

NATIONAL PHARMACEUTICAL REGULATORY AGENCY
MINISTRY OF HEALTH, MALAYSIA

GUIDELINES FOR CONTROL OF COSMETIC PRODUCTS IN MALAYSIA

1st Revision – February 2017

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GUIDELINES HISTORY

No.	Guideline	Description of Amendment	Effective date
1.	Guidelines for Control of Cosmetic Products in Malaysia	Initial Publication	1 st January 2008
2.	Guidelines for Control of Cosmetic Products in Malaysia	1 st Revision	1 st February 2017

PREAMBLE

This **GUIDELINES FOR CONTROL OF COSMETIC PRODUCTS IN MALAYSIA** shall serve as reference for notification process including quality control, inspection and post-market surveillance activities of cosmetics. This document will replace the **GUIDELINES FOR CONTROL OF COSMETIC PRODUCTS IN MALAYSIA Initial Publication 1st January 2008**.

The content of this guideline is adapted from the ASEAN Cosmetic Directive (ACD). This guideline shall be read in conjunction with the current laws and regulations together with other relevant legislations, where applicable, governing cosmetics for human use in Malaysia, which include but not limited to the following:

- Sale of Drugs Act 1952
- Control of Drugs and Cosmetics Regulations 1984
- Dangerous Drugs Act 1952
- Poisons Act 1952
- Medicines (Advertisement & Sale) Act 1956
- Patents Act 1983
- Wildlife Conservation Act 2010 (Laws of Malaysia Act 716)
- International Trade in Endangered Species Act 2008 (Act 686)
- Medical Device Act 2012
- Trade Descriptions Act 2011

The written laws shall take precedence over this guideline in any event of discrepancy.

The scope of this guideline includes information relating to:

- Submission of cosmetic notification through the NPRA Quest online system.
- Regulatory requirements for cosmetic products
- Post market surveillance activities

Cosmetic Notification Holder (CNH) shall understand the content of this guideline and the governing legislations before submission of a cosmetic notification is made.

The NPRA may request for information or specify conditions not described in this guideline that are deemed necessary to ensure the quality, safety and claimed benefit of the cosmetics.

Regular review of regulatory policies will continue, taking into account the global regulatory environment to allow for timely and pertinent changes. CNH may refer to Directives and Circulars published on the NPRA website for the latest updates on regulatory policies.

Changes to the guideline may be made when necessary by the NPRA and CNH is advised to refer to NPRA website for the latest updates of the cosmetic guideline and other related guidelines.

The NPRA reserves the right to amend any part of the guideline whenever it deems fit.

Any enquiry on cosmetic notification may be submitted to:

Cosmetic Section,
Centre for Post Registration of Products & Cosmetic Control,
National Pharmaceutical Regulatory Agency,
Ministry of Health Malaysia,
Lot 36, Jalan Universiti,
46200 Petaling Jaya,
Selangor,
Malaysia.

Email address: kosmetik@npra.gov.my

ABBREVIATIONS

ACD	ASEAN Cosmetic Directive
ASEAN	Association of Southeast Asian Nations
BP	British Pharmacopeia
CDCR	Control of Drugs and Cosmetics Regulations 1984
CFS	Certificate of Free Sales
CNH	Cosmetic Notification Holder
DPS	Director of Pharmaceutical Services
FEO	For Export Only
GMP	Good Manufacturing Practice
INCI	International Nomenclature for Cosmetic Ingredients
ISO	International Organisation for Standardisation
JAKIM	Malaysia Department of Islamic Development (<i>Jabatan Kemajuan Islam Malaysia</i>)
LOA	Letter of Authorisation
NPRA	National Pharmaceutical Regulatory Agency
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PIF	Product Information File
PMS	Post Market Surveillance
ppm	parts per million
TSE	Transmissible Spongiform Encephalopathy
USP	United States Pharmacopeia
WHO	World Health Organisation

GLOSSARY

Cosmetic Notification Holder (CNH)

The CNH refers to a company who is responsible for placing the cosmetic product in the market.

The CNH must be a locally incorporated company or legal entity in the field of cosmetics, with permanent address and registered with Companies Commission of Malaysia (with the scope of business related to the health/cosmetic product as it appears in the `Memorandum and Article of Association` of the company)

The CNH may or may not be the product owner.

Cosmetic Product

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

For the illustrative list of cosmetic product by categories, please refer to [Annex I, part 1](#).

Letter of Authorisation (LOA) / Letter of Declaration

A Letter of Authorisation (LOA) is issued by the product owner including the list of products or brands authorising the CNH to notify the products with the NPRA and be responsible for all matters pertaining to product notification if the CNH is not the product owner.

On the other hand, if the CNH is the product owner, a Letter of Declaration must be produced which state the ownership of brand name including the list of products or brands for the product notification with the NPRA.

Letter of Contract Manufacturing

Contract appointment and acceptance letters between product owner and contract manufacturer(s) describing the product name(s)/brand(s) involved and the role and responsibilities of both parties.

Manufacturer

A manufacturer is a company which is engaged in any process carried out in the course of making the cosmetic products. The manufacturing process includes all operations of purchase of starting materials, bulk intermediates and products, formulation and production (such as grinding, mixing, encapsulation and/or packaging), quality control, release, storage and distribution of cosmetic products and the related controls.

Primary Assembler

A primary assembler is a company which is engaged in a process of enclosing the product in a primary/intermediate container which is labelled or to be labelled before the product is sold or supplied in it.

Secondary Assembler

A secondary assembler is a company which is engaged only in a process of labelling the product container where the product is already enclosed in its primary container and/or packing the product which is already enclosed in its labelled primary container into a carton which is labelled or to be labelled, before the product is sold or supplied.

Product Name

A name given to a cosmetic product, which may be an invented name, together with a trade mark or the brand name.

Examples of non-permissible product name for cosmetic product are listed in [Annex I, part 2](#).

Product Owner

A product owner is a company or entity who is the legal and/or registered owner of the product formulation and/or process with whom the CNH has a contract.

Product Variant

Product variants shall mean items in a range of cosmetic products which are produced by the same manufacturer, similar in composition and are intended for the same use but are available in different colours, fragrances or flavours. In this context:

- Colour shall mean, a substance used as an ingredient of a cosmetic product solely to give tonality to the product;
- Fragrance shall mean, a substance used as an ingredient of a cosmetic product solely to impart odour to the product

- Flavour shall mean, a substance used as an ingredient of a cosmetic product solely to impart taste to the product.

1. INTRODUCTION

Cosmetic products in Malaysia are regulated under the Control of Drugs and Cosmetic Regulations (CDCR) 1984 which were promulgated under the Sale of Drugs Act 1952.

In agreement with the harmonisation of cosmetic through the ASEAN Cosmetic Directive (ACD), cosmetic products in Malaysia are controlled through notification procedure starting from 1st January 2008. The CNH is required to **COMPLY** with all requirements stated in this guideline and to make a declaration upon notification to the Director of Pharmaceutical Services (known as DPS) through National Pharmaceutical Regulatory Agency (NPRA). Regulatory action will be taken in the event of false declaration and/or product found to be non-compliant to the stipulated regulations and guidelines.

Under the CDCR 1984, Regulation 18A (1): No person shall manufacture, sell, supply, import, possesses any cosmetics unless the cosmetic is a notified cosmetic. It is an offence for anyone to conduct such activities without prior notification to the DPS.

2. COSMETIC NOTIFICATION

APPLICATION PROCEDURES

2.1 Who Shall Submit for Cosmetic Notification

The CNH is responsible to notify the DPS prior to manufacture, sell, supply, import or possess any cosmetic product.

2.2 Responsibility of the CNH

CNH is responsible to ensure that:

- a) All transactions with NPRA shall be carried out by CNH's appointed person(s).
- b) Notified product meets all stipulated regulations and guidelines for cosmetic product.
- c) Product Information File (PIF), including updated information/document on product quality, safety and claimed benefit is available and accessible upon request.
- d) If and when directed by NPRA for product recall, CNH must ensure all affected cosmetic products are recalled from the market and discontinued from selling or supplying the product. Product distribution record must be properly kept for recall purpose.

- e) Change(s) to notified product particulars is submitted accordingly.
- f) Manufacturer (and assembler, where applicable) of the cosmetic product is compliant to Cosmetic Good Manufacturing Practice (cGMP).
- g) In the incidence of serious adverse event, CNH shall report to NPRA appropriately.
- h) Particulars given for product notification are truthful where all data and information of relevance to the notification has been provided.
- i) Each consignment continues to meet all legal requirements and conforms to standards and specifications declared for the product.
- j) When a product failed to conform to any of the standards or specifications declared for the product, CNH cannot place reliance on the acceptance of the product notification in any legal proceedings.
- k) Correspondence details such as company's name, address, contact person, telephone number, fax number and email shall be kept updated.
- l) Cessation of the authorisation of the CNH shall be informed to the NPRA in writing.
- m) Any decision to withdraw the notification of a product shall be informed to the NPRA, with reasons.

2.3 Submission of Notification

All submission for notification shall be done online through NPRA Quest system via NPRA's website at <http://npra.moh.gov.my>.

i. Quest Membership Registration

A CNH must first register for a Quest membership. A detailed guide for Quest membership registration is available on NPRA's website. CNH may also refer to Frequently Asked Questions (FAQ) section on Quest System at NPRA's website for more information.

For information on charges and validity of the membership, please refer to [Annex I, part 3: Charges for Quest Membership](#).

The CNH shall be responsible for any act of fraudulence or misuse of Quest membership.

The NPRA reserves the rights to approve or reject any application for the Quest membership.

ii. Notification of Cosmetic Products

For online submission of notification of cosmetic product, CNH must complete the notification form on the Quest system for each cosmetic product and variant, if any and proceed with the payment to the NPRA.

A step by step guidance on online notification submission is described further in Annex I, part 4: Guide Manual for Quest Online Submission of Cosmetic Notification

A general workflow of a notification process is shown in Figure 1.

2.4 Language

Any document and material submitted to NPRA must be in Bahasa Malaysia or English. Translated version from other languages must be endorsed or authorised.

2.5 Privacy Markings

All Information submitted to the NPRA is deemed confidential, although it is not marked as such by the CNH.

2.6 Fee

The processing fee for notification of a cosmetic product is RM50.00 for each product (and variant, if any).

The processing fee for renewal of notification of a cosmetic product is also RM50.00 for each product (and variant, if any).

Any payment made shall **NOT be REFUNDABLE** once the application has been submitted and payment is confirmed. Please refer to Annex I, part 4: Guide Manual for Quest Online Submission of Cosmetic Notification for acceptable mode of payment.

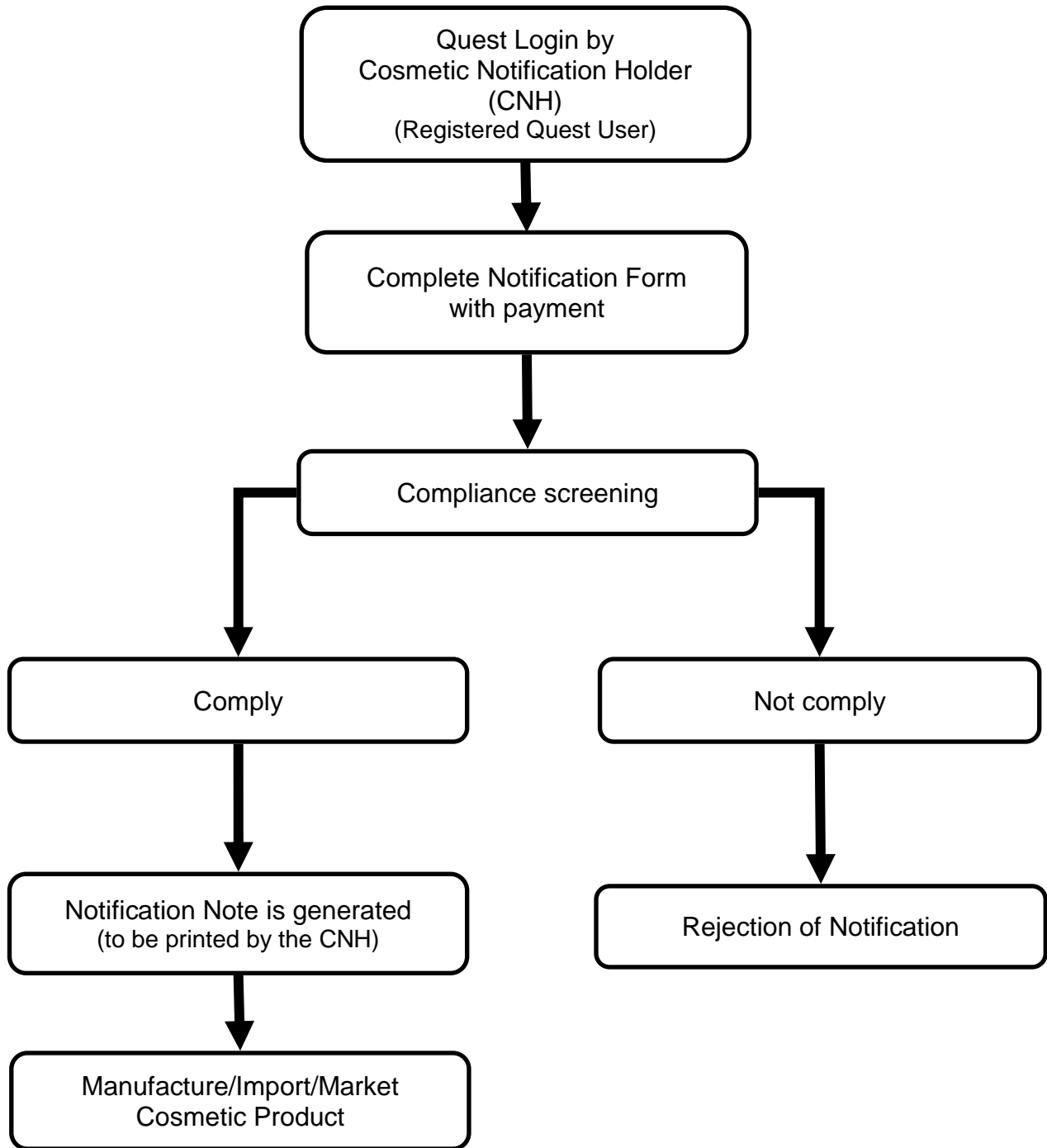


Figure 1: Workflow of a notification process

2.7 Notification Validity Period

The notification of a cosmetic product shall be valid for 2 years. The renewal should be done no later than 1 month prior to notification expiry.

2.8 Manufacture or Importation of Product

CNH may manufacture or import the cosmetic product upon receipt of authorisation given in the Notification Note from the DPS. CNH may generate the Notification Note immediately from the Quest system after confirmation of payment by NPRA subject to meeting all notification requirements.

2.9 Changes in Notification Particulars

Any subsequent changes to the particulars of the notified cosmetic product must be submitted to the NPRA. There are two types of changes:

Type 1 change:

- Changes that only require amendments to the current notification. No charge is imposed and the notification number remains the same.

Type 2 change:

- Changes that require a new notification and is subjected to RM 50.00 processing fee. A new notification number will be issued to the product.

Please refer to Annex I, part 5 for Illustrative List of Types of Changes for Notified Product.

2.10 Notification Number

Notification number is unique for each product and its variant (if any) in the format as below:

NOTyymmxxxxxK (y: year, m: month, x: serial number)

CNH is responsible to ensure the maintenance of valid notification number for product in the market. The existing notification number will be retained for product notification that has been renewed prior to expiry date. A new notification number will be generated for product that is not renewed within the given timeline and for product that has undergone changes requiring new notification.

3. REGULATORY REQUIREMENTS FOR COSMETICS

CNH must ensure compliance to the following requirements prior to notification submission.

3.1 Product Particulars

CNH is required to submit the following information during the notification process:

- Particulars of product including product name, product type, intended use and product presentation
- Name and address of the manufacturer(s) and assembler(s), if any
- Name, address and valid contact number (and e-mail address) of the CNH
- Particulars of person representing the company of CNH including valid contact number
- Name and address of the importer(s), if any
- Full product ingredient list (the content i.e. percentage (%) of the restricted ingredients must be declared)
- Letter of Authorisation/Letter of Declaration/Letter of Contract Manufacturing, where applicable
- Label(s) of the product

3.2 Safety Requirements

A cosmetic product placed on the market must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use. The CNH shall ensure that safety assessment has been conducted for each product. Please refer to Annex I, part 6 for Guideline for Safety Assessment of Cosmetic Product.

3.3 Cosmetic Ingredients

i) Marketing of cosmetic product(s) containing the following ingredients is prohibited:

- Substances listed in Poisons List (unless exempted); Poison Act 1952.
- Substances listed in Annex II, Part 1.
- Substances listed in Annex III, Part 1 which are used beyond the specified limits and outside the conditions laid down.

- Colouring agents other than those listed in Annex IV, Part 1 with the exception of cosmetic products containing colouring agents intended solely for hair colouring.
 - Colouring agents listed in Annex IV, Part 1 which are used outside the conditions laid down, with the exception of cosmetic products containing colouring agents intended solely to for hair colouring.
 - Preservatives other than those listed in Annex VI, part 1.
 - Preservatives listed in Annex VI, part 1 which are used beyond the specified limits and outside the stated conditions laid down therein, unless other concentrations are used for specific purposes apparent from the presentation of the product.
 - UV filters other than those listed in Annex VII, part 1.
 - UV filters listed in Annex VII, part 1 which are used beyond the limits and stated outside the conditions laid down therein.
- ii) The presence of traces of substances listed in Annex II shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms to safety requirements.
- iii) Marketing of cosmetic product(s) containing the following shall be allowed:
- Substances and other ingredients listed in Annex III, Part 2 which are used within the limits and stated the conditions laid down and conforms to the dates as stated in column (g) of Annex III, Part 2.
 - Colouring agents listed in Annex IV, Part 2 which are used within the limits and under the conditions laid down, until the admission dates given in that Annex.
 - Preservatives listed in Annex VI, part 2 used within the limits and under the conditions laid down, until the dates given in column (f) of that Annex. However, some of these substances may be used in other concentrations for specific purposes apparent from the presentation of the product.
 - UV filters listed in Annex VII, part 2 used within the limits and under the conditions laid down, until the dates given in column (f) of that Annex.

3.4 Labelling Requirements

CNH shall ensure that the label of cosmetic product complies with the labelling requirements as defined in Annex I, part 7: Cosmetic Labelling Requirements.

The information on the label shall be in Bahasa Malaysia and/or English.

3.5 Cosmetic Claims

As a general rule, claimed benefits of a cosmetic product shall be justified by substantial evidence and/or by the cosmetic formulation or preparation itself. The CNH shall provide scientifically accepted protocols or study designs in generating the technical or clinical data with justification.

A cosmetic product should not use a name and claims that are regarded as medicinal in nature or beyond the cosmetic scope.

A guidance document on cosmetic claim including some examples of non-permissible claims is available in [Annex I, part 8: Cosmetic Claims Guideline](#).

It is prudent for CNH to seek legal or expert advice to ensure that the proposed claims do not breach existing Acts or Regulations.

3.6 Cosmetic Advertisement

CNH shall ensure that the advertisement of cosmetic product complies with the Guideline for Cosmetic Advertisement. For further details, please refer to [Annex I, part 9: Guideline for Cosmetic Advertisement](#).

3.7 Good Manufacturing Practice (GMP)

All cosmetic products must be manufactured in accordance to the Guidelines for Cosmetic Good Manufacturing Practice or its equivalent. For details, please refer to [Annex I, part 10: Guideline for Cosmetic Good Manufacturing Practice](#) and [Annex I, part 11: List of Equivalent Cosmetic GMP Guidelines](#).

Local manufacturer is subjected to periodical inspection by GMP auditors from the NPRA to ensure continuous compliance.

For foreign manufacturer, documentation to prove GMP compliance is to be made available upon request by the NPRA.

3.8 Product Information File (PIF)

CNH shall be responsible for providing all information, certificates/documents and data requested by the NPRA. The PIF can be either in the form of a “dossier” (i.e. an extensive collection of paper records stored in a specific location) or in electronic format (i.e. soft copy). It should be readily available and accessible upon request by the NPRA.

The PIF shall be in Bahasa Malaysia or English.

The PIF shall be kept updated for all changes made to the notified product such as new ingredients, manufacturers, raw material suppliers and production process. Date of document revision, where appropriate shall be stated for verification.

Please refer to Annex I, part 12 - Guideline for Product Information File (PIF) for information required in a PIF and the recommended format.

3.9 Product Recall

The decision for recall of a product shall be made when there is or may cause potential risk to the user of the products. Recalls may be done voluntarily by the CNH or as directed by the DPS.

The CNH is responsible for conducting recalls of defective or unsafe products. No recall should take place without first consulting/informing the NPRA.

Please refer to Guidelines on Good Distribution Practice, Chapter 10 which is available at NPRA's website.

3.10 Reporting Of Adverse Event

CNH shall report any serious adverse events or high incidences of adverse events occurred, regardless of the source of the report (e.g. consumer and healthcare professional). Please refer to Annex I, part 13: Guide Manual for Adverse Event Reporting for more information.

4. POST MARKET SURVEILLANCE PROGRAMME

4.1 Post Market Surveillance Activities

The NPRA shall monitor compliance of cosmetic products through Post Market Surveillance (PMS) programme. The PMS activities for cosmetics consist of:

- Screening of product formulation and information to ensure that cosmetics do not contain any prohibited or harmful substances and all restricted ingredients are used within the allowable limits and conditions of use. Screening criteria also includes product name and its claimed benefits
- Sample collection and testing
- Monitoring of label compliance
- Audit of premises for compliance to the Cosmetic GMP
- Handling of product complaints

- Monitoring of advertisements
- Monitoring of adverse reactions
- Audit on the PIF
- Risk communication
- Information sharing through ASEAN Post Marketing Alert System (PMAS)

4.2 Product Sampling Requirements

For the purpose of checking the quality and/or label compliance, the NPRA may obtain a cosmetic sample from the market or request the sample from the CNH. The CNH shall ensure that the requested sample for laboratory testing fulfil the following criteria:

- All samples must be from the same production batch
- The sample should be presented in its originally marketed container/packaging and unopened
- The sample label and package insert (if any) must not be taken out from the container/packaging
- The expiry date should not be less than one year, calculated from the sample delivery date to the NPRA
- Sample of a cosmetic product should at least consist of 4 units/containers, with a minimum total content of 40g/40ml (weight/volume of the product content without the container/packaging material)

Information on the limit used for heavy metal and microbial limit test are described in [Annex I, part 14](#).

5. REGULATORY ACTION

5.1 Rejection of Notification Submission

All cosmetic notification submission shall be subjected to screening by NPRA. Cosmetic product found to contain substances that are prohibited or used beyond the limit and conditions allowed as well as product claimed or purported to be used beyond the cosmetic scope will be denied for notification.

5.2 Cancellation of Notification Note

The DPS may, at any time cancel the notification note of any cosmetic product if he has the reason to believe that the product failed to comply with the stipulated regulations and guidelines. The DPS may also amend any conditions to which the notification note is subject.

The cancellation takes effect when the DPS gives a written notice (known as directive) of cancellation. The CNH must follow all instructions given in the directive issued by the DPS including but not limited to recall and disposal of the affected product. A formatted report must be prepared and submitted within the specified time as mentioned in the directive.

5.3 Punitive Action/Penalty

Any person who contravenes any of the provisions of the guidelines and regulations commits an offence and shall be liable on conviction as stipulated under Section 30 (1) of the CDCR 1984.

6. NOTIFICATION WITHDRAWAL

CNH shall inform the NPRA of their decision to withdraw the notification of any cosmetic product before the end of its validity stating the reason for the decision. The onus is on the CNH to inform the manufacturer/contract manufacturer.

The notification of a cosmetic product, once withdrawn, shall not be reinstated and notification note of the withdrawn product shall be deemed invalid. The product may be re-notified through a new notification submission.

7. NOTIFICATION EXEMPTION

A locally registered company may manufacture or import cosmetic product(s) which have not been notified for the following purposes subject to written approval by the DPS:

7.1 Market Sampling

A one-time entry of cosmetic product(s) which have not been notified solely for the purpose of test market or aesthetic studies to ascertain whether the products are well perceived by a potential group of consumers or manufacturers.

These products **SHALL NOT BE FOR COMMERCIAL SALE.**

7.2 In–House Evaluation

In-house evaluation is a process where product samples either from Research and Development (R&D) or production line, are evaluated by the company for the purpose of product selection, in-house sampling or demonstration. These products may also be actual products that are readily available in the country of origin.

These products **SHALL NOT BE FOR COMMERCIAL SALE.**

7.3 Products for Export Only (FEO) or for Re-Exporting

Cosmetic products that are imported to be assembled, enclosed, packed or labelled solely for re-export or manufactured locally solely for export-only are exempted from product notification requirements.

The company should maintain proper records and documents. These records should be available for inspection by NPRA at any time when required.

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

7.4 In Transit

Notification is not required for products taken or sent from any country and brought into the Federation by land, air or water, whether or not landed or transhipped in the Federation, for the sole purpose of being carried to another country either by the same or another conveyance.

7.5 Products to Be Sold or Supplied in Free Trade Zone or International Carriage Entering or Leaving Malaysia

Cosmetic products that are imported for sale/supply in the free trade zone or international carriage by ships, aircraft or other forms of international public transport entering or leaving Malaysia are exempted from product notification requirements.

The company should maintain proper records and documents. These records should be readily available for inspection by NPRA when required.

8. CERTIFICATE OF FREE SALE

A certificate of free sale (CFS) serves as document which state that the product can be freely sold in Malaysia. The certificate is not a mandatory requirement. As such, it will only be issued by the NPRA upon request by the CNH who wish to export their notified cosmetic product to another country that requires the certificate.

The application for CFS can only be made through online submission by the CNH via Quest system and a fee of RM50.00 will be charged for each copy of the certificate. CFS for a product and variant can be combined in one certificate provided that the latter is notified as a variant of the main product.

9. HALAL

Halal logo may be used voluntarily on a notified cosmetic product, for both local and export market, provided that the product has been certified and approved Halal by the Malaysia Department of Islamic Development (Jabatan Kemajuan Islam Malaysia, JAKIM) or any Islamic Body recognised by JAKIM.