

Revised July 2014

**GUIDELINE ON THE
CONTROL OF COSMETIC PRODUCTS**

The information in this Guideline shall be updated or revised from time-to-time. For any new, addition, amendments or deletion made to this Guideline, please refer to the latest version in our website www.hsa.gov.sg.

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Introduction

1 These guidelines provide an explanation of the regulatory requirements relating to the regulation of cosmetic products which are provided for under the following legislation:

- Health Products Act (Amendment of First Schedule) (No.2) Order 2007
- Health Products (Cosmetic Products – ASEAN Cosmetic Directive) Regulations 2007
- Health Products (Cosmetic Products – ASEAN Cosmetic Directive) (Amendment) Regulations 2010

2 Copies of the above legislation are available from:

Toppan Leefung Pte Ltd
Legal Publishing
1 Kim Seng Promenade
#18-01/06
Great World City East Tower
Singapore 237994
Tel: 6826 9691
Email: legalpub@toppanleefung.com
Website: http://www.toppanleefung.com/Header_LegalPub.aspx

3 Singapore has implemented the ASEAN Cosmetic Directive (ACD) from 1 January 2008. Under the current regulatory control, any person who introduces a cosmetic product into the local market must notify the Health Sciences Authority (HSA) before the supply and/or sale of the cosmetic product. The person also has to ensure that the cosmetic product is safe for human use when applied under normal conditions of use, and does not contain any banned or restricted substances stipulated for cosmetic products as listed in the legislation.

4 The information in these guidelines does not apply to a cosmetic product that is:

- Imported into Singapore solely for re-export;
- Manufactured in Singapore solely for export.

Definition of Cosmetic Product

5 A “Cosmetic Product” is any substance or preparation that is intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips, eyes and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, correcting body odours, protecting them or keeping them in good condition.

Product Types

6 The illustrative list provided below is not an exhaustive list on types of cosmetic products.

- Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc)
- Face masks
- Tinted bases (liquids, pastes, powders)
- Make-up powders, after-bath powders, hygiene powders etc
- Toilet soaps, deodorant soaps, etc
- Perfumes, toilet waters and eau de Cologne
- Bath and shower preparations (salts, foams, oils, gels, etc)
- Depilatories
- Deodorants and anti-perspirants
- Hair care products
 - Hair tints and bleaches
 - Products for waving, straightening or fixing
 - Setting products
 - Cleansing products (lotions, powders, shampoos)
 - Conditioning products (lotions, creams, oils)

- Hairdressing products (lotions, lacquers, brilliantines)
- Shaving products (creams, foams, lotions, etc)
- Products for making-up and removing make-up from the face and the eyes
- Products intended for the application to the lips and around the eyes
- Products for care of the teeth and the mouth
- Products for nail care and make-up (manicure and pedicure products)
- Products for external intimate hygiene
- Sunbathing products
- Products for tanning without sun
- Skin whitening products
- Anti-wrinkle products
- Wipes

Product forms and types not listed above should be considered against the definition of a cosmetic product. You may contact the Cosmetics Control Unit if further clarification is required.

Product Presentation

7 The following are explanations of the various presentation types of cosmetic products :

- “A Single product” is a product existing in a single presentation form.
- “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 type)

- “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.
- “Combination products in a single kit” refers to similar and/or different product types packed and sold in a single kit.

More information on the product presentation can be found in Annex A of this Regulatory Guidance.

Labeling Requirements

8 Labeling is required for all cosmetic products. Labels or labeling statements must be in English and be clearly legible. Other languages, if any, may be present on the label. The following information must appear on the container or package of the cosmetic products:

- a Name of cosmetic product
- b Function of the cosmetic product
- c Instructions for use
- d Full ingredients listing
- e Country of manufacture
- f Contents (weight/volume)
- g Batch number
- h Manufacturing/ expiry date (expiry date is required for products with less than 30 months durability)
- i Name and address in Singapore of company responsible for placing the product in the market

- j Special precautions, if any (especially those listed in Annex III, VI, VII in the ASEAN Cosmetic Directive)
- 9 An explanation of the symbol or code (e.g. colour) used as an information in the label should be provided. More information on the labeling requirements can be found in Annex B (ASEAN Cosmetic Labeling Requirements).

Label Display

10 The label must be prominently and conspicuously displayed on the product at the point of sale. Labels or labeling statements shall appear on the outer packaging of the cosmetic products or, where there is no outer packaging, on the immediate packaging of cosmetic products. Where the size, shape or nature of the container or package does not permit all the required information to be specified on the container or package, the use of leaflets, pamphlets, hang tags, display panels etc are allowed. However, the name of the cosmetic product and the batch reference must be displayed on the container or immediate package.

Listing of Ingredients

- 11 All cosmetic products must be labelled with the ingredients contained in the product. The quantity or percentage of each ingredient in the cosmetic product need not be disclosed on the labelling.
- 12 The ingredients should be listed in descending order by weight, except for:
- a Ingredients (except colouring agents) in concentrations of less than 1% (by weight) listed in any order after ingredients present in concentration of 1% or more; and
 - b Colouring agents listed in any order, after the other ingredients.

13 Perfume and aromatic compositions and their raw materials may be referred to by the word “perfume”, “fragrance”, “aroma” or any other similar term. Likewise, flavouring may be referred to as “flavour” or any other similar term.

Nomenclature of Ingredients

14 The nomenclature used should be based on the most recent edition of the International Cosmetic Ingredient Dictionary, Chemical Abstracts Service, British Pharmacopoeia and United States Pharmacopoeia, or any other approved standard references. Botanicals and extract of botanicals should be identified by its genus and species.

Product Notification

15 The company or person responsible for placing a cosmetic product in the market must notify Health Sciences Authority (HSA) using the online Pharmaceutical Regulatory Information System (PRISM) system. Acknowledgement of the notification from HSA must be received before the product can be marketed. Subsequent retention of the notification (re-notification) is required every year if the cosmetic product continues to be supplied in the market.

16 Notification is not required if:

- a cosmetic product that is supplied solely as a sample in connection with any advertising, sponsorship or promotional activity; or
- a cosmetic product that is supplied solely for testing or trial use in connection with any research or development of that product; or
- a cosmetic product that is manufactured by or in accordance with the specifications of a medical practitioner, and supplied solely by that medical practitioner for the use of patients under his care.

Nonetheless, compliance with other requirements such as labeling, safety of ingredients and adverse event reporting, is still required.

Fees

Notification Fee

17 From 1 January 2011, the annual notification fees for cosmetic products is as follows:

1.	Notification fee for Cosmetic Products deemed to be of higher risk¹		
	(a)	Single product	\$25
	(b)	Variant	
	(i)	First 3 variants	\$25/variant
	(ii)	4 th and subsequent variants	\$5/variant
2.	Notification fee for Cosmetic Products deemed to be of lower risk²		
	(a)	Single product	\$10
	(b)	Variant	
	(i)	First 3 variants	\$10/variant
	(ii)	4 th and subsequent variants	\$5/variant

¹Cosmetic Products deemed to be of higher risk are cosmetic products to be applied around the eyes, on the lips, hair dyes containing phenylenediamines and oral and dental care products.

²Cosmetic Products deemed to be of lower risk are all other cosmetic products not listed above such as skin whitening products, moisturisers, etc.

For retention on the cosmetic product, the above fee is applicable.

Global Updates of details of Manufacturer/Assembler/Store/Importer

Please refer to the section on “Changes in particulars” on page 10 and 11.

Good Manufacturing Practice (GMP) Certificate

18 The fee for the application of GMP certificate is as follows:

1.	GMP Certificate (non-mandatory)		
	(1)	Application for GMP certification (3 years' validity)	\$4,000

	(2)	Application for issuance of additional certificate	\$200
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Sample Testing

19 Companies are required to submit samples of cosmetic products for laboratory testing when requested by the Health Sciences Authority, for example to verify the safety or quality of the products. The expenses incurred in the testing will be borne by the companies

Importer Licence and Manufacturer's Licence

20 Importers and manufacturers no longer need to apply for a manufacturer's or importer's licence.

Electronic Submission of Notification

21 On-line notification may be made at the following website:

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/PRISM_e-services/Cosmetic_Products_Oral_Dental_Gums.html.

Companies may submit their notifications via their own computers or at Do-It-Yourself (DIY) kiosk available at:

Health Products Regulation Group
 Health Sciences Authority
 11 Biopolis Way
 #11-01 Helios
 Singapore 138667
 Tel: 65 6866 3474/75
 Fax: 65 6478 9754

Change in particulars

22 A new product notification is required if changes are made to the following:

a Brand name

- b Product name
- c Product types
- d Intended use
- e Formulation
- f Company change of distribution rights

23 For the following type of change that affects more than one product notification, one submission under the “Global Update” in the PRISM is sufficient to effect the change:

- a Manufacturer
- b Assembler
- c Importer
- d Store/ warehouse

The fee for “Global Update” of the above details is \$15 per amendment. A company may select up to a maximum of 20 affected notifications per amendment submitted.

24 For other changes relating to the following, the company will need to inform the Cosmetics Control Unit to effect the amendments:

- a Pack sizes, packaging materials, labels – not applicable if the information were not submitted in Product Notification Form
- b Product presentation without change in product and brand name

25 For changes to be made on the name and/or address of company without change of distribution rights (i.e. no change in Registry of Companies & Businesses or RCB number), the company can effect the change via the “amend company information” under amend@PRISM.

26 For changes to be made on change of person representing the company, the company can amend the change through the Client Registration and Identification Services (CRIS@hsa).

Record Keeping

27 The person responsible for placing a cosmetic product in the market is required to keep records on the supply of the cosmetic product. The record shall contain information on the name and notification number of the product, name and address of person supplied, and the batch number, date and quantity of product supplied. The records should be kept for 2 years after the date of supply.

Product Information File

28 Information about the cosmetic product is to be kept in a Product Information File (PIF), which is retained for a minimum period of 3 years after the product is last placed in the market. Upon specific requests from the Authorities, PIF should be made available and accessible to the Authorities for audits within an agreed upon timeframe usually 15 to 60 calendar days or shorter, depending on the urgency of the audit. Audits may be conducted routinely or on an ad-hoc basis by the regulatory authority. More information on the PIF can be found in Annex C of this Guidance.

Adverse Event Reporting

29 A company must report all serious adverse events to the health authority whenever there is reasonable suspicion or evidence to suggest that the cosmetic product might be the cause of the reaction at the following address:

Adverse Event Management Unit
Vigilance Branch
Vigilance, Compliance and Enforcement Division
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way

#11-01 Helios
Singapore 138667
Tel: 68663530/ 68663531

30 If the serious adverse event has caused death or is life-threatening, the company must report to HSA within 7 days after the company has become aware of the event. The company is required to submit an adverse event report form within the next 8 days.

31 For the other serious adverse events, which have resulted in hospitalisation or any persistent or significant disability or incapacity, the company must submit the adverse report form to HSA within 15 days after the company has become aware of the event.

32 More information on the adverse event reporting and the reporting form can be found in the “Guide Manual for the Industry – Adverse Event Reporting of Cosmetic Products” on our website.

Penalty

33 When deemed necessary, the Health Sciences Authority may direct that a cosmetic product be withheld from sale and supply, and withdrawn from the market.

34 Any person who contravenes any provisions of the legislation on cosmetic products is liable, on conviction, to a fine or to an imprisonment term or to both, the amount of fine and the jail term varies according to the type and seriousness of the offences, as stipulated in the legislation. For example, failure of the person responsible to notify a cosmetic product placed in the market will be liable to a fine up to S\$20,000, or a jail term up to 12 months or both.

Enquiry

35 Enquiries on cosmetic products should be directed to:

Cosmetics Control Unit
Complementary Health Products Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way
#11-01 Helios
Singapore 138667
Tel: 65 6866 3474/75
Fax: 65 6478 9754
Email: HSA_Cosmetics_Control@hsa.gov.sg

36 Information on the ASEAN Cosmetic Directive requirements can be found under the following website link:

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Cosmetic_Products/Overview/ASEAN_Cosmetic_Directive.html

Annex A

PRODUCT PRESENTATION TYPES

Annex A**Product Presentation Types**

- **Single product** exists in a single presentation form.



- **A range of variants similar in composition for the same use but differs in colours, flavours etc**

refers to 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 or flavours.

Examples: lipsticks, eye shadows or nail polish but not composite packs of different types



- **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.

A single palette



Range of palettes



- **Combination products in a single kit**
refers 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).



Annex B

ASEAN COSMETIC LABELING REQUIREMENTS

Annex B**ASEAN COSMETIC LABELING REQUIREMENTS**
(APPENDIX II OF THE ASEAN COSMETIC DIRECTIVE)**A. Objective**

1. This document provides guidance for the labeling requirements of cosmetic products to which Article 6 of the ASEAN Cosmetic Directive 05/01/ACCSQPWG apply.

B. Scope and Definitions

1. For the purpose of this document:

Name of the cosmetic product means the name given to a cosmetic product, which may be an invented name, together with a trade mark or the name of the manufacturer;

Immediate packaging means the container or other form of packaging immediately in contact with the cosmetic product;

Outer packaging means the packaging into which is placed the immediate packaging;

Labeling means information written or printed or graphic matter on the immediate or outer packaging and any form of leaflets;

C. Labeling of Cosmetic Products

1. The following particulars shall appear on the outer packaging of cosmetic products or, where there is no outer packaging, on the immediate packaging of cosmetic products:

- a) The name of the cosmetic product and its function, unless it is clear from the presentation of the product;
- b) Instructions on the use of the cosmetic product, unless it is clear from the product name or presentation;
- c) Full ingredient listing. The ingredients must be declared in descending order of weight at the time they are added. Perfume and aromatic compositions and their raw materials may be referred to by the word “perfume”, “fragrance”, “aroma” or “flavor”. Ingredients in concentrations of less than 1% may be listed in any order after those of concentration of more than 1%. Coloring agents may be listed in any order after the other ingredients, in accordance with the color index number or denomination adopted in Annex IV.

For decorative cosmetic products marketed in several color shades, all coloring agents used in the range may be listed, provided that the terms “may contain” or “+/-“ be added.

The ingredients shall be specified 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 shall not, however, be regarded as ingredients:

- Impurities in the raw materials used;
 - Subsidiary technical materials used in the preparation but not present in the final products;
 - Materials used in strictly necessary quantities as solvents, or as carriers, for perfume and aromatic compositions;
- d) Country of manufacture;
 - e) The name and address of the company or person responsible for placing the product on the local market;

- f) The contents given by weight or volume, in either metric or both metric and imperial system;
- g) The manufacturer's batch number;
- h) The manufacturing or the expiry date of the product in clear terms (e.g. month/year). The date shall be clearly expressed and shall consist either of the month and year or the day, month and year in that order. The date of minimum durability shall be the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with article 3. It should be preceded by the words "expiry date" or "best before". If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

Indication of the expiry date shall be mandatory for cosmetic products the minimum durability of which is less than 30 months.

- i) Special precautions to be observed in use, especially those listed in the column "Conditions of use and warnings which must be printed on the label in Annexes ___", which must appear on the label as well as any special precautionary information on the cosmetic products. Member countries may require specific warnings based on local needs for declaration of ingredients from animal origin. In this case:
 - i. There must be a statement (of any format) on the product label signaling the presence of ingredients of animal origin;
 - ii. For ingredients of bovine or porcine origin, the exact animal must be declared;

- 2. In cases where the size, shape or nature of the container or package does not permit the particulars laid down in paragraphs 1 (a) – (i) to be displayed, the use of leaflets, pamphlets, hang tags, display panel, shrink wrap, etc. shall be allowed. However the following particulars at least shall appear on small immediate packaging:

- a) The name of the cosmetic product;
 - b) The manufacturer's batch number;
3. The particulars referred to in paragraphs 1 and 2 shall be easily legible, clearly comprehensible and indelible;
 4. The particulars listed in paragraph 1 shall appear in English and/or National Language and/or a language understood by the consumer where the product is marketed. Member Countries may require that the information in paragraphs a), b), e), f) and i) be in the national language or a language easily understood by the consumer;

APPENDIX A

List of Standard References to be used for Cosmetic Ingredient Nomenclature

1. International Cosmetic Ingredient Dictionary;
2. British Pharmacopeia;
3. United States Pharmacopeia;
4. Chemical Abstract Services;

**ASEAN COSMETIC DIRECTIVE
GUIDELINES FOR PRODUCT INFORMATION FILE (PIF)**

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1. Introduction and Objective

The ASEAN Cosmetic Directive (ACD) requires persons or companies placing a product on the market to keep a product information file “readily accessible to the regulatory authority of the Member State concerned at the address specified on the label in accordance with article 6 of this Directive”.

The main objective of this ASEAN Product Information File (PIF) Guideline is to provide companies placing a cosmetic product in the market recommendations on how to organize and compile the PIF based on a recommended PIF format. This document also provides guidance on who is responsible to keep the PIF and some guiding points for PIF audits.

2. PIF Organization

Article 8 of the ACD spells out the list of information required in the PIF:

- a) The qualitative and quantitative composition of the product, in case of perfume compositions, the name and code number of the composition and the identity of the supplier;
- b) Specifications of the raw materials and finished product;
- c) The method of manufacture complying with the good manufacturing practice as laid down in the ASEAN Guidelines
- d) Assessment of the safety for human health of the finished product, its ingredients, their chemical structure and level of exposure;
- e) Existing data on undesirable effects on human health resulting from use of the cosmetic product; and
- f) Supporting data for claimed benefits of cosmetic products should be made available; to justify the nature of its effect;

Article 9 of the ACD requires the company to provide information on the method of analysis to the regulatory authority:

- a) The available methods used by the manufacturer to check the ingredients of cosmetic products corresponding with the Certificate of Analysis; and

- b) The criteria used for microbiological control of cosmetic products and chemical purity of ingredients of cosmetic products and/or methods for checking compliance with those criteria”

In view of the above ACD requirements, companies placing products in the market need to organize the PIF in such a way that it meets the requirements and be easily consulted by the Authorities. It is recommended that the PIF be organised into 4 parts as follows:

- Part I: Administrative Documents and Product Summary
- Part II: Quality Data of Raw Material
- Part III: Quality Data of Finished Product
- Part IV: Safety and Efficacy Data

A Table of Contents should be provided for each of the 4 parts.

Part I: Administrative Documents and Product Summary

The first part of the PIF contains the administrative documents and key summary information that are specific to a single product; i.e. this part would provide an ample overview of the finished product.

A. Administrative documentation

- Copy of the Notification form bearing the acknowledgement receipt from the Authorities; this will include the identity of the product, the address of the manufacturer, assembler, importer and company placing the product in the market;
- Authorisation letter by product owner or agreement letter related to the product, if required by the legislation of the Member Country;
- Any other relevant administrative documents that may be prescribed by the local Authorities e.g. Licence to Operate, Certificate of Incorporation of the Company;

- B. Qualitative and Quantitative formula of the product (INCI or other ACD approved reference names and corresponding concentrations of the ingredients):
- For fragrance materials, name and code number of the composition and the identity of the supplier;
- C. Product presentation and label, including:
- Outer and inner labels (photographs and/or drawings will be useful);
 - Consumer information leaflets and instruction for use if part of the product as sold to the consumer;
- D. Manufacturing Statement:
- A statement by the manufacturer or company that the product was manufactured according to the ASEAN GMP Guidelines or any ACC approved equivalent GMP Guidelines;
 - Provide the batch coding system/ key of the product;
- E. Safety Assessment (summary) as per the ASEAN Guidelines for the Safety Assessment of a Cosmetic Product:
- Safety statement (signed statement of opinion, including the name and qualifications of the safety assessor);
- F. Confirmed undesirable effects on human health (summary);
- G. On-pack product claim support (summary):
- Summary report of the Efficacy Assessment of the product, based on its composition or on tests performed;

Part II: Quality Data of Raw Materials

The second part of the PIF should include full technical information on the quality of the raw materials/ ingredients:

- A. Specifications and test methods of raw material/ ingredients:
- Specifications of each ingredient including water specification, if appropriate;
 - Method of analysis corresponding to the specifications for each ingredient, including identification of the ingredients;
 - For fragrance materials, specify the name and code number of the fragrance, name and address of the supplier, declaration of compliance with the latest IFRA guidelines;
- B. Data on the safety of the raw materials based on data from the supplier, on published data or on reports from Scientific Committees like the ASEAN Cosmetic Scientific Body (ACSB), the EU Scientific Committee on Consumer Products (SCCP) or the US Cosmetic Ingredient Review Board (CIR);

Part III: Quality Data of Finished Product

The third part of the PIF supplies the detailed technical information on the quality of the finished product:

- A. Qualitative and Quantitative formula of the product (INCI or other approved ACD reference names and corresponding concentrations of the ingredients):
- The formula should specify the functions of each raw material/ ingredient;
- B. Manufacturing:
- Manufacturer contact details: name, country and address of manufacturer, assembler and packager;
 - Summary of the Manufacturing Process;
 - Additional detailed information on the manufacturing process, quality controls and related manufacturing documents should be made available upon request by the Authority;

C. Specifications and test methods of the finished product:

- The criteria used for microbiological control of cosmetic products and chemical purity of ingredients of cosmetic products;
- Method of Analysis corresponding to the specifications for checking compliance;

D. Product Stability Summary Report, for product durability below 30 months:

- The stability testing data and report or stability assessment to support the expiry date;

Part IV: Safety and Efficacy Data

The fourth and final part of the PIF provides detailed information on the safety assessment and data of the finished product and also relevant efficacy data to support any claims made on the product.

A. Safety Assessment:

- Signed assessment report of the safety for human health of the finished product based on its ingredients, their chemical structure and level of exposure;
- Curriculum Vitae of the safety assessor;

B. The latest compiled report on confirmed or recorded adverse events or undesirable effects on human health resulting from use of the cosmetic product:

- The adverse event report in the PIF is expected to be updated by the company on a regular basis;

C. On-pack product claim support:

- Full signed report of the Efficacy Assessment of the product, based on its composition or on tests performed;

- Supporting data including literature review for claimed benefits of cosmetic products should be made available to justify the nature of its effect;

3. Who is responsible to keep the PIF

Article 8 of the ACD states that the company or person responsible for placing the cosmetic product in the market shall keep the PIF readily accessible to the regulatory authority at the address specified on the label, which, according to the labelling requirements [Appendix II, C (e)] is “the name and address of the company or person placing the product on the local market”. The definition of such has been given in the “Guidance document on product notification to the Regulatory Authority” as “the local company responsible for placing the cosmetic product 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.” This clearly refers to a company or person having an address in the local market, and to the company or person responsible for bringing in the product into that market; whether this is an importer, a manufacturer or a distributor.

It is recommended that the PIF is kept for a minimum period of 3 years after the product is last placed in the market.

4. PIF Audits

4.1 Types of audits

Since the PIF must be at the address specified on the label, Authorities can audit the PIF at that address. There are 2 possibilities:

- **Routine audits:** The Authorities will announce these audits in advance. It is recommended that the audit be announced sufficiently in advance (i.e. at least 1 month) for the company to prepare for the audit;
- **Ad-hoc audits:** these may be triggered by results found on samples from the market, by consumer complaints, etc. It is recommended that

the audit be announced at least 48 hours in advance. In case of extreme urgency the auditing can take place without announcement;

4.2 Documents to be made readily available

While the whole PIF should be available, in order to facilitate the preparation of the industry, in particular the SMEs as well as the importers/ distributors, the documents in Part I of the PIF should be made readily available especially for initial investigative audits.

4.3 Documents to be made accessible to Authorities within reasonable time

Upon specific request from the Authorities, documents, detailed information or reports in other parts of the PIF should be available and made accessible to the Authorities within an agreed upon timeframe: within 15 to 60 calendar days or shorter, depending on the urgency of the audit.

Noting that due to trade secrets, the product owner may not disclose some of the product information in any part of the PIF, to the distributor/importer, the person or company placing the product in the market will need to make their own arrangements with the product owner to provide the relevant and necessary information directly to the Authorities upon request.

4.4 Background or supplementary documents

In general the information provided in the PIF should be sufficient for review to ensure “the safety, quality and claimed benefits of all cosmetic products marketed in ASEAN” as specified in article 1(a) of the ASEAN Harmonized Cosmetic Regulatory Scheme.

However, in some specific cases, other background or supplementary information supporting the PIF documents (e.g. product experience, microbiological challenge tests, additional confirmatory test methods, production records, etc.) may be necessary. The company or person

responsible for placing the product in the market should then make all efforts to provide the requested information to the Authorities.

4.5 Document media

There are no specific requirements on what media type the PIF documents should be presented. Hence the company may choose any suitable media i.e. paper, electronic, etc. provided they are convenient and could be easily consulted by the Authorities.

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Officer(s):

Ms Chew-Kun Yoke Cheng

Cosmetics Control Unit
Complementary Health Products Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way, #11-01 Helios
Singapore 138667
www.hsa.gov.sg

Tel: 65 6866 3474/

65 6866 3475

Fax: 65 6478 9754

Email: HSA_Cosmetics_Control@hsa.gov.sg

