Annex I, part 12

GUIDELINE FOR PRODUCT INFORMATION FILE (PIF)

1. INTRODUCTION AND OBJECTIVE

The guideline requires the CNH to keep a product information file "readily accessible to the NPRA at the address specified on the label".

The main objective of this 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 ORGANISATION

2.1 Product Information Requirements

Below is 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 Guideline for Cosmetic Good Manufacturing Practice

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

f) Supporting data for claimed benefits of cosmetic products should be made available; to justify the nature of its effect

The CNH is also required 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

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.

2.2 Recommended PIF format

The CNH needs to organize the PIF in such a way that it meets the stipulated requirements and easily consulted by the NPRA. It is recommended that the PIF is 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 is specific to a single product i.e. this part will provide an ample overview of the finished product.

A. Administrative documentation
- Copy of the Notification Note; this will include the identity of the product, the name and address of the manufacturer, assembler, importer and CNH
- Letter of Authorisation by product owner or Letter of Declaration and Letter of Contract Manufacturing, if applicable
- Any other relevant administrative documents that may be prescribed by the local authorities e.g. License to Operate, Certificate of Incorporation of the Company

B. Qualitative and Quantitative formula of the product (International Nomenclature for Cosmetic Ingredients (INCI) or other 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
- Consumer information leaflets and instruction for use if part of the product as sold to the consumer

D. Manufacturing Statement:
- A document issued/endorsed by recognised body indicating that the product was manufactured according to the Guidelines for Cosmetic GMP or any it's equivalent
- Provide the batch coding system/ key of the product

E. Safety Assessment (summary) as per the 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 acceptable or recognised standard for fragrance

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 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 NPRA

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:
    - 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

The CNH shall keep the PIF readily accessible to the regulatory authority at the address specified on the label.

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, the NPRA can audit the PIF at that address. There are 2 possibilities:

- **Routine audits**: The NPRA will announce these audits in advance. It is recommended that the audit be announced sufficiently in advance (e.g. 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 NPRA within reasonable time:

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

4.4 Proprietary Information:

Noting that due to trade secrets, the product owner may not disclose some of the product information in any part of the PIF, the CNH will need to make their own arrangements with the product owner to provide the relevant and necessary information directly to the NPRA upon request.

4.5 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 in the market".

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 CNH should then make all efforts to provide the requested information to the NPRA.

4.6 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 NPRA.