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2017 ONE ASIA

Cosmetics & Beauty Forum

OVERVIEW on COSMETIC REGULATORY FRAMEWORK in INDONESIA

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Outline

- Background:
  ASEAN Harmonized Cosmetic Regulatory Scheme
- ASEAN Cosmetic Directive
- Cosmetic Regulatory Framework (Indonesia overview)
- Import Cosmetic
- Monitoring of Cosmetics Side Effects

ASEAN Harmonized Cosmetic Regulatory Scheme

Vision:

One single Regulatory Scheme for the Region

ASEAN TEN NATIONS, ONE COMMUNITY AND ONE STANDARD

STRENGTHENING REGIONAL REGULATORY FRAMEWORKS THROUGH PARTNERSHIP

Background: ASEAN Harmonized Cosmetic Regulatory Scheme

- Different regulations in different countries made life for about 3,000 Cosmetic SMEs and MNCs in ASEAN difficult to move their products across the region;

- Unlike other products e.g. pharmaceuticals, some cosmetic categories are low risk consumer driven products " they want to look good & feel better". This drives new technologies and innovation by the industry;

- Consumers tend to keep up with new fashions. This drives shorter "life cycle" of products (3-6 months);

- Government encourage innovation of cosmetics without compromise with "safety and quality" of cosmetics.

Background

In 1997, the ASEAN Cosmetic Association officially requested the ASEAN secretariat to facilitate harmonisation of regulations

ASEAN Secretariat gathered the RAs from the 10 countries and industry to work on the proposal beginning of 1998

Vision:

One Single Regulatory Scheme for the Region by the 1st January 2008

Objectives

1. To enhance cooperation amongst Member Countries in ensuring the **safety**, **quality** and **claimed benefits** of all cosmetic products marketed in **ASEAN;**

2. To eliminate restrictions to trade of cosmetic products amongst Member States through adoption and implementation of harmonised technical requirements (ASEAN Cosmetic Directive)

After 6 years of negotiation, the ASEAN Agreement on Harmonisation was decided and signed by ASEAN Economic Ministers on 2nd Sept 2003 in Cambodia by all 10 countries

ASEAN Harmonised Cosmetic Regulatory Scheme

The ASEAN Cosmetic Directive :

all Member Countries obliged to implement by 1 January 2008 – *Notification Procedure*

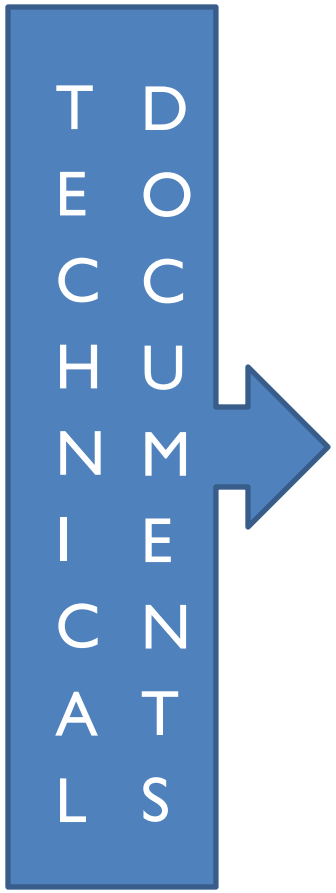
The ASEAN Cosmetic Directive (Contents)

1. General provisions
2. Definition and Scope of Cosmetic Product
3. Safety requirements
4. Ingredient listings
5. ASEAN Handbook of Cosmetic Ingredients
6. Labeling
7. Product Claims
8. Product Information
9. Methods of Analysis
10. Institutional Arrangements
11. Special Cases
12. Implementation

Definition of Cosmetic

- 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"

…..ASEAN COSMETIC DIRECTIVE



Comprises:

- ASEAN Guidelines for Product Information File (PIF)
- ASEAN Guidelines for Safety Assessment of Cosmetic Product
- ASEAN Cosmetic Labeling Requirements
- ASEAN Cosmetic Claims Guidelines
- ASEAN Guidelines on Good Manufacturing Practice (GMP) for Cosmetic
- A Guide Manual for Adverse Event Reporting
- ASEAN Sunscreen Labeling Guidelines

. . . . .ASEAN COSMETIC DIRECTIVE

Annexes:

Annex II : List of Substances Which Must Not Form Part of The Composition of Cosmetic Products

Annex III : List of Substances that Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down

Annex IV : List of Colouring Agents Allowed for Use in Cosmetic Products

Annex VI : List of Preservatives Allowed for Use in Cosmetic Products

Annex VII : List of UV Filters which Cosmetic Products May Contain

…..ASEAN COSMETIC DIRECTIVE

- Benefit:
  - The product to trade cycle will be shortened
  - Research breakthroughs and new product technologies can be made available to consumer faster
  - Provide consumer with wider choice of cosmetic products
  - Helps in building cosmetic/ingredient safety database for the industry

…..ASEAN COSMETIC DIRECTIVE

Article 1. General provisions

- Company or person placing the cosmetic in the market shall NOTIFY the regulatory authorities of each Member State where the product will be marketed

- Company or person responsible for placing the cosmetic in the market shall keep the product's technical and safety information readily accessible to the regulatory authority

Principles

- Manufacturer
  - responsible to guarantee product safety
    - to ensure cosmetic products are safe and do not contain prohibited substance
- Government
  - maintain a vigorous program of enforcement & post market surveillance
    - to allow for an efficient control and withdrawal from the market of products having undesirable effects.
- Consumer
  - adequate information – "informed choice"
    - to allow consumer to make an informed choice.

Cosmetic Regulatory Framework (Indonesia's overview)

Our Vision

Becoming an innovative, credible and internationally recognized drug and food regulatory authority for public protection.

Our Mission

- ✓ **To conduct pre-market evaluation and post-market control based on international standard.**
- ✓ **To implement quality management system consistently.**
- ✓ **To optimize partnership with stakeholders in various lines.**
- ✓ **To empower public in protecting themselves from the risk and harmful drug and food to health.**
- ✓ **To build the learning organization.**

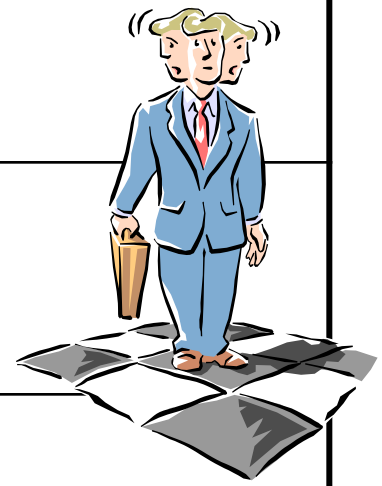
Cosmetic Regulatory Framework (Indonesia overview)

Basic of safety requirements

- Must not cause damage to human health when applied under normal or reasonably foreseeable condition of use
- Manufacturer has to gather the necessary technical information
- Component & finished product evaluated for aspect of safety
- Products produced under GMP
- Safety data available
- Labeling meets requirement

CHANGE OF PARADIGM

BEFORE ASEAN HARMONIZATION	AFTER ASEAN HARMONIZATION
1. Registration System	1. Notification System
2. Pre Market Evaluation	2. Post Market Control
3. Post Marketing Vigillance	3. Product Safety Evaluation (PSE)



safety, quality and claim benefit

Transposition of ACD into Indonesia National Regulation

- Decree of Minister of Health No. 1175/Menkes/Per/VIII/2010 concerning **License of Cosmetic Production**
- Decree of Minister of Health No. 1176/Menkes/Per/VIII/2010 concerning **Notification of Cosmetic**
- Decree of the Head of National Agency for Drug and Food Control No. HK.03.1.23.12.10.11983 Year 2010 concerning of **Criteria and Procedures for Submission of Cosmetic Notification**, as amended by Decree of the Head of National Agency for Drug and Food Control No. 34 Year 2013
- Decree of the Head of National Agency for Drug and Food Control No. HK.03.1.23.12.10.12123 Year 2010 concerning of **Guidance for Product Information Document** as amended by Decree of the Head of National Agency for Drug and Food Control No. 14 Year 2017

Con't...

- Decree of the Head of National Agency for Drug and Food Control No. 19 year 2015 concerning **Technical Requirements of Cosmetic.**
- Decree of the Head of National Agency for Drug and Food Control No. 18 year 2015 concerning **Technical Requirements of Cosmetic Ingredients.**
- Decree of the Head of National Agency for Drug and Food Control No. HK.03.1.23.12.11.10051 Year 2011 concerning of **Mechanism of Side Effects Cosmetics Monitoring**
- Decree of the Head of National Agency for Drug and Food Control No. HK.03.1.23.07.11.6662 Year 2011 concerning of **Requirements of Microbe and Heavy Metal Contamination in Cosmetic**
- Regulation of the Head of National Agency for Drug and Food Control No. HK.03.1.23.04.11.03724 Year 2011 concerning of **Cosmetic Entering Control**

Implementation of ASEAN Cosmetic Directive

Cosmetics should be notified by the manufacturer / importer to the NADFC and guaranteed its quality and safety by :

Complying the regulation

GMP compliance

Providing the Product Information File

Reporting serious adverse events/cosmetics side effects

NOTIFICATION HOLDER RESPONSIBILITIES

- To ensure that manufacturer manufactures safe product
  - -has good system in place to ensure product safety
  - -comply to ASEAN Cosmetic GMP requirements
- Collect information on post marketing experience and transfer such information to the manufacturer on a timely basis, determine trends and keep adequate records
- Competent personnel to handle product complaint and recall
- Keep the PIF for each product
- Report any Serious Adverse Event to the authorities

MANUFACTURER RESPONSIBILITIES

- Comply to ASEAN Cosmetic GMP
- Quality control
  - ✓ chemical
  - ✓ microbiological
- Appropriate labeling
  - ✓ presentation of the product
  - ✓ instruction for use, warnings (if relevant)
- Adequate complaint/AE handling procedure

REGULATOR RESPONSIBILITIES

- To ensure public health and safety;
  -PMS activities; product sampling, PIF audit

- Good collaboration with industry
  -to investigate complaint/serious adverse events & take proper action

- To remove unsafe products from the market
  -product recalls, notification cancellation, media announcement

Notification Procedures (Online System)

www.pom.go.id *subsite* notifikasi kosmetik

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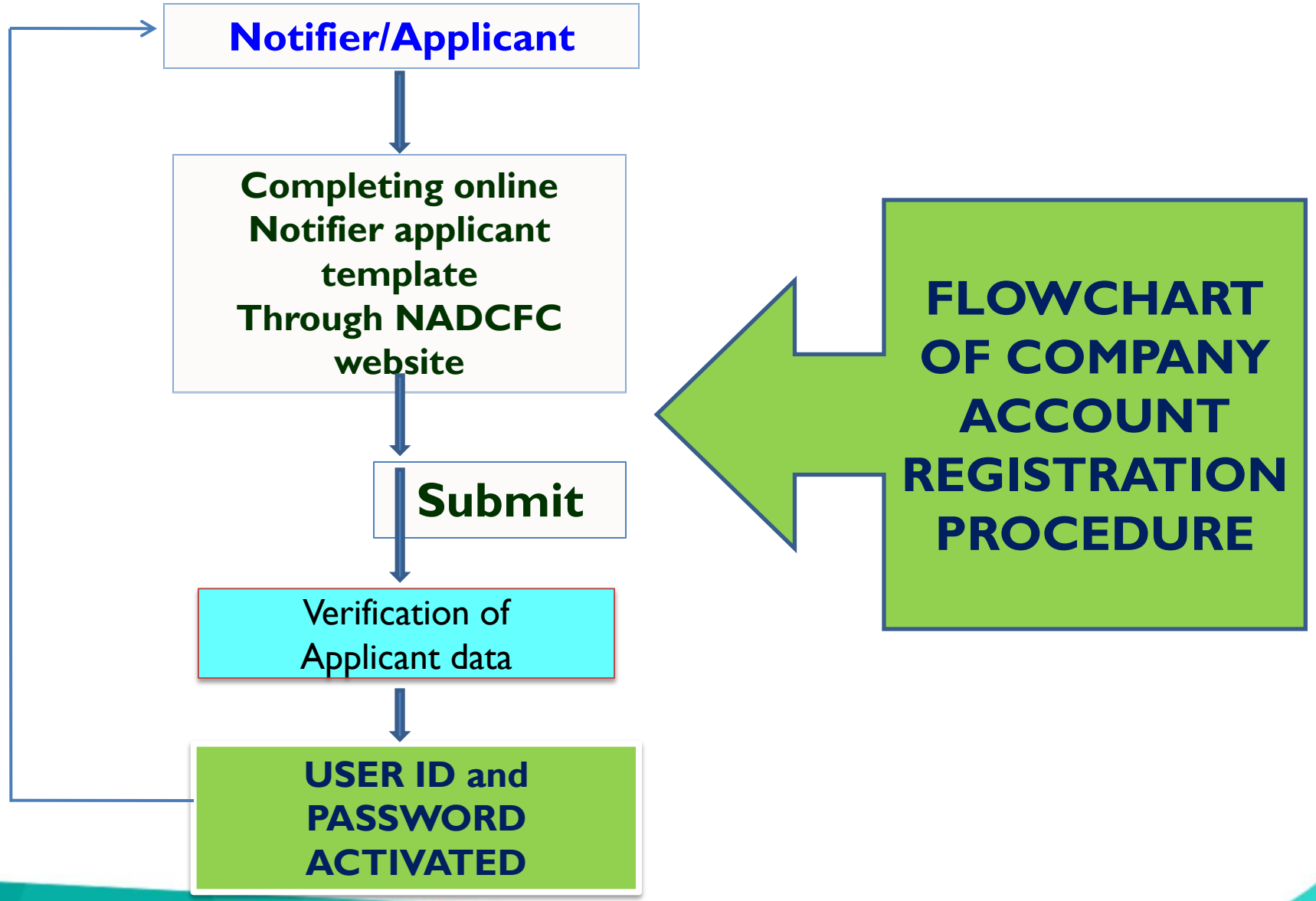
Step 1 : Company Account Registration

Administration Requirement

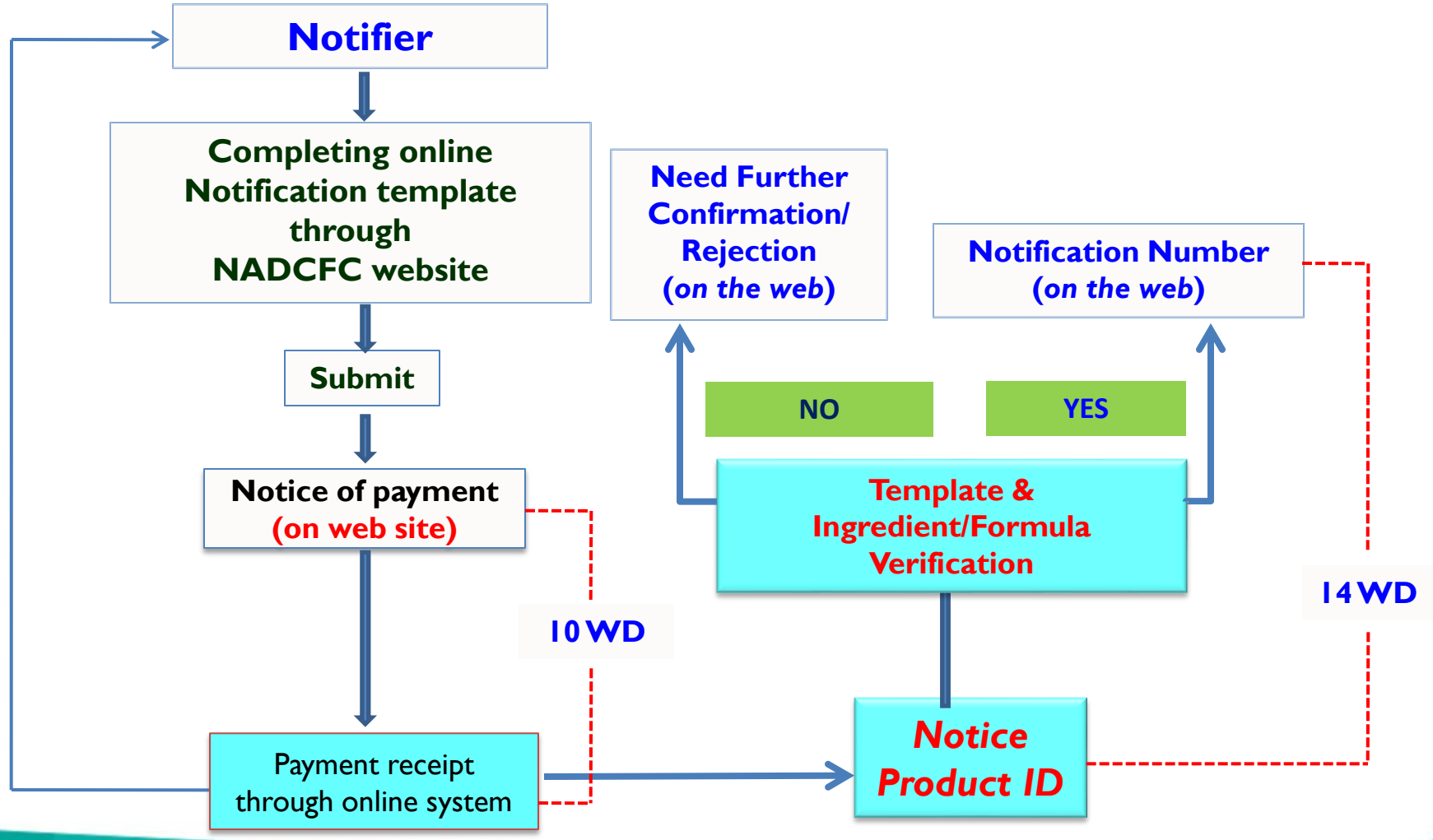
Local Company	Importer	Contract Manufacturer
• Cosmetic product Manucaturer License • Trade Bussiness License	• Letter of Authorisation from the principle of country of origin • Certificate of Good Manufacturing Process **(GMP)** & Certificate of Free Sale **(CFS) issued by government autorities** of country of origin • Importer Identification Number	• Letter of contract agreement that is approved by notary • Trade Bussiness License of the company who is responsible for marketing of product • Cosmetic product Manucaturer License • Certificate of Good Manufacturing Process (GMP) of the contract manufacturer

Step 2 : Cosmetic Product Notification (14 wd)

Completing online Notification template (data and formula)


Notifier/Applicant
Completing online Notifier applicant template Through NADCFC website
Submit
Verification of Applicant data
USER ID and PASSWORD ACTIVATED
FLOWCHART OF COMPANY ACCOUNT REGISTRATION PROCEDURE

Flowchart of Notification Procedures

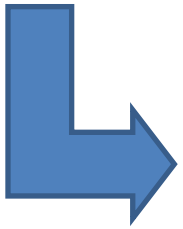


Simponi

- Notification payment by online system
- Launching on May 22nd 2017
- Applicable for 75 bank perception
- It applied for all notification process

Notification Fee

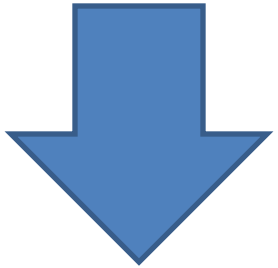
- Each notification submitted charged as PNBP (Penerimaan Negara Bukan Pajak)
- Nominal of PNBP depends on the country where cosmetics are manufactured
- 2 (two) types of PNBP



- 1.500.000 IDR → for cosmetics manufactured outside ASEAN countries member state
- 500.000 IDR → for cosmetics manufactured in the ASEAN countries member state

Validity Period of Notification Number

- 3 (three) years.
- Upon expiration of the notification periode, the applicant must renew notification number



RENEWAL NOTIFICATION

RENEWAL NOTIFICATIONS

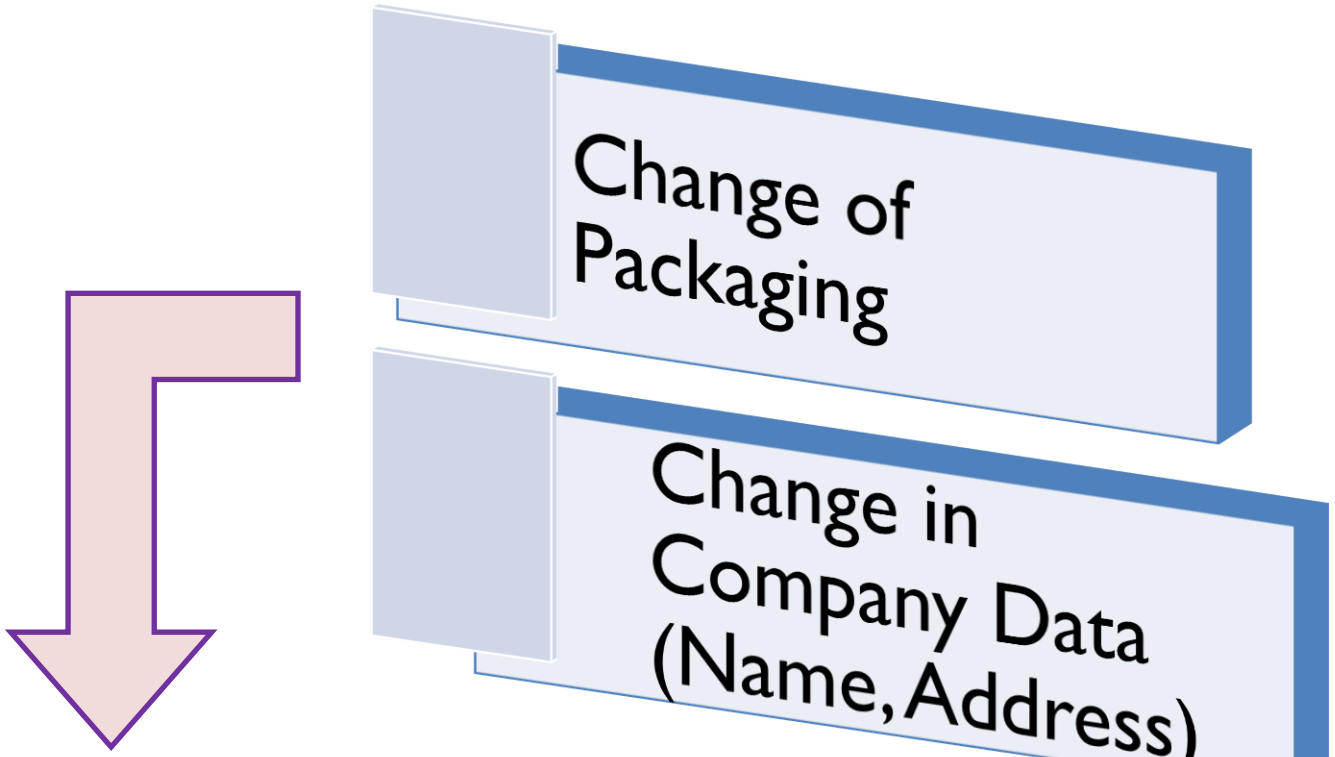
Requirement:

- **There are not any changes in the formula or data administration**
- **Pay for notification fee (same as previous)**

same notification number with the previous

extend the validity period of notification number for another 3 (three) years

Variation Notifications



Notification fee: Rp 100.000,-/submission
No change in the notification validity period

IMPORT COSMETIC

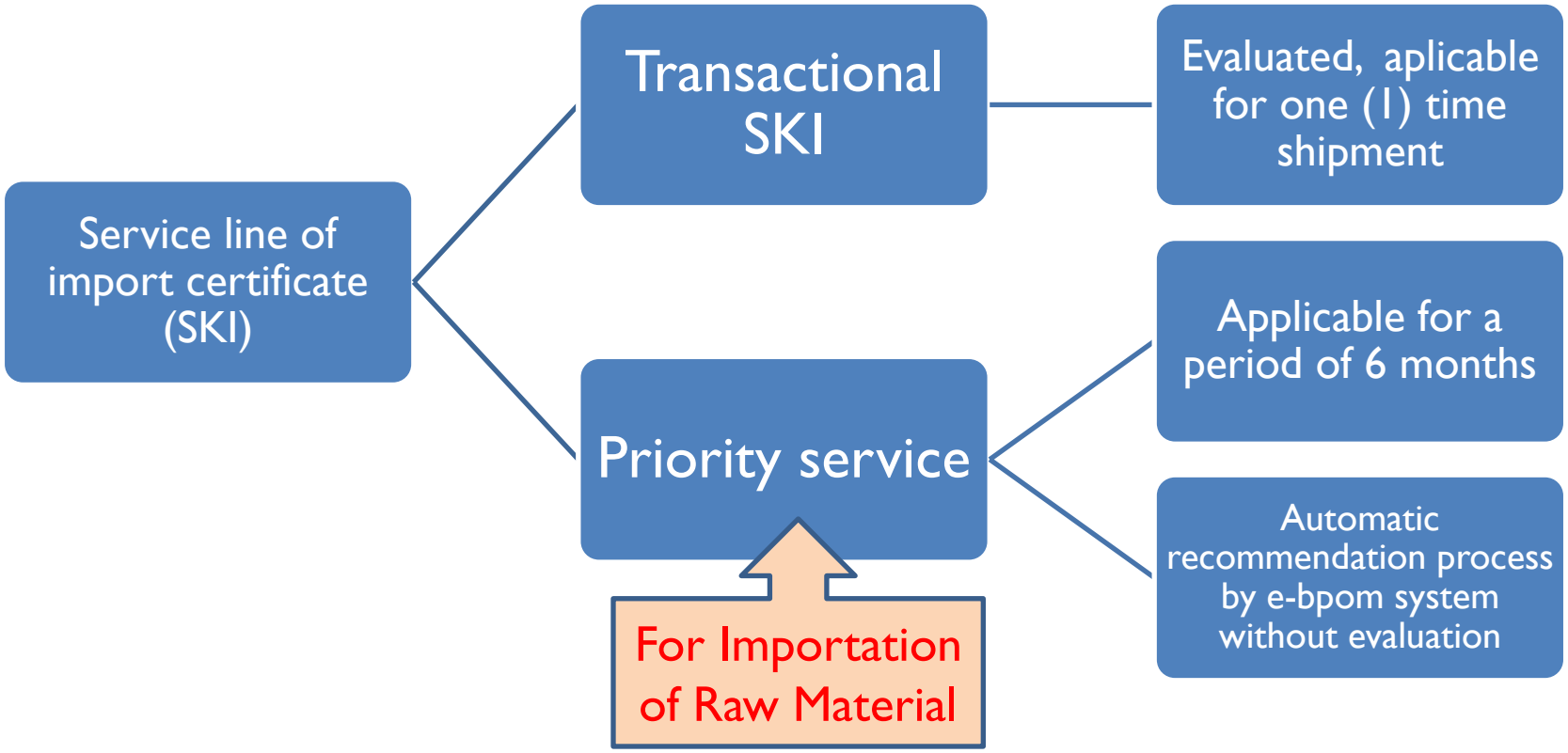
REGULATION

- Decree of the Head of National Agency for Drug and Food Control No. 12 year 2015 concerning Drug & Food Importation into Indonesian Territory Control
- Decree of the Head of National Agency for Drug and Food Control No. 13 year 2015 concerning Drug & Food Raw Material Importation into Indonesian Territory Control

WHAT IS IMPORT LICENSE

- Approval letter of Foof and Drug importation into Indonesia in order to facilitate the flow of goods for the benefit trade (custom clearance and cargo release) within the framework Indonesia National Single Window

Import License (SKI)



SKI also applies in Free Trade Zone and Free Port and Bonded Zone

IMPORTER REGISTRATION

Register using mechanism of Single Sign On to get user ID and password on www.e-bpom.pom.go.id or Indonesia National Single Window (INSW) portal

User ID can be as login access to NADFC & INSW Portal

In case application is submitted by proxy, then the proxy must get authorization letter signed by notary

The applicant perform data entry online and upload the supporting document

The document will be verified by online

SUPPORTING DOCUMENT ON REGISTRATION

- Application letter must be signed by director or authorized director
- Statement letter signed by the person in charge and fairly stamped
- Importer Identification Number (original)
- Business License (original)
- Taxpayer ID Number (original)
- Authorization letter in the form of general deed signed by a notary if the importation is done by a third party
- HS Code List of imported product

NADFC EFFORTS To Support Industries

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Workshop and Training

- Safety Assessment of Cosmetics Course

Dissemination information

Involve other sectors e.g. University

Coaching Clinic

Supervision on Compliance

OVERVIEW COSMETIC MARKET IN INDONESIA

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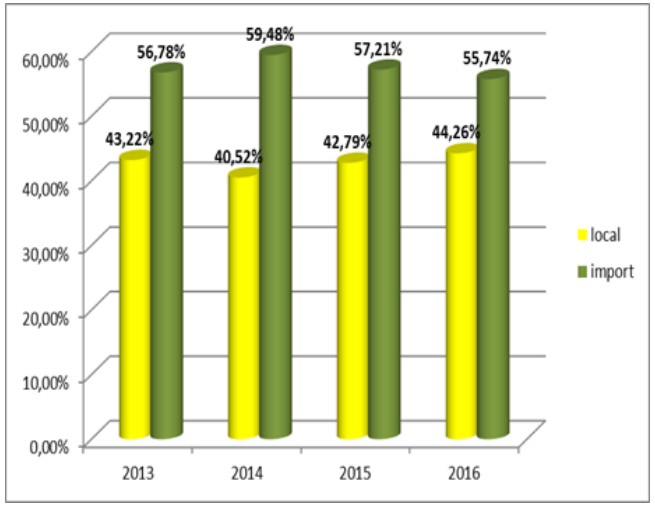
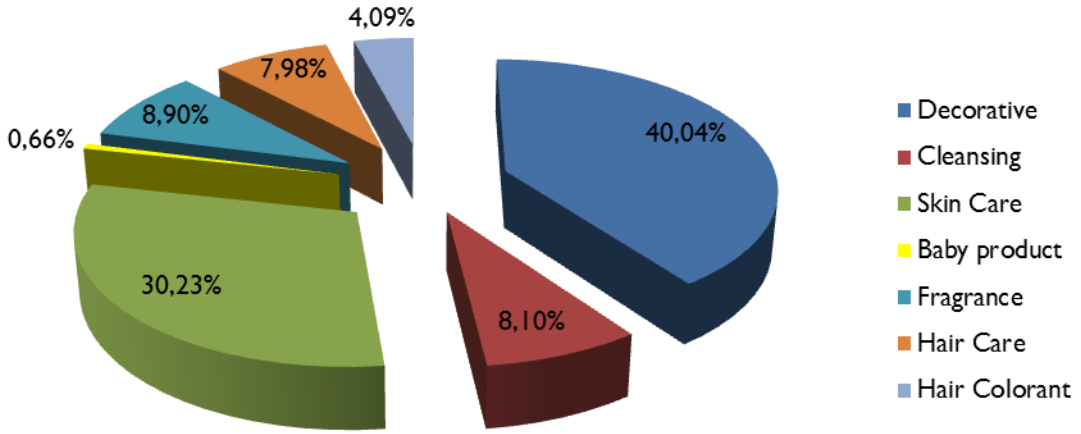
Total number of Notifications



Products for Each Categories Year 2013 - 2016

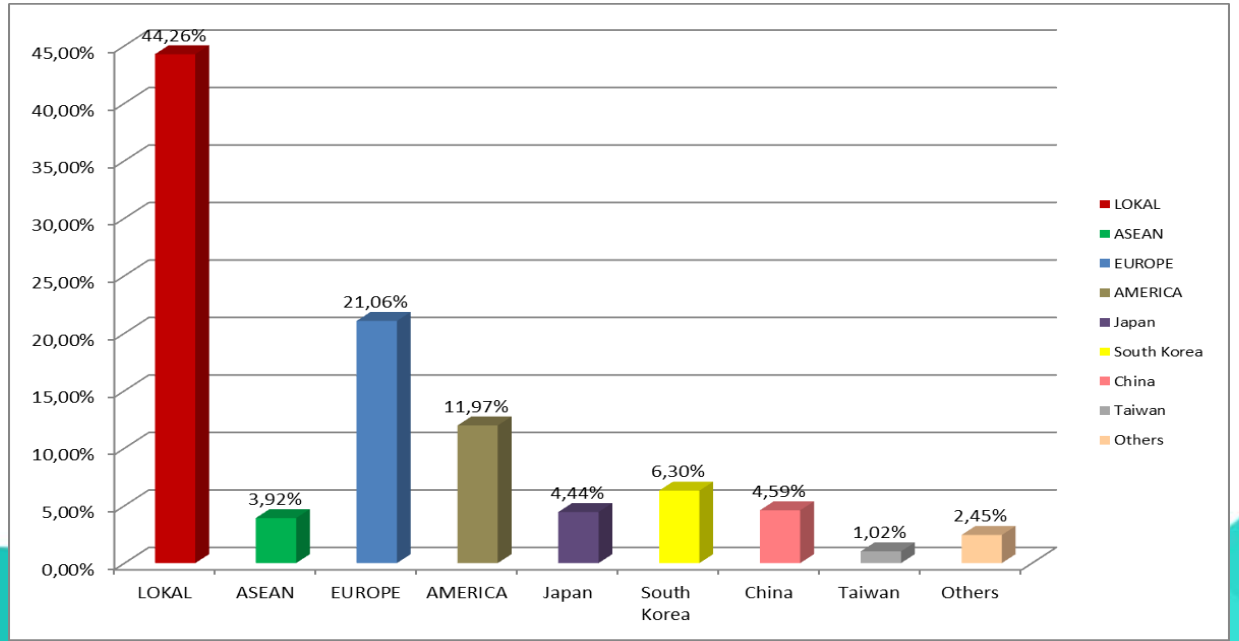


70% of Cosmetic Market in Indonesia is dominated by MNC (Multi National Company)

- 75% of Decorative Market is dominated by Local Company
- 75% of Skin Care Market is dominated by MNC
- 90% of Toiletris Market is dominated by MNC

*) PERKOSMI

Notification Product by Country



Cosmetic NOTIFICATION Product Approval from KOREA

SYSTEM	YEAR	TOTAL IMPORT	Korea Products	% Korea Products*
Notification	2015	20139	1563	7,76
	2016	24748	2798	11,31
	2017 (till September 2017)	18581	1982	10,67

* product percentage compared to total imported product

Time line registration/notification process

SYSTEM	Regulation
Registration	Evaluation process : 30 WD
Notification	14 WD

MONITORING OF COSMETICS SIDE EFFECTS

Regulation

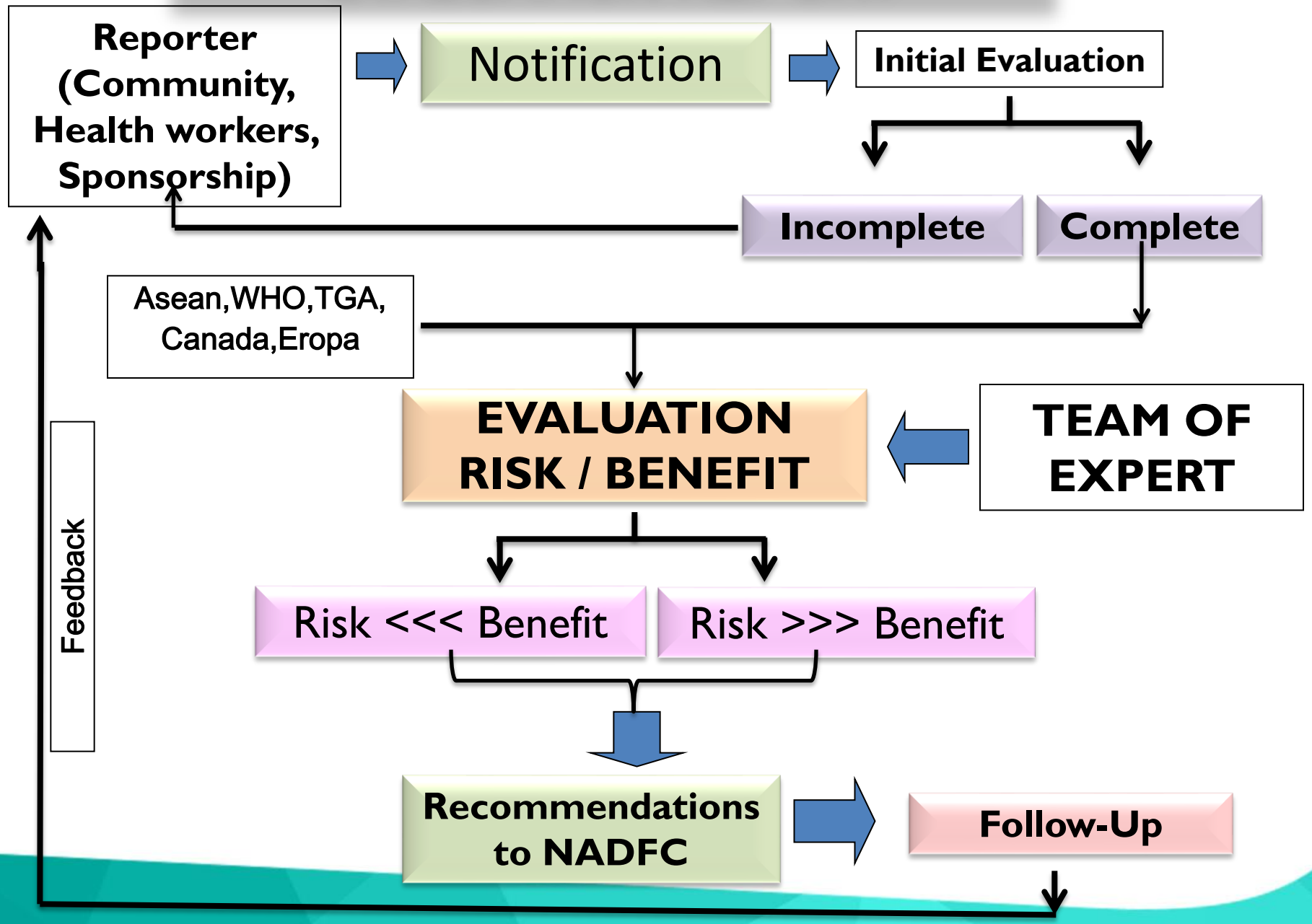
- National Health Act No. 36 of 2010
- Consumer Protection No. 8 of 1999
- Decree of the Head of National Agency for Drug and Food Control No. HK.00.05.41.1384 year 2005 concerning **Criteria and Procedure of Traditional Medicine Registration.**
- Decree of the Head of National Agency for Drug and Food Control No. HK.00.05.41.3644 year 2004 concerning **Provision of Food Supplement Control.**
- Decree of the Head of National Agency for Drug and Food Control No. HK.00.05.41.1381 year 2005 concerning **Criteria and Procedure of Food Supplements Registration.**
- Decree of the Head of National Agency for Drug and Food Control No. HK.03.1.23.12.11.10051 year 2011 concerning **Mechanism of Monitoring Cosmetic Side Effects**
- Decree of Minister of Health No. 1176/Menkes/Per/VIII/2010 concerning **Notification of Cosmetic**

DEFINITION

Side Effect

Response to an adverse and undesirable that occurring at **normally doses** used in humans for the prevention, diagnosis, or treatment of disease or for the modification of physiological function

EVALUATION REPORT



NA-DFC
The National Agency of Drug and Food Control

Terima Kasih

1500533
HALOBPOM

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