAN Cosmetic Directive to facilitate the development of a quality management system by manufacturers producing cosmetic products that are intended for the ASEAN market.

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

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

29. How can I comply with the ASEAN Cosmetic GMP? What Should I do ?

A. With the joint effort of the regulatory authority and the industry, 13 training modules on the ASEAN cosmetic GMP have been developed to provide a consistent interpretation and implementation of the GMP Guidelines in ASEAN. It contains minimum requirements to ensure safe and quality products. You may obtain this information from your local regulatory authority 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 information on the training of the 13 modules. (Please refer to Appendix 2)

E. LABELING

30. 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 the information that has to appear on the label. Please see the ASEAN Cosmetic Labeling Requirements Technical Document for detailed requirements.

All cosmetic products marketed in the ASEAN must comply with the ASEAN Cosmetic Labeling Requirements by January 2008, when the ASEAN Cosmetic Directive is implemented. The industry should therefore start revising the labels in accordance to the ASEAN requirements and work on the transition so existing inventory can be exhausted and all labels on marketed products can be compliant by year 2008.

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 the date stipulated by the regulatory authority.

31. Does ASEAN Cosmetic Labeling Requirements require ingredients to be reflected on the packaging?

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

32. Is Expiry Date a mandatory labeling requirement under the ASEAN Cosmetic Labeling Requirements?

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

33. Is there a standard format to be followed for the labeling of the Expiry Date or the Manufacturing Date?

A. No, the common technical document does not dictate any standard format for Exp Date or Mfg Date. Any format can be used (**eg month/year**), provided it is presented clearly and legibly, without causing any confusion among consumers

34. Do we need to reflect the Manufacturer's name and address on the label?

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.

35. 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.

F. CLAIMS

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

A. If the claim is promising cosmetic benefit and not medicinal or therapeutic benefit, it is acceptable as long as it can be substantiated. 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 for further information.

37. 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.

G. FREQUENTLY ASKED QUESTIONS ON PRODUCT NOTIFICATION

38. 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 only be marketed after notification has been sent to the regulatory authority and acknowledgement has been received. Member countries shall

endeavour to ensure that notifications will receive acknowledgement within three working days.

39. After filing a product notification and receiving an acknowledgement (e.g. 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.

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

No, 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 respective 3 ASEAN Member Countries.

41. If the cosmetic product is meant solely for export or re-export, must notification be filed with the regulatory authority?

Cosmetic products that are imported solely for direct re-export or locally manufactured solely for export are 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 Member Country, notification in that ASEAN Member Country is required.

Country specific requirements for manufacturers or importers of cosmetic products meant solely for export or re-export must be complied with.

42. Are samples including Hotel's sample, and professionally used cosmetic exempted from notification and the requirements of ACD ?

All product samples must be notified to the authority and comply with all the requirements of the ACD

43. 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, if required by the regulatory authority, full ingredient listing (one can use "may contain" to list the colorants used in each product in 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.

44. Can a company that is not registered to operate business in the ASEAN Member Country where the product will be marketed, file the product notification?

No, only a company registered to operate business in the ASEAN Member Country where the product will be marketed can file a product notification.

45. What are the supporting documents to be submitted with a product notification?

The following documents should be submitted with the notification:

- Full ingredient listing (as per labeling requirements) and the percentage of restricted ingredients appearing in the annexes of the Directive, if required by regulatory authority;
- Clear & legible colour photographs or draft drawing/artwork of the product labels, package inserts, inner and outer cartons, if required by regulatory authority;
- Copy of the Business Licence of the registrant or company responsible for placing the product in the market, to be submitted once, if required by regulatory authority;
- Letter of authorization from the product owner or manufacturer, if required by regulatory authority;

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

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

Types of Change	Product Notification
Brand name	New
Company change due to change of distribution rights	New
Product types	New
Product presentation(single product, palettes in a range, etc)	Amendment
Intended use	New
Product name	New
Formulation	New
Manufacturer and or assembler (name and/or address)	New
Name and/or address of company without change of distribution rights	Amendment
Person representing company	Amendment
Pack sizes, packaging materials, labels.	Amendment, but not applicable if the information need not be submitted in Product Notification Form.

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H. GUIDANCE DOCUMENT ON PRODUCT NOTIFICATION TO THE REGULATORY AUTHORITY

Particulars of a product

47. 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 (e.g. L'oreal Feria Color 3D Hot Ginger). If there are different shades, the shade name/number for each shade shall be declared.

48. 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.

49. 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.

50. 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.

1"A range of variants similar in composition for the same use but differs in colours, flavours etc" 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).

1"Palette(s) in a range of one product type" refers to a range of colours as defined above, which may be presented in a series of palettes.

1"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).

¹ For these presentation types, only one notification needs to be submitted.

51. 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.

52. Particulars of company

It refers to the local company responsible for placing the cosmetic products in the market, which may be a local manufacturer or 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, etc. The business registration number or its equivalent should be indicated in the notification form, if applicable.

53. 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 if required by regulatory authority

54. 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;
- 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.

c.) For a range of colours/shades or products in a single kit, complete the Product Ingredient List in the following format:

- List ingredients in the Base Formulation
- May contain' and list each colour/shade

d) For combination products in a kit, list each product and its corresponding formulation individually. You can extend the form when more space is needed.

I. A GUIDE MANUAL FOR THE INDUSTRY ON ADVERSE EVENT REPORTING.

55. 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 Authorities.

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

56. Definitions and terminologies

a. Adverse Event:

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

b. 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

57. 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).

58. What should be reported?

a. Every cases 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.

b. 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”² adverse reaction that has a high incidence before reporting to the regulatory authority.

59. When to report an Adverse Event?

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

b. 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.

² 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.

J. APPENDICES

Annex 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

PRODUCT INGREDIENT LIST

9. Please check the following boxes

I have examined the latest revisions of the Annexes II to VII of the ASEAN Cosmetic Ingredient Listing as published in the latest amendment of the ASEAN Cosmetic Directive 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.

[To submit ingredient list with percentages of restricted ingredients and packaging materials as required by member country]

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

****) If product is not compliance with ACD, please provide details of non-complianc***

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 event⁴ 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 Form⁵ 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;
 - 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 acceptance of my product notification by 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 representing the local 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

COSMETIC PRODUCT [CONFIDENTIAL]

APPENDIX 2

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

<p>FOR OFFICIAL USE ONLY</p> <p>Date received: Product Notification No.</p>
--

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?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Did person seek medical attention?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Outcome	<input type="checkbox"/> Recovered (Date: _____)	<input type="checkbox"/> Death (Date: _____)
	<input type="checkbox"/> Not yet recovered	<input type="checkbox"/> Unknown
Source of report	<input type="checkbox"/> Healthcare professional	<input type="checkbox"/> Consumer <input type="checkbox"/> Others (specify)

[Signature of person making report & date of report]

APPENDIX 3

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

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