Needs Analysis for Narrowing Development Gaps in the Cosmetic Sector of Cambodia, Lao PDR, Myanmar & Viet Nam - Implementing the ASEAN Cosmetics Directive (ACD)

Needs Analysis for Narrowing the Development Gaps in the Cosmetic Sector of Cambodia, Lao PDR, Myanmar and Viet Nam when Implementing the ASEAN Cosmetics Directive (ACD)

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1 Introduction

1.1 Project Background

The Author was commissioned by the ARISE project to moderate a 2-day workshop (22 - 23 Jan 2012) in Jakarta, Indoensia, with the regulators of Cosmetics products from Cambodia, Lao PDR, Myanmar and Viet Nam (CLMV). The aim of the workshop was to understand the needs of CLMV when regulating the cosmetics sector.

Based on the information gathered during this 2-day workshop in Jakarta, a number of key challenges were identified by CLMV regulators. It is worthy to note that the challenges faced by CLMV are common, and not confined to an individual member state.

With the common needs of CLMV member states identified, these were analysed. Recommendations contained in this report, arising out of the proceedings of the 2-day workshop, aims to suggest measures that can be undertaken for the effective implementation of these regional requirements at the national level. In particular, these measures aim to narrow the development gap between ASEAN-6 and CLMV in implementing the ASEAN Cosmetics Directive (ACD).

1.2 Overview of ASEAN Cosmetics Directive Implementation

The ASEAN Cosmetics Directive (ACD) had already been implemented in some ASEAN Member States (AMS). Specifically, the ASEAN Harmonised Cosmetics Regulatory Scheme (AHCRS) was signed in 2003 and the ASEAN Cosmetic Directive (ACD), which is Schedule B of the AHCRS entered into force in 2008 as a means to achieve the goals of integration. The ACD establishes a harmonised regulatory regime in ASEAN for the cosmetic sector. At present, the ASEAN Cosmetic Committee (ACC) is focusing on the comprehensive implementation of the ACD throughout ASEAN.

The full adoption of the ACD presupposes the availability of a necessary technical regulations supported by suitable quality infrastructure. The ACC has recognised that special needs of CLMV in this regard need to be addressed in order to facilitate the full implementation of ACD. A component of the ARISE programme specifically identifies and includes provision of support to ASEAN in working towards establishing an enhanced national quality infrastructure in CLMV towards achieving the overall goals of market integration.

1.3 Regulatory Control Regime Envisaged by the ASEAN Cosmetics Directive

The ACD establishes harmonized rules for the manufacture, import, export, and placing in the market of an AMS, of cosmetics products.

Key features of the ACD can be summarized as follows:-

- Closely aligned with the European Cosmetic Directive;
- Provides common definition for cosmetics, details ingredients not permitted in cosmetics and lists approved Preservatives, Colourants and UV filters; and
- Provides Labelling Requirements, Guidelines on Cosmetic Good Manufacturing Practice (GMP), and Cosmetic Claims.

The key controls envisaged by the Directive can be summarized as follows:-

- Notification to the Regulator of an ASEAN Member State (AMS), by the company or person responsible, prior to placing the cosmetic products in the market. This is in lieu of pre-market approval;
- The company or person responsible for placing the cosmetic products in the market shall for control purposes keep the product's technical and safety information readily accessible to the regulatory authority of the Member State concerned; and
- Emphasis on post market surveillance, with duties and obligations such as reporting of serious adverse event, imposed on the company or person responsible for placing the cosmetic products in the market of AMS.

1.4 A Guide to this Report

This report is intended to provide an overview of the current level of implementation of a number of specific requirements in ACD – as outlined in the various Articles – and the needs of CLMV to narrow their development gaps of the cosmetics industry. The needs analysis addresses challenges faced by CLMV in implementation, namely notification prior to cosmetics placement in the market, complilation of product information file, reporting of serious adverse events, and post market surveillance system.

Section 2 provides a definition for cosmetics, and contains a non-exhaustive list of products that can be classified as cosmetics.

Section 3 provides a legislative overview of the ASEAN Cosmetics Directive in a tabular format. This section provides a brief overview of the structure of ACD, as well as the salient requirements elucidated within each Article of the ACD. To give effect to the provisions of the ACD, technical requirements are written into Annexes and Appendices. The latter part of this section also deals with salient requirements elucidated within the Annexes and Appendices of the ACD.

With Section 3 providing a legislative overview of the ASEAN Cosmetics Directive, Section 4 provides a brief overview of the regulatory regime, as well as the responsibilities imposed on the company or person placing the cosmetic product in the market of an ASEAN member state.

Based on the responsibilities imposed on a cosmetic product dealer, as outlined in Section 4, Section 5 provides an analysis into the current baseline conditions in CLMV, and the current requirements imposed by CLMV regulators in implementing ACD, for the following pre-market and post-market areas:-

- ❖ Needs Analysis for Article 1 of the ACD (Notification to Regulator Before Placement of Product in AMS);
- ❖ Needs Analysis for Article 3 (1) of the ACD (Reporting of Serious Adverse Event);
- ❖ Needs Analysis for Article 8 of the ACD (Product Information File to be Readily Available to Regulator);
- ❖ Needs Analysis for Article 12 (5) of the ACD (Post Marketing Surveillance).

Section 6 provides and outline an implementation strategy to address those specific needs identified in Section 5.

2 What is a Cosmetic Product?

2.1 Definition of Cosmetics

According to Article 2 (1) of the ACD, a “cosmetic product” shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the 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.

Products affected by the Directive (non-exhaustive) include:-

a) Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc.).
b) Face masks (with the exception of chemical peeling products).
c) Tinted bases (liquids. pastes, powders).
d) Make-up powders, after-bath powders, hygienic powders, etc.
e) Toilet soaps, deodorant soaps, etc.
f) Perfumes, toilet waters and eau de Cologne.
g) Bath and shower preparations (salts, foams, oils. gels, etc.).
h) Depilatories.
i) Deodorants and anti-perspirants.
j) Hair care products.
    - hair tints and bleaches.
    - products for waving, straightening and fixing,
    - setting products,
    - cleansing products (lotions, powders, shampoos),
    - conditioning products (lotions, creams, oils),
    - hairdressing products (lotions, lacquers, brilliantines).
    - Shaving products (creams, foams, lotions, etc.).
k) Products for making-up and removing make-up from the face and the eyes.
l) Products intended for application to the lips.
m) Products for care of the teeth and the mouth.
n) Products for nail care and make-up.
o) Products for external intimate hygiene.
p) Sunbathing products.
q) Products for tanning without sun.
r) Skin-whitening products.
s) Anti-wrinkle products.

Products to be considered as cosmetic products within the meaning of this definition are listed in Appendix I of the ACD.

Cosmetic products containing any substances in Annex V shall be excluded from the scope of the ACD. Member States may take measures as they deem necessary with regard to those products.

3 Legislative Overview

3.1 Structure and Brief Requirements of the ASEAN Cosmetics Directive

The ACD is structured into 12 Articles, with the following features and requirements:-

Articles of the ACD	*Salient Requirements*
General provisions (Article 1)	• Company or person responsible for placing the cosmetic products in the market shall notify regulator of place of manufacture or of initial importation **before** the product is placed in the market of an AMS
Definition and scope (Article 2)	• Definition and scope of a cosmetic product • Defines what is in scope and what is out of scope
Safety requirements (Article 3)	• Requires that cosmetics must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking into account product's presentation, its labeling, instructions for its use and disposal, warning statements as well as any other indication or information provided
Ingredient listings (Article 4)	• Requires that AMS shall adopt the Cosmetic Ingredient Listings of the EU Cosmetic Directive 76/768/EEC, including the latest amendments. • Requires compliance to a list of prohibited substances, as well as limits on permitted substances
ASEAN Handbook of Cosmetic Ingredients (Article 5)	• Provides for national authorization (limited to a maximum of 3 years) of certain cosmetic products that contain substances not permitted in the lists of substances allowed • Requires that AMS Member State carry out an official check on cosmetic products which it has authorized • Requires that cosmetic products thus manufactured with a national authorization must bear a distinctive indication
Labelling (Article 6)	• Requires that only cosmetics product label that is in full compliance with the ASEAN Cosmetic Labeling Requirements can be marketed
Claims (Article 7)	• Requires that AMS take all necessary measures to ensure that cosmetics product claims comply with ASEAN Cosmetic Claims Guideline • Requires that claimed benefits of a cosmetic product shall be justified by substantial evidence and/or by the

Articles of the ACD	*Salient Requirements*
	cosmetic formulation or preparation itself
Product information (Article 8)	• Requires that the company or person responsible for placing the cosmetic product in the market shall keep product information readily accessible to the regulatory authority of AMS. • Product information is specified as:- ○ qualitative and quantitative composition of the product, ○ specifications of the raw materials and finished product, the method of manufacture complying with the good manufacturing practice as laid down in the ASEAN Guidelines For Cosmetic Good Manufacturing Practice, ○ assessment of the safety for human health of the finished product, its ingredients, its chemical structure and its level of exposure, ○ existing data on undesirable effects on human health resulting from use of the cosmetic product; and ○ supporting data for claimed benefits of cosmetic products should be made available, in order to justify the nature of its effect.
Methods of analysis (Article 9)	• Requires that the company or person responsible for placing the cosmetic products in the market, shall make available to the regulator:- ○ available methods used by the manufacturer to check the ingredients of cosmetic products corresponding with the Certificate of Analysis; and ○ 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
Institutional arrangements (Article 10)	• ASEAN Cosmetic Committee (ACC) shall coordinate, review and monitor the implementation of the ACD • ASEAN Consultative Committee for Standards and Quality (ACCSQ) and the ASEAN Secretariat shall provide support in coordinating and monitoring the implementation of the ACD and assist the ACC in all matters relating thereto • Provides for the establishment of an ASEAN Cosmetic Scientific Body (ACSB) to assist the ACC in reviewing the ingredient lists, technical and safety issues. • Requires that the ACSB shall consist of representatives from the regulatory authorities, the industry and the academe

Articles of the ACD	*Salient Requirements*
Special cases (Article 11)	• Allows AMS to provisionally prohibit the marketing of a cosmetic product in its territory or subject it to special conditions, if the Member State finds out that on the basis of a substantiated justification, the cosmetic product, although complying with the requirements of the Directive, represents a hazard to health or for reasons specific to religious or cultural sensitivity
Implementation (Article 12)	• Requires that AMS undertake appropriate measures to ensure that technical infrastructures necessary are in place to implement the ACD. • Requires that Member States ensure that post marketing surveillance is in place and shall have full authority to enforce the law on cosmetic products found to be not complying with the ACD

In implementing the Articles of the ACD, Annexes and Appendices are agreed upon from time to time by the ASEAN Cosmetics Committee, and they form an integral part of the ACD.

3.2 Technical Documents to ACD - Appendix I to Appendix VI

At the time of publication of this report, the ACD is structured into Appendix I to Appendix VI, with the following features and requirements:-

Appendix of the ACD	*Salient Requirements*
Definition of Cosmetic Product and Illustrative List by Category of Cosmetic Products (Appendix I)	• The definition of a cosmetic product which has been adopted by the ACCSQ Product Working Group on Cosmetics is that of the European Directive. It delves into details between an earlier and current definition of cosmetics, in order to help one understand the thought processes behind the words used, to look at the way that the original 1976 definition was modified in 1993. • Emphasises that regulators recognise that cosmetic products may have functions other than six individually listed
ASEAN Cosmetic Labelling Requirements (Appendix II)	• Provides guidance for labeling requirements of cosmetic products to which Article 5 of the ASEAN Cosmetic Directive 05/01/ACCSQPWG apply • Defines (i) name of the cosmetic product, (ii) immediate packaging, (iii) outer packaging, and (iv) registration holder.

Appendix of the ACD	*Salient Requirements*

ASEAN Cosmetic Claims Guidelines (Appendix III)	• Provides guidance in relation to cosmetic/drug interface in respect of product claims
	• Explains that products are determined to be either "cosmetic" or "drug" based on two factors:
	  ○ Composition of the product, and
	  ○ The proposed use of the product
	• Provides that as a general rule, cosmetic products must only make cosmetic claimed benefits; and not medicinal or therapeutic claimed benefits. Any cosmetic claimed benefits made shall be aligned with what is accepted internationally and shall be justified either by technical data and/or cosmetic formulation or preparation itself

ASEAN Cosmetic Product Registration Requirements (Appendix IV) Note: Appendix IV is no longer in use in some ASEAN Member State	• Requires that ASEAN Product Registration Requirements/ Procedures shall be reduced to their simplest form • that ASEAN Product Registration Requirements/ Procedures shall be reviewed to evaluate if it can already be replaced by the ASEAN Cosmetic Directve scheme for all cosmetic products with focus on post-marketing surveillance system • Applies to all cosmetic products that are currently required to be registered in the respective ASEAN countries • Defines registration as the submission of information on the product and undergoing an evaluation and approval process prior to marketing the product
Common Requirements for Import/Export of Cosmetic Products (Appendix V) Note: Appendix V is no longer in use in some ASEAN Member State	• Only regulatory requirements imposed by health authorities are considered in Appendix V • The requirements are applicable to Phase 1 of the harmonized scheme only • Cosmetic products will be allowed for importation provided they comply with local registration and licensing requirements, labeling requirements and requirements on restriction of ingredients. The registrant or company / person responsible for placing the product in the market will be required to maintain records of primary distribution for the purpose of product recall. Requirements for the export of cosmetic products will be based on the requirements of individual countries, if any.
ASEAN Guidelines for Cosmetic Good Manufacturing Practice (Appendix VI)	• Clear delineation from drug or pharmaceutical product GMP • A general guidance document for cosmetics manufacturers to develop its own internal quality management system and procedures. • Final products must meet the quality standards appropriate to their intended use to assure

Appendix of the ACD	*Salient Requirements*
	consumer's health and benefit. • To offer assistance to the cosmetic industry in compliance with the provisions of the ASEAN Cosmetic Directive.
ASEAN Cosmetic Ingredient Listings (Appendix VII)	• tabulated list of substances which must not form part of the composition of cosmetic products • tabulated list of substances which cosmetic products must not contain except subject to restriction and conditions laid • list of substances provisionally allowed (note: empty list) • list of coloring agents allowed for use in cosmetic products • list of colouring agents provisionally allowed for use in cosmetic products (note: empty list) • list of excluded (i.e. strontium and its compound, with some exceptions) from the scope of the directive • list of preservatives which cosmetic products may contain • tabulated list of preservatives allowed • list of preservatives provisionally allowed (note: empty list) • tabulated list of permitted uv filters which cosmetic products may contain • list uv filters which cosmetic products may provisionally contain (note: empty list) • ASEAN additional list of UV filters which cosmetic products may contain (as proposed by Thailand, decision on inclusion/ exclusion not stated on document) • ASEAN Handbook Of Cosmetic Ingredients o Tabulated list of substances which must not form part of the composition of cosmetic products. Specify prohibitied substances for individual ams. o List of substances which cosmetic products must not contain except subject to restriction and condition (e.g. maximum concentration and labeling requirements) laid down. Specific to individual AMS. o List of colouring agents allowed for use in cosmetic products. Specific to individual AMS. o List of preservatives allowed. Specific to individual AMS. o List of UV filters which cosmetic products may contain. Specific to individual AMS. o Contact points for cosmetics regulators in AMS.

It is important to note that the legislative references detailed in the text continue to be the subject of ongoing review both at ASEAN and national level and may change in time.

4 Regulatory Control Regime

4.1 Features of the ASEAN Cosmetic Directive

The ASEAN Cosmetic Directive is closely aligned to the European Cosmetics Directive, and has the following features:-

- Product notification for all cosmetic products
- Emphasis on post market surveillance, in lieu of registration or approval
- Commitment via industry self-declaration, in the assurance of cosmetic product safety and quality
- Compliance with all requirements of Directive:-
    - Ingredient listings (Annexes II to VII)
    - Labelling
    - Cosmetic GMP
    - Serious Adverse Event Reporting
    - Product information file

4.2 What are the responsibilities of the Company's and Person Placing Cosmetics in the Market of an AMS?

When transposed into national legislation, the ACD imposes regionally harmonised requirements on the company or person placing cosmetic products in an AMS market:-

a. Ensure product conforms to all the requirements of the ACD, including
    i. The ASEAN Cosmetic GMP guidelines (Appendix VI)
    ii. The safety requirements (Article 3)
    iii. The ASEAN Cosmetic Labelling requirements (Article 6 & Appendix II)
b. Notify Regulator prior to sale in the local market of an AMS (Article 1)
c. Keep Product Information File (PIF) for each product (Article 8)
d. Report Serious Adverse Event(s) to the regulator

5 Current Requirement and Challenges Faced by CLMV in Implementing ACD

The following pages (pages 14 to 21) summarise the outcomes from the workshop carried out as part of this project. It captures the current baseline conditions in CLMV, and the current requirements imposed by CLMV regulators in implementing ACD, for the following pre-market and post-market areas:-

- ❖ Needs Analysis for Article 1 of the ACD (Notification to Regulator Before Placement of Product in AMS);
- ❖ Needs Analysis for Article 3 (1) of the ACD (Reporting of Serious Adverse Event);
- ❖ Needs Analysis for Article 8 of the ACD (Product Information File to be Readily Available to Regulator);
- ❖ Needs Analysis for Article 12 (5) of the ACD (Post Marketing Surveillance)

5.1 Needs Analysis for Article 1 of the ACD (Notification to Regulator before Placement of Product in AMS)

Articles of the ACD	Salient Requirements
General provisions (Article 1)	• Company or person responsible for placing the cosmetic products in the market shall notify regulator of place of manufacture or of initial importation **before** the product is placed in the market of an AMS

Situation at the time of workshop based on feedback received

Requirements for Notification to Cambodia	Requirements for Notification to Lao PDR	Requirements for Notification to Myanmar	Requirements for Notification to Viet Nam
• Name of importer registered with MOH • Letter of Authorisation (LOA) from Country of Origin (COO) • Labelling (French, Cambodian or English) • GMP certificate outside ASEAN • Free Sales Certificate (FSC) outside ASEAN • Sample or Artwork • Certificate of Analysis	• Name of company, distributor or importer • Name of product • Formulation • Letter of Authorisation from Country of Origin • Labelling (Laotian or English) • Physical Sample • Certificate of Analysis	• Name of importer or manufacturer • Ingredients list • % of restricted substances • Letter of Authorisation from Country of Origin • Business licence • Free Sales Certificate from ASEAN or Country of Origin • Certificate of Analysis • Sample or artwork	• Name of importer or local manufacturer • Business licence number • Letter of Authorisation from Country of Origin • Free Sales Certificate from ASEAN or outside ASEAN • Notarisation and legalization required for LOA and FSC

Challenges Faced by Regulator for Notification to Cambodia	Challenges Faced by Regulator for Notification to Lao PDR	Challenges Faced by Regulator for Notification to Myanmar	Challenges Faced by Regulator for Notification to Viet Nam
• Manual process • 5-10 working days turnaround, notification workload • Up to 2,000 notification workload per annum	• Manual process • 5-7 working days turnaround, notification workload • Up to 500 notification workload per annum	• Manual process • 5-10 working days turnaround, notification workload • Up to 1600 notification workload per annum, valid for 2 years	• Manual process • 15,000 notification workload per annum • 6 person team based in Hanoi • No public register

• 6 person team - 3 for cosmetics notification, 3 inspectors shared with pharma • Difficulty in laboratory testing • Difficulty in screening hardcopy for prohibited ingredients • Budget constraint in setting up online system • Lack knowledge on cosmetics ingredients	• 2 person team • Capability in laboratory testing for 3 out of 8 prohibited substances • Budget constraint in setting up online system • Lack knowledge on cosmetics • Administrative review of notification for completeness • Post market capabilities rest with Food & Drug	• 3 person team • Difficulty in understanding restricted ingredient listing • Budget constraint in setting up online system • Ministry has plans to upgrade FDA in 2013-2014	• Incomplete notification received • Administrative review of notification • Pilot trial of online submission for 10 companies

5.2 Needs Analysis for Article 3 (1) of the ACD (Reporting of Serious Adverse Event)

Safety Requirements (Article 3)

Note: To be read together with the Discussion Paper on Post Marketing Surveillance/Product Safety, adopted by the ASEAN Cosmetic Committee in its second meeting held in Bangkok June 7-8, 2004

Source: A Guide Manual For The Industry: Adverse Event Reporting For Cosmetic Products

- Requires that cosmetics must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking into account product's presentation, its labeling, instructions for its use and disposal, warning statements as well as any other indication or information provided

Situation at the time of workshop based on feedback received

Requirements for Reporting of Serious Adverse Event (SAE) in Cambodia	Requirements for Reporting of Serious Adverse Event (SAE) in Lao PDR	Requirements for Reporting of Serious Adverse Event in Myanmar	Requirements for Reporting of Serious Adverse Event in Viet Nam
• Received 2 cases of SAE involving bleaching cosmetics products • Received from provincial health authority	• Received 2 cases of SAE involving whitening cosmetics products	• No reported cases	• No mechanism, no reported cases

Challenges Faced by Regulator for Reporting SAE to Cambodia	Challenges Faced by Regulator for Reporting SAE to Lao PDR	Challenges Faced by Regulator for Reporting SAE to Myanmar	Challenges Faced by Regulator for Reporting SAE to Viet Nam
• No mechanism	• No mechanism	• No separate PV unit to review cosmetics adverse events	• No mechanism

5.3 Needs Analysis for Article 8 of the ACD (Product Information File to be Readily Available to Regulator)

Product information (Article 8)

- Requires that the company or person responsible for placing the cosmetic product in the market shall keep product information readily accessible to the regulatory authority of AMS.
- Product information is specified as:-
    - qualitative and quantitative composition of the product,
    - specifications of the raw materials and finished product, the method of manufacture complying with the good manufacturing practice as laid down in the ASEAN Guidelines For Cosmetic Good Manufacturing Practice,
    - assessment of the safety for human health of the finished product, its ingredients, its chemical structure and its level of exposure,
    - existing data on undesirable effects on human health resulting from use of the
    - cosmetic product; and
    - supporting data for claimed benefits of cosmetic products should be made available, in order to justify the nature of its effect.

Situation at the time of workshop based on feedback received

Requirements for PIF in Cambodia	Requirements for PIF in Lao PDR	Requirements for PIF in Myanmar	Requirements for PIF in Viet Nam
• No local manufacturer • For imported products, requires Part 1 and 3 • For whitening products, conducts 1-2 PIF audits per month • Leadtime of 2-7 working days for industry to provide PIF	• PIF requires 3 months after regulator acknowledges notification • Part 1, 3 required for imported cosmetics	• 4 local manufacturers • Requires part 1, 2, 3 from local manufacturers • No PIF audit	• Part 1 to be submitted during inspection. Local manufacturers and importers to be inspected selected from notifications. • Part 2, 3, 4 to be submitted 1 month after inspection, from both local manufacturers and importers • Conducts 30 inspections per

			annum
Challenges Faced by Regulator in Cambodia	**Challenges Faced by Regulator in Lao PDR**	**Challenges Faced by Regulator in Myanmar**	**Challenges Faced by Regulator in Viet Nam**
• For imported products, requires Part 1 and 3 - Part 1 is normally received complete • Conducts 20 inspection per year • 3 post market dedicated staff • No laboratory testing	• Receives Part 1 almost complete • Receives COA for Part 3 • Local importer faces English language issue • Conducts 2 inspections per annum	• Lack of manpower • Lack of experience auditing PIF • Difficulty in getting documents • Reluctance of industry in extending PIF to regulator, citing confidentiality issues	• Part 1 to be submitted during inspection – regulator is able to obtain part 1 • Part 2, 3, 4 from local manufacturer – Part 2,3 normally incomplete • Small & Medium Enterprises (SMEs) and local manufacturers lack knowledge to prepare Part 4 • MOH lacks expertise to evaluate PIF

5.4 Needs Analysis for Article 12 (5) of the ACD (Post Marketing Surveillance)

Articles of the ACD	Salient Requirements
Implementation (Article 12-5)	Member States shall ensure that post marketing surveillance is in place and shall have full authority to enforce the law on cosmetic products found to be not complying with this Directive.
Appendix V – Common Requirements For Import / Export of Cosmetic Products B (5) - Record Keeping By Registrant or Company/person Responsible for Placing the Product in the Markets	The registrant or company/person responsible for placing the product in the market must keep records of the primary distribution of their products, for the purpose of product recall according to the respective country's procedures.
Appendix VI – ASEAN Guidelines for Cosmetic Good Manufacturing Practice Item 13. Product Recalls	There should be a system of recall from the market of products known or suspected to be defective.

Situation at the time of workshop based on feedback received

Requirements for PMS in Cambodia	Requirements for PMS in Lao PDR	Requirements for PMS in Myanmar	Requirements for PMS in Viet Nam

• Experience with 1 x voluntary recall (mouthwash) since implementation of ACD
• Experience with 1 x mandatory recall (bleaching agent); based on consumer notification
	• Experience with 2 x mandatory recall since implementation of ACD
	  ○ 1 x cosmetics adultered with western pharmaceutical ingredients
	  ○ 1 x cosmetics with no manufacturer information on label
		• Experience with 1 x voluntary recall (mouthwash) since implementation of ACD	• Experience with 1 x voluntary recall since implementation of ACD

Existing Laboratory Equipment Available in Cambodia	Existing Laboratory Equipment Available in Lao PDR	Existing Laboratory Equipment Available in Myanmar	Existing Laboratory Equipment Available in Viet Nam
• Has equipment but lack reference material	• Capability to test on (i) heavy metal adulterant (ii) preservative efficacy microbiological test (iii) steroids adulterant (iv) efficacy of preservatives in cosmetics	• No equipment to test	• Capability to test on (i) preservative efficacy microbiological test

Enforcement Power Available to Cambodia	Enforcement Power Available to to Lao PDR	Enforcement Power Available to to Myanmar	Enforcement Power Available to to Viet Nam
• Ministerial decree to mandate recall of a defective health product • No penalty for company / person for failing to recall	• Minister of Health empowered to recall a defective health product • No penalty for company / person for failing to recall	• Minister of Health empowered to recall a defective health product • No penalty for company / person for failing to recall	• Minister of Health empowered to recall a defective health product • Fine for company for failing to recall

6 Gap Analysis and Recommendations

In identifying the challenges faced by CLMV regulators, as outlined in section 5, these challenges can be collectively categorised into six key challenges:-

a) Notification content requirements;
b) Meeting notification workload and turnaround time;
c) Completeness of Product Information File received, understanding PIF contents;
d) Outreach to stakeholders;
e) Mechanism and Awareness for reporting of serious adverse event; and
f) Swift and effective recall mechanism for defective cosmetics products.

6.1 Premarket – Notification System

The number of headcount at the disposal of any of the CLMV regulators totals not more than 6 persons. At the same time, the regulators are indunated with notifications ranging from 500 to 15000 per annum. For information, and for purpose of illustration, the Cosmetics control unit of Singapore processed 38,878 new cosmetics notifications from Apr 2011 to Mar 2012.

To meet the expected increase in notification workload during steady state, and improve its notification turnaround time, it is recommended that CLMV regulators:-

Proposed Measure	Details of Measure	Resources / Actions Needed
a) Adopt a tiered two-step towards the notification acknowledgement process, whereby CLMV internal workflow is redesigned into (i) an administrative review phase, and (ii) a technical review phase.	(i) An administrative review of all notifications, whereby incomplete notifications are rejected upfront. Incomplete notifications do not move on to the technical review phase, thereby improving notification turnaround time and relieving technical staff from administrative burden. (ii) A technical review phase where the expertise of scientific officers are deployed optimally to tackle the challenges posed by scientifically complex issues.	• A common online system shared by CLMV – cost sharing basis • Design an online system for CLMV, taking into consideration (for best practices) existing systems implemented by ASEAN-6 • Understanding current workflow for notification process, fact finding from CLMV; different regulators have different approving workflow • Online system to have in-built triage capability (definition, ingredients screening), so that products deemed high risk (e.g. whitening) can be escalated to

		scienfitic officers for closer attention. This will improve the notification acknowledgment process. • Hardware requirement and purchase ▪ Training to use system for CLMV regulators ▪ Technical training on reviewing contents of the ASEAN notification template, namely on ASEAN claims guidelines, definition, screening ingredients.
b) Impose penalty for failure to notify	(i) Failure to notify regulators in the premarket phase by errant importers creates a non-level playing field for the industry, especially for compliant importers (ii) Missing information on importer and product identity hinders effective post market surveillance activities	▪ Legislative review of CLMV penal code or cosmetics regulations to ensure compliance from all importers ▪ Create legislative instruments (if missing) to address gaps, and to harmonise requirements alongside Singapore, Malaysia and the Philippines. Currently, Singapore, Malaysia and the Philippines penalize importers for failing to notify.
c) Impose notification fees	(i) Fees recovered from notification can be allocated towards computer system maintenance and post market surveillance costs. (ii) Building a sustainable and self funding cosmetic control regime	▪ Policy changes needed on targeted allocation of collected fees. ▪ Internal policy changes needed to move towards building a sustainable and self funding cosmetic control regime.

6.2 Postmarket – Audit of Product Information File

According to Article 1(3) of the ACD, it states that,

> *"The company or person responsible for placing the cosmetic products in the market, shall notify the regulatory authority responsible for cosmetics (hereafter referred to as regulatory authority) of each Member State where the product will be marketed of the place of the manufacture or of initial importation before the product is placed in the market."*

The aim is to focus on having an effective post-marketing surveillance (PMS) system, to complement the notification scheme. To achieve this aim, limited and scare resources have to be freed up from the labourous notification process to concentrate on building up an effective PMS system. To that end, regulators have to be equipped to audit the PIF:-

Proposed Measure	Details of Measure	Resources / Actions Needed
a. Improve technical knowledge on auditing PIF	(i) How to prepare PIF, in order to guide local manufacturers (ii) How to evaluate ingredients, formulation, intended use, and claims collectively, in order to audit PIF for product safety (iii) How to evaluate safety data for raw materials	• Due to limited resources, a train-the-trainer format is preferred • Expert with a holistic overview of cosmetics; capable of training on how to evaluate ingredients, formulation, intended use, and claims collectively.

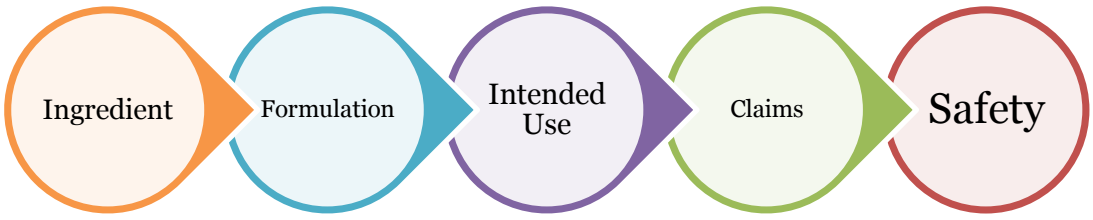

Figure 1: Understanding how to evaluate ingredients, formulation, intended use, and claims collectively, in order to audit a cosmetic PIF, thereby ascertaining product safety

6.3 Postmarket – Post Market Surveillance

According to Article 12 (5) of the ACD, it states that:-

> *"Member States shall ensure that post marketing surveillance is in place and shall have full authority to enforce the law on cosmetic products found to be not complying with this Directive."*

With the focus on post marketing surveillance, CLMV have to be equipped (and be allowed to allocate resources) to monitor and supervise the cosmetics industry. It is recommended that:-

Proposed Measure	Details of Measure	Resources / Actions Needed
a) Effective post market surveillance system	(i) How to set up an effective post market system; mechanisms for reporting serious adverse events to CLMV, how to notify ASEAN of unsafe products (ii) Technical support for evaluation of serious adverse events reports (SAE) on cosmetics (iii) Training on expeditious recall system	• Technical support on setting up an effective post market surveillance system • Guidance document in local language to provide clarity on definition of serious adverse event, how to report SAE to regulator, etc. • Technical training for evaluation and trending of cosmetics SAE reports by cosmetics experts • Legislative review and clarity on penalty regime for non-compliance: To enforce compliance, the regulator must be backed by the force of law to compel the company or person responsible for placing the cosmetic product in CLMV to report serious adverse event that occurred. • Legislative review on enforcement power available to CLMV regulators: to impose on company / person for failing to effectively recall

Proposed Measure	Details of Measure	Resources / Actions Needed
		defective cosmetics from the market. To enforce compliance, the regulator must be backed by the force of law to impose sanctions on the company or person responsible for placing the cosmetic product in CLMV, for failing to effectively recall defective cosmetics. Whilst most recalls are conducted on a voluntary basis by the manufacturer, a penalty regime must be present as a backup resort. This also reinforces to the industry the resolve and importance the regulator places on post market surveillance, and also has the desirable outcome of encouraging good record keeping.

To attain the goal of ensuring that "*the company or person responsible for placing the product in the market must keep records of the primary distribution of their products, for the purpose of product recall according to the respective country's procedures*", the regulator must be backed by the force of law (as a last resort). This will have the desirable effect of compelling the industry to adopt measures to ensure compliance, such as having good distribution record keeping practices.

6.4 Postmarket – Access to Laboratory Network

According to Article 12 (5) of the ACD, it states that:-

> *"Member States shall ensure that post marketing surveillance is in place and shall have full authority to enforce the law on cosmetic products found to be not complying with this Directive."*

Access to the ASEAN Cosmetic Testing Laboratory network, whereby analytical testing of cosmetics for toxic and carcinogenic substances that are prohibited or restricted under ACD, can be carried out for CLMV submitted samples.

An effective and robust laboratory, whose reports can stand up to scrutiny in a Court of Law, is an integral part of any regulatory control regime. To that end, it is recommended that:-

Proposed Measure	Details of Measure	Resources / Actions Needed
a) Access to ASEAN Cosmetic Testing Laboratory network - analytical testing of cosmetics for toxic and carcinogenic substances that are prohibited or restricted under ACD	(i) Identification of existing ASEAN Cosmetic Methods (ACMs), identification and validation of new ACMs, Reference Materials and Proficiency Testing (ii) Legal infrastructure to accept overseas test reports for enforcement purposes	• Technical training on ASEAN Cosmetic Methods (ACMs), Reference Materials and Proficiency Testing • Identification of baseline analytical tests (i.e. lowest common denominator) needed, taking into consideration the ASEAN Cosmetic Methods (ACMs), Reference Materials and Proficiency Testing, to effectively implement post market controls. • In identifying the baseline analytical test (i.e. lowest common denominator), CLMV should identify, for the purpose of enforcement, the "must-have" tests, and differentiate it from the "good-to-have" tests. See section 6.4.1 below. • Legislative review on Evidence Act within CLMV national legislation: explore

	possibility of accepting and relying on cross border test reports for enforcement purposes - laboratories are expensive to equip and maintain. With the battery of validated test methods required for enforcement purposes, no one CLMV member state can be expected to be fully equipped. For the purpose of enforcement, it is necessary that the ASEAN laboratory network test reports can stand up to scrutiny, and be accepted in CLMV for enforcement and prosecution purposes.

6.4.1 Illustrative List of Tests That CLMV should Identify, for the Purpose of Enforcement

This section and the list of tests are provided for illustrative purposes only. There exists an array of tests available for enforcement of the ACD, to test for prohibited substances, or permissible levels of permitted substances. CLMV regulators should identify, for the purpose of enforcement, the list of "must-have" analytical tests needed, *vis-à-vis* "good-to-have" tests desired. Taking into consideration resource constraints, such as budget, manpower, technical & scientific knowledge, cost of maintaining a laboratory, prioritizing based on AMS risk management framework is needed.

(A) Testing of Cosmetics Products (eye make-up, face make-up, hair-care products, lip products and skin care products):

Colourants

- Pigment Orange 5 (CI 12075)
- Metanil Yellow (CI 13065)
- Rhodamine B (CI 45170)
- Acid Green 1 (CI 10020)
- Acid Yellow 1 (CI 10316)
- Acid Yellow 11 (CI 18820)
- Acid Black 1 (CI 20470)
- Acid Violet 9 (CI 45190)
- Acid Red 88 (CI 15620)
- Acid Violet 43 (CI 60730)
- Hansa Yellow (CI 11680)
- Orange 1 (CI 14600)

- Ponceau 2R (CI 16150)
- Ponceau 3R (CI 16155)
- Ponceau SX (CI 14700)
- Solvent Yellow 33 (CI 47000)
- Solvent Green 7 (CI 59040)
- Sudan I
- Sudan II
- Sudan III
- Sudan IV
- Parared

Retinoic Acid (Tretinoin)

Heavy Metals

- Arsenic
- Cadmium
- Copper
- Chromium
- Lead
- Mercury
- Neodymium
- Thallium

(B) Testing of Talcum Powder:

- Hexachlorophene

(C) Testing of Eye Make-up and Skin Care Products:

- Boric acid

(D) Testing of Creams:

- Steroids
- Hydroquinone

(E) Testing of Skin Care Products:

- Oestrogenic Hormones
- Tretinoin

(F) Testing of Hair Dyes:

- Ortho-phenylenediamine
- Meta-phenylenediamine
- Para-phenylenediamine
- Solvent Red 24

- Oxidatives amino - hair dyes

6.5 Postmarket – In Country Laboratory Equipment

According to Article 12 (5) of the ACD, it states that

> *"Member States shall ensure that post marketing surveillance is in place and shall have full authority to enforce the law on cosmetic products found to be not complying with this Directive."*

Taking into consideration the need for effective enforcement, which is backed by an effective and robust laboratory, whose reports can stand up to scrutiny in a Court of Law, it is desirable that CLMV can leverage on the ASEAN Cosmetic Testing Laboratory network. However, if legislative constraints do not permit acceptance of overseas test reports for enforcement purposes, then, CLMV may require in-country laboratory equipment. To that end, it is recommended that:-

Proposed Measure	Details of Measure	Resources / Actions Needed
a) Acquistion of laboratory equipment for enforcement purposes	(i) Identification of type of equipment needed, based on "must-have" analytical tests identified in section 6.4.	• Mapping existing laboratory equipment available in CLMV, and its capability, against the list of "must-have" analytical tests identified in section 6.4 • Financial assistance from Dialogue Partners to support the acquisition of local laboratory resources, to narrow gap in local laboratory equipment • Training on test methods (ACM and new methods), based on the acquired laboratory equipment • Access to reference standards

6.6 Good Manufacturing Practices

According to Appendix VI, ASEAN Guidelines for Cosmetic Good Manufacturing Practice, it states that,

> *"The Good Manufacturing Practices presented here is only a general guideline for the manufacturers to develop its own internal quality management system and procedures. The important objectivemust be met in any case, i.e. the final products must meet the quality standards appropriate to their intended use to assure consumer's health and benefit."*

Without quality in built into a product, there can be no safety. To that end, regulators have to be equipped with the knowledge on how to (i) conduct an audit of a local cosmetics manufacturing facility, (ii) understand how an overseas audit is conducted, and (iii) the scope of overseas audit. This will equip CLMV regulators with the technical knowledge to set the criteria for acceptance / rejection of submitted GMP certificates:-

Proposed Measure	Details of Measure	Resources / Actions Needed
d) Improve knowledge of Cosmetics GMP	(i) Criteria for acceptance of overseas GMP certificate (ii) How to evaluate self declaration for GMP (iii) Training for industry to meet GMP requirements (iv) Training for regulators on how to audit a local manufacturing plant	• Technical support on cosmetics GMP training • Guidance document to clarify type of overseas GMP certificate accepted – provides clarity to industry, and internal guidance to CLMV regulators • Training on scope of overseas manufacturing site audit – what is covered in an audit, what is not covered in an audit, frequency of audit, in order to determine acceptance criteria. • Training on (i) overseas self declaration on GMP scheme - what is covered in a self declaration, what is not covered in a self declaration, legislative landscape, in order to determine acceptance criteria.

6.7 Documentation Control: ASEAN Cosmetics Directive, Annex and Appendix

To assist CLMV in their implementation of ACD, it is recommended that a taskforce be formed to produce and publish revised editions of technical documents, incorporating amendments and mapping it to the ACD, under the direction of ASEAN Cosmetics Committee.

At present, there are various sources to seek documents relating to ACD. To aid compliance and provide clarity to industry, document control is an essential measure. It ensures that only approved, current documentation is used and relied on by CLMV regulators and industry. Inadvertent use of out-of-date documents when transposing ASEAN harmonized requirements can have significant negative consequences; amending legal instruments (e.g. National Regulations and Circulars) is a protracted process for most countries.

Proposed Measure	Details of Measure	Resources / Actions Needed
a) Document Review Taskforce	(i) Taskforce formed under the direction of ASEAN Cosmetics Committee (ii) Taskforce be empowered to produce and publish revised editions of technical documents, incorporating amendments and mapping it to the ACD. (iii) Institute documentation control procedure, whether for electronic or hardcopy, in accordance to internationally accepted standard such as ISO 9001 - 4.2.3 Document Control.	• Taskforce to be equipped and funded with professional secretariat support • Experience in drafting and implementing documentation control, according to internationally accepted standard • Taskforce should be empowered:- i. Taskforce should have permission to make clerical, editorial or other changes of a non-substantive nature to the technical documents. ii. Revised document should be transmitted to the ACC for approval; revised document should be deposited with the ASEAN Secretariat, and published online. iii. The revised editions should be authoritative and is, for all purposes, the

	sole and only proper technical document in respect of ACD.

7 Conclusion

Good enforcement of the ACD requirements involve two key aspects:- (i) good monitoring of the notification acknowledgement process, and (ii) quick response from the post market surveillance team to safeguard cosmetics users, and a clear enforcement and penalty regime to coerce compliance.

In emphasizing post market surveillance activities as being complementary to the premarket notification acknowledgement process, it is recommended that CLMV emphasize to the local company or person responsible for placing cosmetic products in their market, and manufacturers, their legal duties and obligations such as reporting of serious adverse event and recall.

In this regard, attention is drawn to CLMV of the need to be vigilant of the following, and to put into action an implementation roadmap:-

a) Creating a long term and substainable control regime – redesigning workflow and leveraging on IT systems to cope efficiently with notification workload, imposing fees to maintain IT systems
b) Be mindful of creating disincentive and unintended consequences due to regulation – for example, in Viet Nam, requiring the submission of Product Information File (PIF) from importers who notify. This may create a disincentive to notify. Importers may feel penalized that they are burdened with additional PIF submission, and those who fail to notify are, firstly not sanctioned, and secondly not burdened with PIF submission.
c) Penalising those who fail to notify
d) Creating an enforcement and sanction regime - mapping between penal codes and cosmetics regulations to identify gaps, clearly communiucating sanctions or penalties to deter offenders
e) Communicate and put to action regulators' willingness to sanction offenders using existing post market enforcement powers

It is opined that the seven measures recommended in section 6 of this report are feasible and implementable, with the assistance of targeted assistance programs. If executed, it aims to narrow the development gap between ASEAN-6 and CLMV in implementing the ASEAN Cosmetics Directive (ACD).