

Cosmetics Regulatory Requirement in Thailand & Impacts of TPP

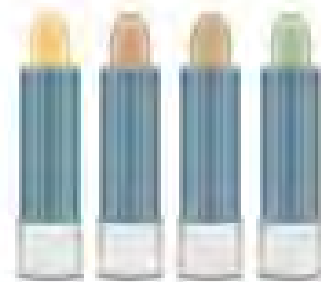
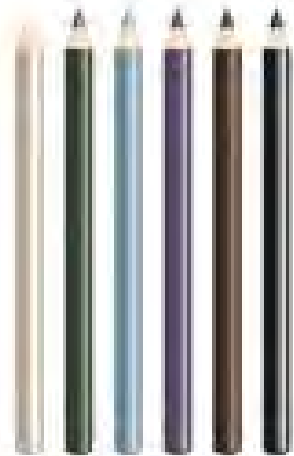
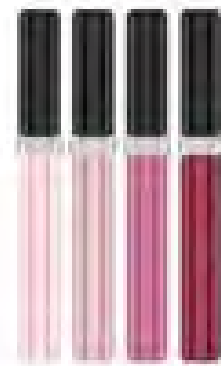
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Scope

- ▶ Definition “Cosmetics”
- ▶ Criteria on regulating Cosmetics products
- ▶ Marketing authorization process
- ▶ ASEAN Harmonized Cosmetic Regulatory Scheme (AHCERS)
- ▶ Notification Procedure in Thailand
- ▶ Post-marketing Surveillance (PMS) in Thailand
- ▶ Strengthen Consumer Awareness in Thailand
- ▶ Conclusion



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Thai Cosmetics Act 2015: Definition of “Cosmetics”

- ▶ any substance or preparation
- ▶ intended to be placed in contact (by applying, massaging/ rubbing, sprinkling/spraying, dropping, introducing, perfuming, or by any other means) with
 - ▶ various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or
 - ▶ the teeth & mucous membrane of oral cavity with a view exclusively/ mainly to
 - ▶ clean, perfume, change appearance and/or
 - ▶ correct body odors, protect/ keep them in good condition

TPP

- ▶ Annex 8 D COSMETICS
- ▶ Cosmetics product may include
 - ▶ a product that is intended to be rubbed, poured, sprinkled, sprayed on or applied to the human body, the mucous membrane of the oral cavity and teeth
 - ▶ to cleanse, beautify, protect, promote attractiveness or alter appearance

TPP

Identify &
publicly inform
regulatory
authorized
agency

No separate
marketing
authorization
(shades or
fragrances)

No
overlap
authority

Criteria

Risk-
based
approach

Consider
relevant
scientific,
guidance

Collaborate
regional
initiatives

TPP

Timely

Reasonable

Manage
conflict of
interest

Marketing
authorization
process

Objective

Impartial
manner

Transparent

TPP



Submission
of prices & cost

Animal
testing

NO

Labeled
with
notification
number

Requirement
of Certificate of
Free Sale

TPP

- Notification
- Post-marketing surveillance (PMS)

Permit
- relabeling or
- using supplementary labeling

Share information of
- laws and Regulations
- information of PMS

Avoid re-testing of products differ only
- shades extensions or
- fragrance variants

Organizational Structure of Cosmetics Control group, Bureau of Cosmetics and Hazardous Substances Control, Thai Food and Drug Administration

Pre -
marketing
Section

Post -
marketing
Section

System
Development
Section

Standard
Establishment
Section



ASEAN Harmonized Cosmetics

Regulatory Scheme (AHCRS)

Vision: One single Regulatory Scheme

for the Region

**ASEAN TEN NATIONS,
ONE COMMUNITY AND ONE
STANDARD**



**STRENGTHENING REGIONAL REGULATORY
FRAMEWORKS
THROUGH PARTNERSHIP**

Scale 1:32,000,000 at 5°N
Mercator Projection

ASEAN Harmonized Cosmetic Regulatory Scheme (AHCERS)

- **Agreement between ASEAN nations to**
 - Work together to ensure safety, quality, efficacy of cosmetics
 - Eliminate trade restrictions of cosmetics amongst member nations/ to facilitate free movement of cosmetics in ASEAN region
- **Signed** by ASEAN Economic Ministers (Sept 2003) in Cambodia
- Member nations **bound to adopt & implement ASEAN Cosmetics Directive (ACD)** since 1st January 2008

Principles of ASEAN Cosmetic Directive

▶ Manufacturer/ Importer

- ▶ responsible to guarantee product safety
- to ensure cosmetic products not contain prohibited substance

▶ Government

- ▶ maintain a vigorous program of enforcement & post market surveillance
- efficient control & withdrawal products having undesirable effects

▶ Consumer

- proper decision on cosmetics consumption based on adequate accessible information

INGREDIENTS

▶ Cosmetics - a mixture of ingredients

e.g.: colorants, preservatives, UV Filters, fragrance, etc.

Adopt EU Directives + ASEAN list

Negative list

▶ Prohibited list (Annex II)

▶ Restricted list (Annex III part 1, Annex III part 2)

Positive list

Annex IV (Colorants), Annex VI (Preservatives),

Annex VII (UV Filters)

Information required during notification

▶ **Particulars of Product**

- Name & brand name
- product type, intended use
- product presentation & list of variant or shades

▶ **Particulars of manufacturer/ assembler**

▶ **Particulars of Importer(s)**

▶ **Particulars of person representing the local company**

▶ **Full Ingredient List** (% of restricted ingredients)

▶ **Declaration & Confirmation**

- Product meets ACD that transposed into local legislation
- Industries
 - ensure PIF readily accessible to authority
 - keep distribution records for recall purposes
 - report any serious adverse event
 - notify changes made to submitted particulars
 - Information supplied is truthful

Cosmetics Notification Procedure: Thailand

1. Submission through **online/ manual application** to Thai FDA/ Provincial Health Offices
2. **Notification validity** period: 3 years
3. **Notification Systems**
 - 3.1 **HELLO System**
 - Processing time: 1-3 days
 - Auto system for low risk & competent authority for high risk
 - ▶ if complies with Thai cosmetic regulation ➡ issue notification acknowledgement
 - ▶ if application is refused ➡ give reasons for the reject

Cosmetics Notification Procedure: Thailand (2)

3.2 PRIVUS System: Cosmetics Notification through online system

- new system be equipped with 'smart system' to auto-screen prohibited & restricted substances in the formulation
- conduct post auditing for high risk products

4. Product labeling

- trade name & name of cosmetics, categories, net weight/ volume
- all ingredients list, Instruction of use, Batch or lot no.
- name & address of importer, name & country of manufacturer
- manufacturing date/ Expiry date
- Caution/warning
- Notification no. (to traceability for post marketing surveillance)

Thailand



Thailand



Thailand



Submission
of prices &
cost

NO

Requirement
of Certificate of
Free Sale

Thailand

- Notification
- Post-marketing surveillance
(PMS)

Permit relabeling / using supplementary labeling

Share information
- laws & regulations
- information of PMS via website
(www.fda.moph.go.th)

Avoid re-testing of products differ only shades extensions / fragrance variants

Post- marketing Surveillance (PMS): Thailand

- ▶ Post audit/ Periodical product sampling for quality & safety
- ▶ Complaint service activity
- ▶ Inspection premises (Manufacturers, OEM, Importers, Sellers)
- ▶ Monitor compliance of premises, products, advertising, labeling
- ▶ Product Information File (PIF)
- ▶ Vigilance System, Recall, Market Withdrawal, Safety Alert
- ▶ Public Notification on Analysis Results & Cosmetics Safety
- ▶ Warning Letters Related to Cosmetics

Strengthen Consumer Awareness in Thailand

- ▶ **Hotline (1556)**
- ▶ **e-mail 1556@fda.moph.go.th**
- ▶ **Complaint Service Center at Thai FDA**
- ▶ **Young FDA Inspector**
- ▶ **ORYOR Smart Application**
- ▶ **Communication through public media**

Conclusion

Impacts of TPP on Cosmetics Control in Thailand

1. Notification number

Be necessary on the cosmetics labeling for

- ▶ Consumers' assuring the notification of cosmetics products
- ▶ Post-marketing surveillance (PMS)

2. Animal testing

Be necessary in *some cases* depending on laboratory potential

