

# Product Information File (PIF): What to Expect From the Audit?

# Presentation Layout

❖ Introduction

❖ PMS Programme

❖ Product Information File (PIF)

❖ PIF Audit

❖ Future Plan

# Introduction

- Cosmetic product is controlled through notification procedure.
- No pre market approval = declaration of compliance by the CNH to the relevant Acts, Regulations, Guidelines and Directives/ Circulars.
- Compliance is monitored by the NPCB through PMS programme.

# PMS Programme

❖ Product Screening	❖ Sample Collection/ Testing
❖ Advertisement Monitoring	❖ Label Checking
❖ PIF Audit	❖ GMP Audit
❖ Handling of Complaint	❖ Monitoring of Adverse Event
❖ ASEAN Alert	

# PIF : Key Points

- PIF = Document to support the Safety, Quality and Claimed Benefit of the marketed cosmetic products.
- CNH to ensure that PIF is accessible for audit at the address specified on the label within the given timeframe.
- Language : English or Bahasa Malaysia

***Reference : Guidelines for Product Information File (PIF)***

# PIF : General Content

## Quality

### **Ingredients/Raw Material :**

- Identity, concentration used and its function (perfume : name and code number of the composition and supplier's identity)
- Raw material specifications and test methods

# PIF : General Content

## Quality

### **Finish Product:**

- Manufacturing
  - Manufacturer's details (including assembler, if any)
  - Documents to ensure that the product is manufactured in accordance to the Guidelines for Cosmetic Good Manufacturing Practice (GMP) or its equivalent\*
  - Summary of manufacturing process
- Finish product specification and test methods
- Stability report (mandatory for product with durability below 30 months)

\*ASEAN endorsed GMP standard

# PIF : General Content

## Safety

- Safety assessment on ingredient / raw material
- Safety assessment on finish product based on its ingredient, their chemical structure and level of exposure
- Post market safety data : undesirable effects
- Signed assessment report by the qualified safety assessor



# PIF : General Content

## Claimed Benefit

Supporting data to justify the cosmetic claim made on product label or in advertisement:

- Ingredient based and/or Formulation based approach can be accepted to support the claim provided that it is scientifically justified.
- There are ways to measure such claim such as:
  - Expert assessment
  - Instrumental assessment
  - Self assessment

# PIF Audit : Objective

- To verify compliance declared by the CNH during the notification submission.

# PIF Audit: Product Criteria

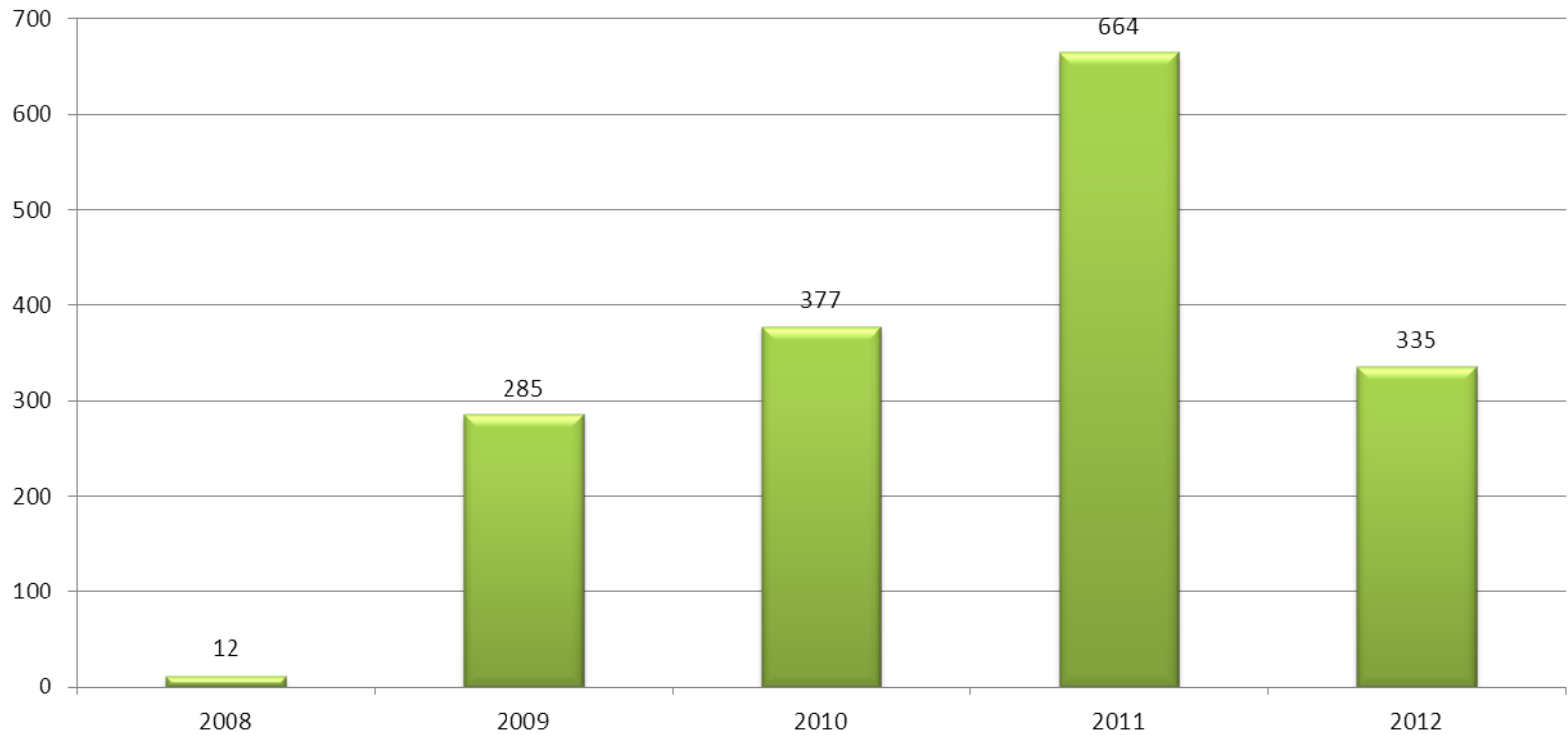
- Whitening product
- High risk product : used around the eye area and baby product
- Manufacturer /CNH with history of product cancellation and/or recall, product that failed laboratory testing
- Manufacturer with poor Good Manufacturing Practice (GMP) status

# PIF Audit: Criteria

- Other factors that triggers PIF audit:
  - Suspicious product name
  - Complaint
  - Advertisement
  - Label

# PIF Audit : Statistic

## Product Information File (PIF) Audit



# PIF Audit : Findings

Common findings :

- Lack of understanding/competency to prepare the PIF
- PIF not updated - Inconsistent with the information declared during notification submission.

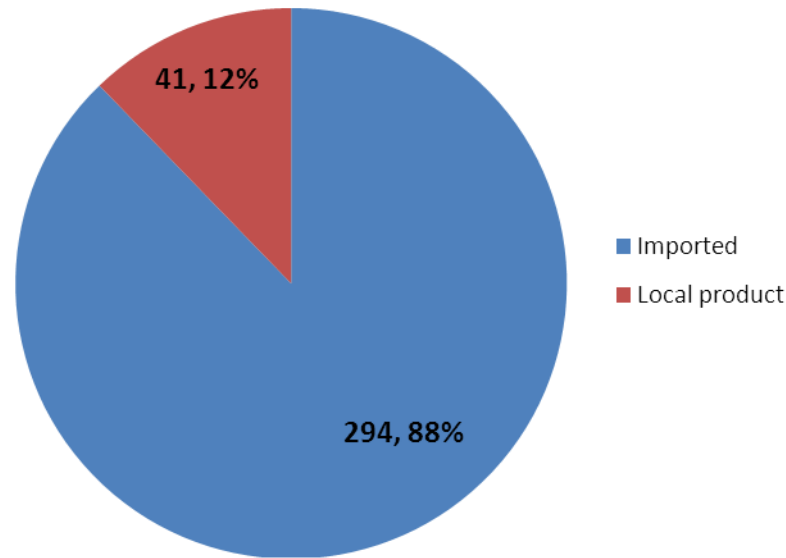
# PIF Audit : Findings

Common findings :

- Incomplete PIF
  - insufficient data to support safety, quality and claimed benefit
- Label does not comply with the labeling requirements :
  - incomplete ingredient list, absence of warning statement, CNH name and address not stated on label, etc.

# PIF Audit : Findings

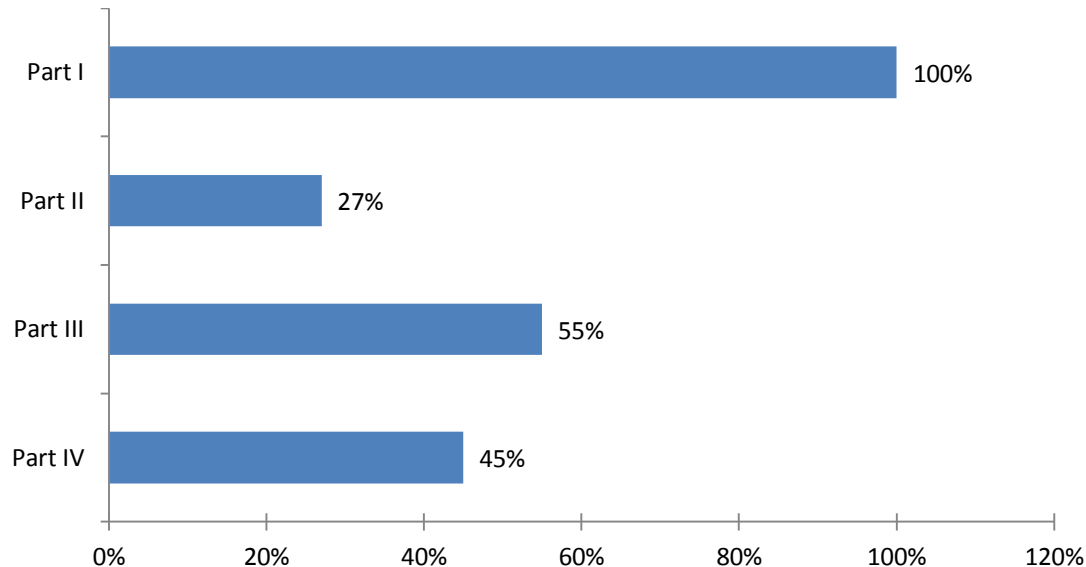
- PIF audit for year 2012 :
  - Targeted number of PIF audit = 1098
  - Achieved number of PIF audit = 335 (30.5%) from 17 companies. Most of them are imported product.





# PIF Audit : Findings

- Only 6 out of 17 companies enable to provide complete PIF for the audit. The rest can be described further as in Figure below :



# PIF Audit : Current Approach

- To broaden the PIF audit criteria such as :
  - By including more products from MNCs:
    - To evaluate the compliance level particularly related to safety and claimed benefit.
  - Targeting more on 'External Personal Care' such as antibacterial, antidandruff, etc. to evaluate the document to support such claim.
- To increase no. of PIF audit.

# PIF Audit : Current Approach

- More training programme to the cosmetic industry.
- To work more proactively with the ASEAN member countries to facilitate the industry in the preparation of PIF.

# PIF Audit : Punitive Action

- **Current :**

- i) Warning letter and CNH to provide the required document and corrective action within the given period.

- The CNH in many case could not provide the required document even at later time.

- ii) Cancellation of Notification Note and product are ordered to be recalled from the market

- Product with therapeutic claims or beyond the cosmetic scope.

# PIF Audit : Punitive Action

**By 2014:**

**i) Major Findings:**

Any major findings will cause in **cancellation of notification note** and product are ordered to be recalled from the market. The findings may include but not limited to:

- Unable to provide PIF within the given period.
- Incomplete PIF : particularly related to safety and quality data.
- Product with therapeutic claims or beyond the cosmetic scope.

# PIF Audit : Punitive Action

**By 2014:**

**i) Minor Findings:**

In this case, a warning letter with/without recall may be issued to the CNH for corrective action within the specified period. The finding may include but not limited to:

- Insufficient claim substantiation which does not impact the safety of consumer.
- Incomplete label

Thank you for your support !!!