經濟部

出口化粧品至東協法規與程序

經濟部工業局
INDUSTRIAL DEVELOPMENT BUREAU
MINISTRY OF ECONOMIC AFFAIRS

工業技術研究院
Industrial Technology
Research Institute

推動粧點美麗新時尚計畫

出口化粧品至東協
法規與程序

出版機關：經濟部工業局 推動粧點美麗新時尚計畫
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序

東南亞國家協會（簡稱東協）為臺灣化粧保養品產業外銷出口之第 3 大區域；依據海關資料統計，2013 年臺灣出口至東協之化粧保養品金額達新臺幣 41.7 億元，相較於 2012 年新臺幣 36.4 億元，成長率達 12.9%，為臺灣化粧保養品廠商除大陸、香港地區之外，另一產品出口之主要市場。

東協為全球新興經濟體，區域內 10 會員國共有 6 億以上人口，經濟成長強勁，市場潛力巨大；其中，尤以擁有 2.4 億人口，且為全球最大伊斯蘭教國家的印尼，以及僅次於沙烏地阿拉伯，掌握全球第 2 多伊斯蘭教金融資產的馬來西亞，為臺灣化粧保養品產業可積極拓展之新興市場。東協在包含進口程序、作業等化粧保養品之相關管理規定方面，仿照歐盟模式，以制定統一之化粧品法規(ASEAN Cosmetic Directive , ACD)供會員國修訂後各別於其國境內施行；惟因各會員國國情、語言差異以及各會員國尚未完全與 ACD 調和，致使臺灣廠商未能充分了解相關規定，而於出口時遭遇阻礙。因此，為了增進廠商對於東協相關化粧保養品進口規定之了解，本手冊蒐集東協主要國家之化粧保養品管理法規、進口流程及登錄規定等，作為臺灣廠商外銷之參考。另因應東協區域內之伊斯蘭教國家對於進口產品認證之要求，本手冊另收錄清真認證（HALAL）之相關資料供廠商參考。

本手冊蒐集資訊內容繁複，幸得衛生福利部食品藥物管理署醫粧組化粧品科前科長林澄琴女士、臺灣化粧品工業同業公會張簡啟瑞顧問、臺南市化粧品公會前理事長暨外洲企業有限公司林培火董事長、安芳美容科技股份有限公司郭蒼木總經理、富美生物科技股份有限公司李佳益總經理、妮傲絲翠股份有限公司林妙貞專員、歐萊德國際股份有限公司周玉鈴高級專員、和康生物科技股份有限公司陳啟祥副總經理，及益美化工實業股份有限公司陳韋如專員等先進之鼎力協助，方能完成本手冊，謹在此致謝。

經濟部工業局

103 年 11 月

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第一章 東南亞國協(ASEAN)

壹、主管機關與指令

一、 東協與其化粧品管理主管機關介紹

東南亞國家協會(ASEAN) 成立於 1967 年，包括 10 個成員國，即汶萊、柬埔寨、印尼、寮國、馬來西亞、緬甸、菲律賓、新加坡、泰國和越南。其化粧品主要負責單位及網址，詳如下表：

國家	負責單位	網址
馬來西亞	National Pharmaceutical Control Bureau (NPCB)	http://www.BPFK.gov.my
新加坡	Centre for Pharmaceutical Administration (CPA)	http://www.hsa.gov.sg
菲律賓	Bureau of Food and Drugs (BFAD)	http://www.doh.gov.ph
印尼	The National Agency of Drug and Food Control	http://www.pom.go.id/new
汶萊	Department of Pharmaceutical Services	http://www.moh.gov.bn
越南	Drug and Cosmetic Management Division	http://www.moh.gov.vn
寮國	Food and Drug Department	http://www.moh.gov.la
緬甸	Food and Drug Administration	http://www.moh.gov.mm
柬埔寨	Bureau of Drug and Cosmetic	http://www.moh.gov.kh
泰國	Cosmetic Control Group	http://www.fda.moph.go.th

二、 東協化粧品指令(ACD)

東協採用歐盟模式制定了統一的化粧品法規，以提升東協地區內化粧品的品質和安全。根據要求，成員國應於 2008 年 1 月 1 日起開始執行新的《東協化粧品指令》(ACD)。目前，馬來西亞、新加坡、菲律賓、緬甸、寮國和柬埔寨已經完全執行了 ACD，而其它成員國也基本在 2008 年陸續完成法規的準備階段。東協化粧品管理法規統一的原則為：採用歐盟的化粧品定義、銷售者要對產品安全性負責及統一標籤和命名。

東協化粧品指令(ACD)相關網址：

ASEAN Cosmetics Association-http://aseancosmetics.org

貳、法規重要規定

一、 化粧品定義及範圍

定義	化粧品：接觸於人體各外部器官（表皮(皮膚)、毛髮、指(趾)甲、口(嘴)唇和外生殖器）或口腔內的牙齒和口腔黏膜，以清潔、發出香味、改善外觀、改善身體氣味或保護身體使之保持良好狀態為主要目的的物質和製劑。
分類	1. 用於皮膚的乳霜、乳液、化粧水、凝膠和油脂(手、臉、腳等) 2. 面膜 (不包括化學換膚產品) 3. 粉底 (液體、膏狀、粉體) 4. 彩粧用粉、沐浴後用粉、衛生用粉等 5. 香皂、除臭肥皂等 6. 香水、花露水和古龍水 7. 沐浴和淋浴用品(沐浴鹽、沐浴精、沐浴油、凝膠等) 8. 脫毛劑 9. 除臭劑和止汗劑 10.頭髮用產品 -染髮劑和漂色劑 -燙髮、直髮和定型產品 -造型產品 -洗髮用品(洗髮液、洗髮粉和洗髮精) -頭髮護理產品 (液狀、乳狀、油狀) -美髮產品 (美髮液、髮膠、潤髮油) 11.剃鬍產品 (乳狀、泡沫、液狀等) 12.臉和眼部彩粧品和卸粧品 13.用於唇部產品 14.牙齒和口腔護理產品 15.指甲用產品及彩色指甲油 16.女性外部私密處用衛生產品 17.日光浴產品 18.防曬產品 19.皮膚美白產品 20.抗皺產品

出處：ACD - Appendix , Appendix I Annex I (2008)

二、 產品登錄 (Notification)

化粧品上市前無須經過核准，但負責化粧品於市場上銷售的企業或人員必須於化粧品上市前進行產品登錄，將產品相關資訊登錄於主管機關，並得到許可後，產品才可以銷售。任何一個成員國生產或銷售的化粧品，如果滿足相關要求，則可以進入另一成員國的市場。

東協規範登錄時需提供之相關資訊：

1. 產品品名與品牌
2. 產品種類
3. 預定可使用的方式
4. 產品呈現方式
5. 製造廠名稱與地址
6. 填裝廠名稱與地址
7. 於當地負責產品上市的公司名與地址
8. 當地公司負責人的聯絡資料
9. 進口商名稱與地址
10. 產品全成分表
11. 業者安全聲明書

表一、東協登錄制度

法源	東協化粧品指令 ASEAN Cosmetic Directive (ACD)及各國法規
申請方式	線上
申請人	境內負責人
審核	採線上自動篩選機制
申請資訊程序	上市前先需登入各國登錄系統填寫資料
收件處	線上
變更	線上申請(有列出需要重新申請項目)
廢止	未說明
費用	各國收費不同(約 500~2,000 新台幣不等)

表二、東協主要國家登錄系統

東協國家	登錄系統
馬來西亞	線上登錄 NPCB website www.bpfk.gov.my/Quest2
新加坡	HSA online system 註冊帳號: CRIS (Client Registration and Identification Service) http://www.hsa.gov.sg/publish/hsaportal/en/services/cris.html 登入 PRISM (Pharmaceutical Regulatory Information System) http://www.hsa.gov.sg/publish/hsaportal/en/services/prism.html
印尼	填寫資料上傳 The National Agency of Drug and Food Control Indonesia(BPOM) http://notifkos.pom.go.id/bpom-notifikasi/index.php?language=1
泰國	填寫資料送審 One Stop Service Center Cosmetic Controlled Division Bureau of Cosmetic and Hazardous Substances Control Food and Drug Administration Inquiry Tel. 0-2590-7441 Follow-up the application Tel. 0-2590-7422-3
菲律賓[1]	填寫登錄表單並以電子郵件方式傳送 aseannotification@fda.gov.ph
汶萊[2]	填寫資料送審 Cosmetic Unit, Drug Administration Section, 8th Floor Unit 3, Block 2G, Ong Sum Ping Condominium, Bandar Seri Begawan, Brunei Darussalam. Tel/Fax：2230001/2230041

表三、東協主要國家產品登錄制度相關內容

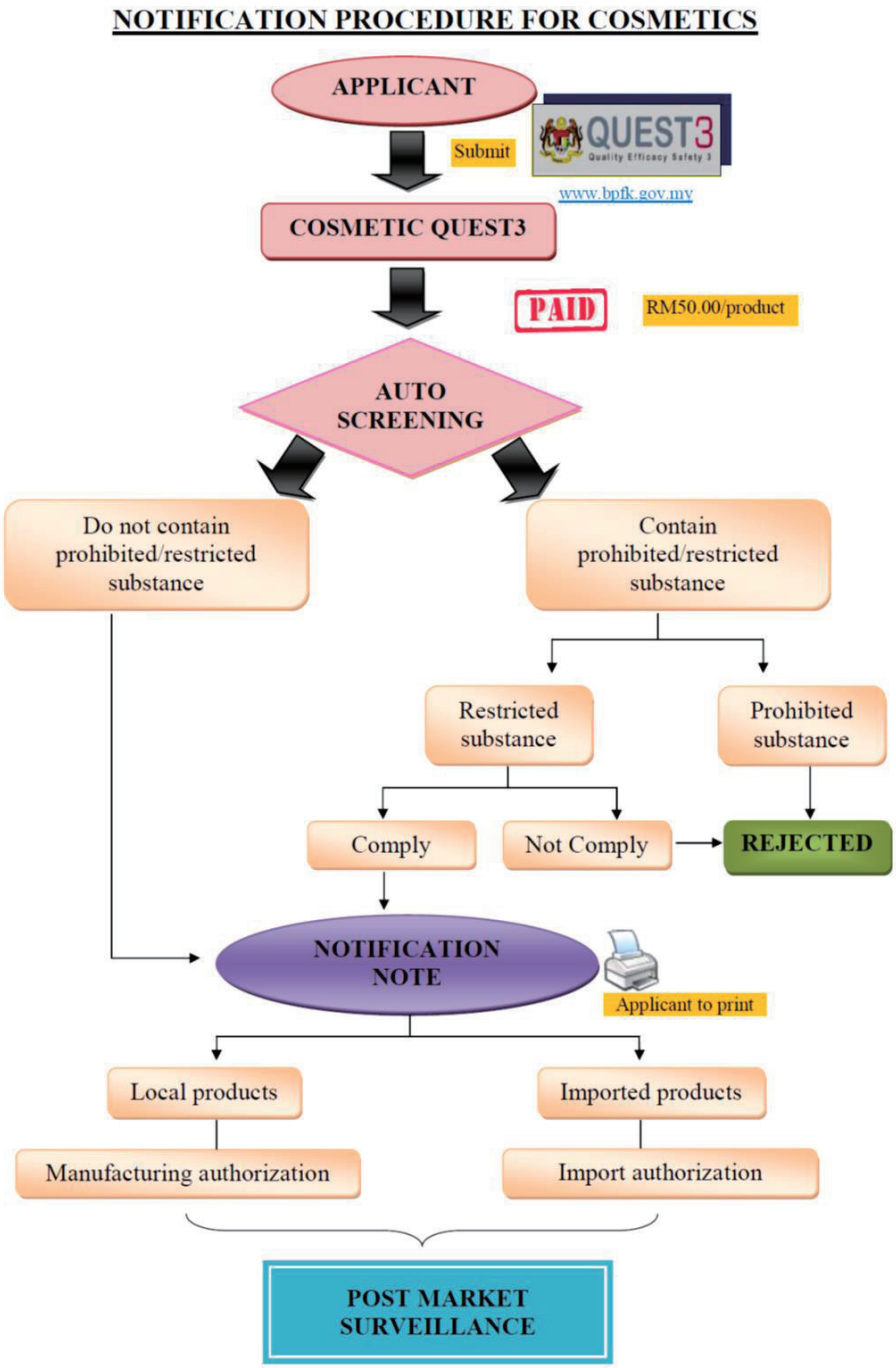
東協國家	登錄語言	登錄費用	通知發放方式	效期	東協國家
馬來西亞	英語或 馬來語	50RM (約 480NT)	自行列印	2 年	馬來西亞
新加坡	英語	$10~25 (約 220 ~ 550NT)	自行列印	1 年	新加坡
泰國	英語或泰語	國內製造 1,000-Baht 國外進口 2,000-Baht	---	1 年	泰國

出處：

[1]Philippines-Food and Drug Administration http://www.fda.gov.ph/industry-corner/downloadables/197-asean-cosmetic-harmonization

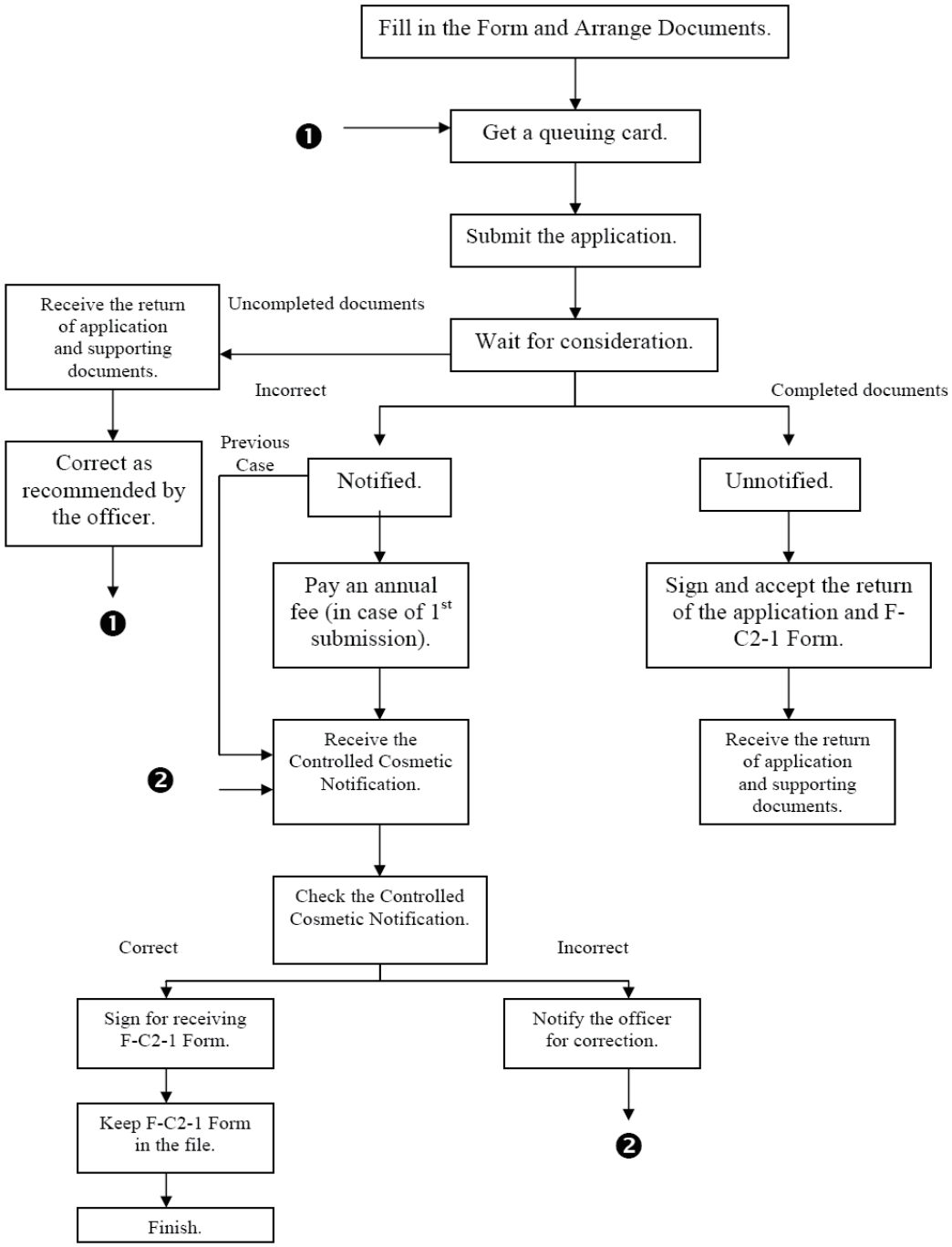
[2]Guidelines for Notification of Cosmetic Products in Brunei Darussalam (December 2007)

圖一、馬來西亞線上登錄 NPCB 系統說明流程圖



出處：行政院衛生署食品藥物管理局 101 年度研究成果報告-化粧品衛生管理條例相關規範之研擬

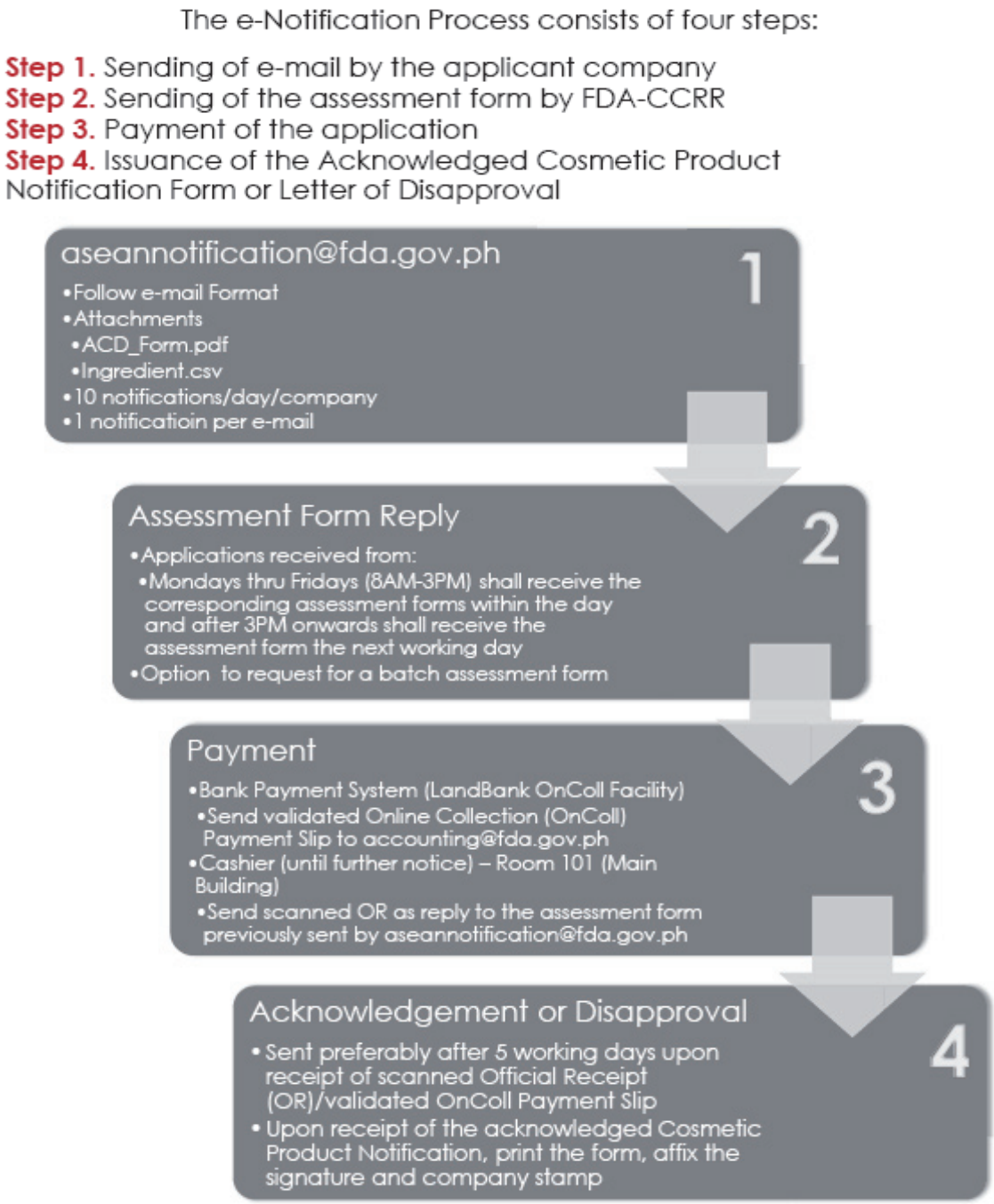
圖二、泰國化粧品登錄說明流程圖



註：F-C2-1 Form 為委託書(Power of Attorney)。

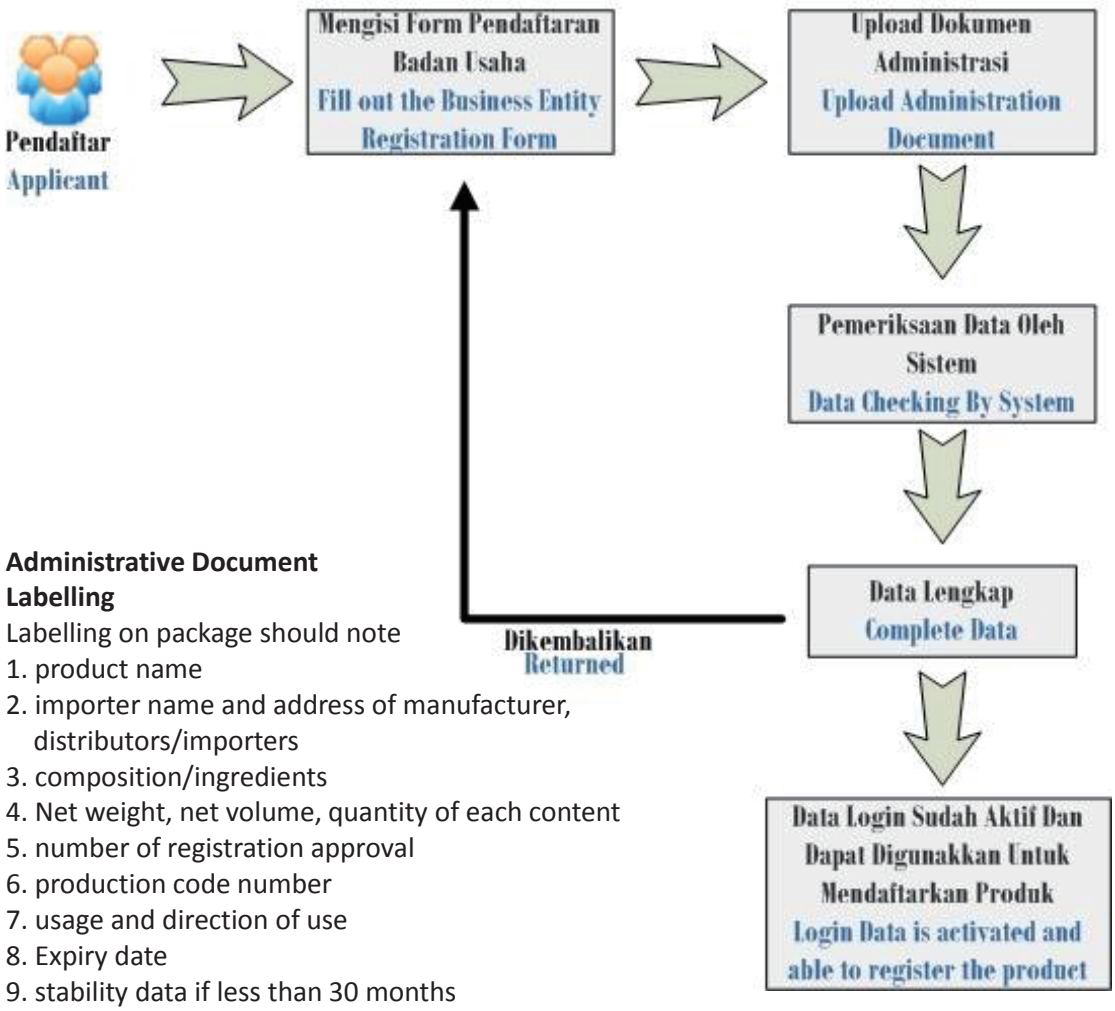
資料來源：MANUAL FOR NOTIFICATION OF CONTROLLED COSMETIC (2008)

圖三、菲律賓化粧品登錄說明流程圖



資料來源：ELECTRONIC COSMETIC PRODUCT NOTIFICATION (e-NOTIFICATION) GUIDE BOOKLET, FDA Philippines-CCRR

圖四、印尼化粧品登錄說明流程圖



Administrative Document

Labelling

Labelling on package should note

1. product name
2. importer name and address of manufacturer, distributors/importers
3. composition/ingredients
4. Net weight, net volume, quantity of each content
5. number of registration approval
6. production code number
7. usage and direction of use
8. Expiry date
9. stability data if less than 30 months
10. Other information which related to safety and or quality
11. usage & direction of use should be in Indonesia language *)
12. notifying "For Export only" (for exported cosmetic)

*) Except for Common Used Product

Technical Document

Formula & Efficacy

- Formula (qualitative & quantitative) include function of each substance
- Direction of use: usage and direction of use, warning & precaution, if any

Quality & Technology

- Manufacturing process: standard operational Procedure
- Specification of raw material
- Specification of finished product

資料來源：Notifikasi Kosmetika Online System- Procedure

圖五、菲律賓化粧品登錄表單

Republic of the Philippines
Department of Health
Food and Drug Administration
Alabang, Muntinlupa City

ASEAN Cosmetic Directive

NOTIFICATION OF COSMETIC PRODUCT

☑ *Tick where applicable*

PARTICULARS OF PRODUCT

1. Name of brand & product:

1.1 Brand

1.2 Product Name

1.3 Product Variants or Shade Names. Separate each with a comma (,).

2. Product type(s)

- ☐ Creams, emulsions, lotions, gels and oils for skin (hands, face, feet, etc.)
- ☐ Face masks (with the exception of chemical peeling products)
- ☐ Tinted bases (liquids, pastes, powders)
- ☐ Make-up powders, after-bath powder, hygienic powders, etc.
- ☐ Toilet soaps, deodorant soaps, etc
- ☐ Perfumes, toilet waters and eau de Cologne
- ☐ Bath or shower preparations (salts, foams, oils. gels, etc.)
- ☐ Depilatories
- ☐ Deodorants and anti-perspirants
- ☐ Hair care products

- hair tints and bleaches (including permanent hair dyes)
- products for waving, straightening and fixing,
- setting products,
- cleansing products (lotions, powders, shampoos),
- conditioning products (lotions, creams, oils),
- hairdressing products (lotions, lacquers, brilliantines)

☐ Shaving product (creams, foams, lotions, etc.)
☐ Products for making-up and removing make-up from the face and the eyes
☐ Products intended for application to the lips
☐ Products for care of the teeth and the mouth
☐ Products for nail care and make-up
☐ Products for external intimate hygiene
☐ Sunbathing products
☐ Products for tanning without sun.
☐ Skin whitening products
☐ Anti-wrinkle products
☐ Others (please specify)

3. Intended use

4. Product presentation(s)

☐ Single product
☐ A range of product variants similar in composition for the same use but differs in colours, flavours etc.
☐ Palette(s) in a range of one product type
☐ Combination products in a single kit
☐ Others (please specify)

[1]PARTICULARS OF MANUFACTURER (S)/ASSEMBLER(S)
[Please attach in a separate sheet if there are more than one manufacturer/assembler]
5. Name of manufacturer:

---

[1] *A manufacturer is a company which is engaged in any process carried out in the course of making the cosmetic product. The manufacturing process includes all operations of purchase of starting materials, bulk intermediates and products, formulation and production (such as grinding, mixing, encapsulation and/or packaging), quality control, release, storage and distribution of cosmetic products and the related controls.*

A primary assembler is a company which is engaged in a process of enclosing the product in a primary/immediate container which is labelled or to be labelled before the product is sold or supplied in it.

A secondary assembler is a company which is engaged only in a process of labelling the product container where the product is already enclosed in its primary container and/or packing the product which is already enclosed in its labelled primary container into a carton which is labelled or to be labelled, before the product is sold or supplied.

Address of manufacturer (state country):

C o u n t r y AFGHANISTAN

Tel: Fax:

6. Name of assembler (Please tick accordingly. May tick more than one box):

☐ Primary assembler ☐ Secondary assembler

Address of assembler (state country):

C o u n t r y AFGHANISTAN

Tel: Fax:

PARTICULARS OF LOCAL COMPANY RESPONSIBLE FOR PLACING THE COSMETIC PRODUCT IN THE MARKET

7. Name of company:

Address of company:

Tel: Fax:

Business Registration Number /License to Operate Number (if applicable, submit a copy of the Business Registration Certificate):

PARTICULARS OF PERSON REPRESENTING THE LOCAL COMPANY

8. Name of person:

Tel: Email:

Designation in the company:

Note: If the applicant is a service provider authorised by the company, he is required to provide a letter of authorisation or any additional particulars as required by the regulatory authority.

PARTICULARS OF IMPORTER

9. Name of Importer:

Address of importer:

Tel: Fax:

PRODUCT INGREDIENT LIST

10. Please check the following boxes

☐ I have examined the latest revisions of the Annexes II to VII of the ASEAN Cosmetic Ingredient Listing as published in the latest amendment of the ASEAN Cosmetic Directive and confirmed that the product in this notification does not contain any prohibited substances and is in compliance with the restrictions and conditions stipulated in the Annexes.

☐ I undertake to respond to and cooperate fully with the regulatory authority with regard to any subsequent post-marketing activity initiated by the authority.

No	Full Ingredient name (use INCI or approved nomenclature in standard references)	
	(Please attached the list of Ingredient in CSV, Comma Delimited Format)	**Percentage (%) of Restricted Ingredients**
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		

DECLARATION

1. I hereby declare on behalf of my company that the product in the notification meets all the requirements of the ASEAN Cosmetic Directive, its Annexes and Appendices, which have been transposed into local legislation.

2. I undertake to
   i. Ensure that the product's technical and safety information is made readily available to the regulatory authority concerned ("the Authority") and to keep records of the distribution of the products for product recall purposes;
   ii. Notify the Authority of fatal or life threatening serious adverse event[2] as soon as possible by telephone, facsimile transmission, email or in writing, and in any case, no later than 7 calendar days after first knowledge;
   iii. Complete the Adverse Cosmetic Event Report Form[3] within 8 calendar days from the date of my notification to the Authority in para 2ii. above, and to provide any other information as may be requested by the Authority;

[2] As defined in the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products
[3] Set out in Appendix I to the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products

iv. Report to the Authority of all other serious adverse events that are not fatal or life threatening as soon as possible, and in any case, no later than 15 calendar days after first knowledge, using the Adverse Cosmetic Event Report Form;
v. Notify the Authority of any change in the particulars submitted in this notification;
vi. Ensure that if and when directed by the authority I will recall the product from the market, and discontinue selling or supplying the product

3. I declare that the particulars given in this notification are true, all data, and information of relevance in relation to the notification have been supplied and that the documents enclosed are authentic or true copies.

4. I understand that I shall be responsible for ensuring that each consignment of my product continues to meet all the legal requirements, and conforms to all the standards and specifications of the product that I have declared to the Authority.

5. I understand that I cannot place reliance on the acceptance of my product notification by the authority in any legal proceedings concerning my product, in the event that my product has failed to conform to any of the standards or specifications that I had previously declared to the Authority.

_____
[Name and Signature of person representing the local company]

_____ _____
[Company stamp] [Date]

資料來源：FDA Philippines-ASEAN Cosmetic Directive Form

圖六、汶萊化粧品登錄表單

FOR OFFICIAL USE
Date received:
Product Notification No.:
BRU L _ _ _ _ _ _ _ _ K

COSMETIC PRODUCTS NOTIFICATION FORM
DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM

Completed Notification Form to be submitted to:
Cosmetic Unit,
Drug Administration Section,
8th Floor Unit 3, Block 2G,
Ong Sum Ping Condominium,
Bandar Seri Begawan,
Brunei Darussalam.

Tel/Fax: 2230001

☑*Tick where applicable*

PARTICULARS OF PRODUCT

1. Name of brand & product:

1.1 Brand

1.2 Product Name

1.3 List of Variants or Shade Names

_____
_____
_____

2. Product type(s)

- ☐ Creams, emulsions, lotions, gels and oils for skin (hands, face, feet, etc.)
- ☐ Face masks (with the exception of chemical peeling products)
- ☐ Tinted bases (liquids, pastes, powders)
- ☐ Make-up powders, after-bath powder, hygienic powders, etc.
- ☐ Toilet soaps, deodorant soaps, etc
- ☐ Perfumes, toilet waters and eau de Cologne
- ☐ Bath or shower preparations (salts, foams, oils. gels, etc.)
- ☐ Depilatories
- ☐ Deodorants and anti-perspirants
- ☐ Hair care products
  - hair tints and bleaches (including permanent hair dyes)
  - products for waving, straightening and fixing,
  - setting products,
  - cleansing products (lotions, powders, shampoos),
  - conditioning products (lotions, creams, oils),
  - hairdressing products (lotions, lacquers, brilliantines)
- ☐ Shaving product (creams, foams, lotions, etc.)
- ☐ Products for making-up and removing make-up from the face and the eyes
- ☐ Products intended for application to the lips
- ☐ Products for care of the teeth and the mouth
- ☐ Products for nail care and make-up
- ☐ Products for external intimate hygiene
- ☐ Sunbathing products
- ☐ Products for tanning without sun.
- ☐ Skin whitening products
- ☐ Anti-wrinkle products
- ☐ Others (please specify)

_____

3. Intended use

_____
_____
_____

4. Product presentation(s)

- ☐ Single product
- ☐ A range of product variants similar in composition for the same use but differs in colours, flavours etc.
- ☐ Palette(s) in a range of one product type
- ☐ Combination products in a single kit
- ☐ Others (please specify)

[1]PARTICULARS OF MANUFACTURER (S)/ASSEMBLER(S)

[1] *A manufacturer is a company which is engaged in any process carried out in the course of making the cosmetic product. The manufacturing process includes all operations of purchase of starting materials, bulk intermediates and products, formulation and production (such as grinding, mixing, encapsulation and/or packaging), quality control, release, storage and distribution of cosmetic products and the related controls.*

[Please attach in a separate sheet if there are more than one manufacturer/assembler]

5. Name of manufacturer:

Address of manufacturer (state country):

Country

Tel: Fax:

6. Name of assembler (Please tick accordingly. May tick more than one box):

☐ Primary assembler ☐ Secondary assembler

Address of assembler (state country):

Country

Tel: Fax:

PARTICULARS OF LOCAL COMPANY RESPONSIBLE FOR PLACING THE COSMETIC PRODUCT IN THE MARKET

7. Name of company:

Address of company:

A primary assembler is a company which is engaged in a process of enclosing the product in a primary/immediate container which is labelled or to be labelled before the product is sold or supplied in it.

A secondary assembler is a company which is engaged only in a process of labelling the product container where the product is already enclosed in its primary container and/or packing the product which is already enclosed in its labelled primary container into a carton which is labelled or to be labelled, before the product is sold or supplied.

Tel: Fax:

Business Registration Number /License to Operate Number (if applicable, submit a copy of the Business Registration Certificate):

PARTICULARS OF PERSON REPRESENTING THE LOCAL COMPANY

8. Name of person:

Tel: Email:

Designation in the company:

Note: If the applicant is a service provider authorised by the company, he is required to provide a letter of authorisation or any additional particulars as required by the regulatory authority.

PARTICULARS OF IMPORTER

9. Name of Importer:

Address of importer:

Tel: Fax:

PRODUCT INGREDIENT LIST

10. Please check the following boxes

☐ I have examined the latest revisions of the Annexes II to VII of the ASEAN Cosmetic Ingredient Listing as published in the latest amendment of the ASEAN Cosmetic Directive and confirmed that the product in this notification does not contain any prohibited substances and is in compliance with the restrictions and conditions stipulated in the Annexes.

☐ I undertake to respond to and cooperate fully with the regulatory authority with regard to any subsequent post-marketing activity initiated by the authority.

[To submit ingredient list with percentages of restricted ingredients and packaging materials as required by member country]

No	Full Ingredient name (use INCI or approved nomenclature in standard references)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	

DECLARATION

1. I hereby declare on behalf of my company that the product in the notification meets all the requirements of the ASEAN Cosmetic Directive, its Annexes and Appendices which have been transposed into local legislation.

2. I undertake to abide by the following conditions:
   i. Ensure that the product's technical and safety information is made readily available to the regulatory authority concerned ("the Authority") and to keep records of the distribution of the products for product recall purposes;
   ii. Notify the Authority of fatal or life threatening serious adverse event[2] as soon as possible by telephone, facsimile transmission, email or in writing, and in any case, no later than 7 calendar days after first knowledge;
   iii. Complete the Adverse Cosmetic Event Report Form[3] within 8 calendar days from the date of my notification to the Authority in para 2ii. above, and to provide any other information as may be requested by the Authority;
   iv. Report to the Authority of all other serious adverse events that are not fatal or life threatening as soon as possible, and in any case, no later than 15 calendar days after first knowledge, using the Adverse Cosmetic Event Report Form;
   v. Notify the Authority of any change in the particulars submitted in this notification;
   vi. Ensure that if and when directed by the authority I will recall the product from the market, and discontinue selling or supplying the product

3. I declare that the particulars given in this notification are true, all data, and information of relevance in relation to the notification have been supplied and that the documents enclosed are authentic or true copies.

4. I understand that I shall be responsible for ensuring that each consignment of my product continues to meet all the legal requirements, and conforms to all the standards and specifications of the product that I have declared to the Authority.

5. I understand that I cannot place reliance on the acceptance of my product notification by the authority in any legal proceedings concerning my product, in the event that my product has failed to conform to any of the standards or specifications that I had previously declared to the Authority.

_____
[Name and Signature of person representing the local company]

_____ _____
[Company stamp] [Date]

[2] As defined in the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products
[3] Set out in Appendix I to the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products

圖七、泰國化粧品登錄表單

Document No. 5
Jor.Khor. Form

(For Official Use)
Product Notification No. ……..
Date received ……

TEMPLATE FOR NOTIFICATION OF COSMATIC PRODUCT

PARTICULARS OF PRODUCT

1. NAME OF BRAND&PRODUCT:

1.1 Brand

เอบีซี ABC

1.2 Product Name

ครีมกันแดด Sunscreen Cream

1.3 List of Variants or Shade Names (please identify)

2. Product Type

Sun Protection Product 10596

3. Intended Use

Apply for sun protection.

4. **Product presentation** (Please mark ✓ at the selected item)

☑ Single product

☐ A range of product in composition for the same use but differs in colours, flavours

☐ Palettes in a range of one product type

☐ Palettes in a range of many product types

☐ Combination of one product type in a single kit

☐ Combination of many product types in a single kit

☐ Others (Please identify)……

5. PARTICULARS OF MANUFACTURER (S)/IMPORTER/ASSEMBLER (S)[Please attach in a separate sheet if there are more than one manufacturer/ assembler]

5.1 Name of manufacturer _____APPLE INC._____
Address of manufacturer locating at _____Trok/Soi_____
Road_____Moo_____Tumbon/Sub-district_____
Amphur/District_____Province_____Zip Code_____
Telephone No._____Fax No._____E-mail Address_____
Country (in case of production in overseas)_UNITED STATES OF AMERICA_

5.2 Name of Assembler_____
(Please mark ✓ at the desired item which can choose more than 1 items.)
☐ Primary Assembler ☐ Secondary Assembler

Address of Assembler residing at _____Trok/Soi_____
Road_____Moo_____Tumbon/Sub-district_____
Amphur/District_____Province_____Zip Code_____
Telephone No._____Fax No._____E-mail Address_____
Country_____

5.3 Name of Importer _____Suksamang Company Limited_____
Address of Importer located at __1__ Trok/Soi____Bumratnaradul Hospital_____
Road_____Tiwanon_____Moo__-_____Tumbon/Sub-district __Taladkwan____
Amphur/District _____Muang_____Province_____Nonthaburi___Zip Code 11000
Telephone No._____02-5999900__Fax No._____-_____E-mail Address_-___

6. List of Particulars of Company Responsible for Placing the Cosmetic Product in the Market

6.1 Name of Company Suksamang Company Limited

Business Registration No.
1234543211111
[Please attach a copy of commercial registration or a copy of certificate of juristic person registration (as the case may be).]

Address of Company located at 1 Trok/Soi Bumratnaradul Hospital
Road Tiwanon Moo - Tumbon/Sub-district Taladkwan
Amphur/District Muang Province Nonthaburi Zip Code 11000
Telephone No. 02-5999900 Fax No. - E-mail Address -

6.2 Particulars of Person Representing the Company for Placing the Cosmetic Product in the Market
Name of Person Mr. Raden Lundai
Telephone No. 02-599-9900 E-mail Address: LUNDAI@hotmail.com

Designation in the company Director

7. **Product Ingredient List**

I have examined the details of substances used in the cosmetics product as hereby notified. There was no prohibited ingredient. The operator has complied with all related regulations, notifications, and code of practices. I hereby certify that I shall be responsible for all actions and fully coordinate with the officers when the follow-up examination on cosmetics product is required after issuing into the market.

Please deliver the list of substances together with quantity of substances under the maximum limit specified by law.

No.	List of All Substances	
1	Ethylhexyl p-methoxy cinnamate 7.5%	UV Absorber
2	Oxybenzone 2.5%	UV Absorber
3	2 – Ethylhexyl Salicylate 2.5%	UV Absorber
4	Methylparaben 0.1%	Preservative
	[calculated as 4-Hydroxybenzoic acid=0.09%]	
5	Propylparaben 0.1%	Preservative
	[calculated as 4-Hydroxybenzoic acid=0.08%]	
6	Water	Solvent
7		
8	[Total 4-Hydroxybenzoic acid=0.09+0.08=0.17%]	
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		

DECLARATION

1. I hereby declare on behalf of my company that the product in the notification meets all the requirements of the Cosmetics Act of the Kingdom of Thailand.
2. I undertake to
   (1) Ensure that the product's technical and safety information is made readily available to the regulatory authority concerned ("the Authority") and to keep records of the distribution of products recall purposes;
   (2) Notify the Authority of fatal or lift threatening serious adverse event as soon as possible by telephone, facsimile transmission, email or in writing, and in any case, no later than 7 calendar days after first knowledge;
   (3) Complete the Adverse Cosmetic Event Report Form within 8 calendar days from the date of my notification to the Authority in para 2 above, and to provide any other information as may be requested by the Authority;
   (4) Report to the Authority of all other serious adverse events that are not fatal or life threatening as soon as possible, and in any case, no later than 15 calendar days after first knowledge, using the adverse Cosmetic Event Report Form;
   (5) Notify the Authority of any change in the particulars submitted in this notification;
   (6) Ensure that if and when directed by the authority I will recall the product from the market, and discontinue selling or supplying the product
3. I declare that the particulars given in this notification are true, all data, and information of relevance in relation to the notification have been supplied and that the documents enclosed are authentic or true copies.
4. I understand that I shall be responsible for ensuring that each consignment of my product continues to meet all the legal requirements, and conforms to all the standards and specifications of the product that I have declared to the Authority.
5. I understand that I cannot place reliance on the acceptance of my product notification by the authority in any legal proceedings concerning my product, in the event that my product has failed to conform to any of the standards or specifications that I had previously declared to the Authority.

Signature *Raden Lundai*

(Mr. Raden Lundai)

Name and Signature of Notifier

[Company's Seal (if any)]

5/1/51

Date

資料來源：MANUAL FOR NOTIFICATION OF CONTROLLED COSMETIC (2008)

圖八、印尼化粧品登錄表單

CONTOH *TEMPLATE* PENDAFTARAN PEMOHON NOTIFIKASI

1. Status Pemohon Notifikasi: (pilih salah satu)
   Ada 3 (tiga) pilihan:
   - ☑ Industri Kosmetika
   - ☑ Importir Kosmetika
   - ☑ Usaha perorangan/badan usaha yang melakukan kontrak produksi

   Catatan: Tampilan yang akan muncul sesuai dengan status yang dipilih

   - ☑ **Industri Kosmetika:**
     - Nama Perusahaan : .....
     - Alamat : .....
     - Kota/Kabupaten : .....
     - Kode Pos : .....
     - Provinsi : .....
     - Telepon : .....
     - Fax : .....
     - Alamat Email : .....
     - NPWP : .....
     - File NPWP (pdf) : *(upload file pdf)*
     - No. Izin Produksi Kosmetika : .....
     - Masa Berlaku Izin Produksi Kosmetika: (diisi dengan tgl,bln,thn)
     - File Izin Produksi Kosmetika (pdf): *(upload file pdf)*
   - ☑ **Importir Kosmetika**:
     - Nama Perusahaan : .....
     - Alamat : .....
     - Kota/Kabupaten : .....
     - Kode Pos : .....
     - Provinsi : .....
     - Telepon : .....
     - Fax : .....
     - Alamat Email : .....
     - NPWP : .....
     - File NPWP (pdf) : *(upload file pdf)*
     - Angka Pengenal Impor : .....
     - File Angka Pengenal Impor (pdf): *(upload file pdf)*
     - File Surat Penunjukan Keagenan (pdf): *(upload file pdf)*
     - Merek yang diageni : .....
     - Masa berlaku Surat Penunjukan Keagenan (Tgl/Bl/Th): ..

     Data Pabrik:
     - Nama : .....
     - Alamat : .....
     - Kota/Kabupaten : .....
     - Kode Pos : .....
     - Provinsi : .....
     - Negara : .....

1

- File Sertifikat CPKB atau surat keterangan penerapan CPKB* (pdf): *(upload file pdf)*

☑ **Usaha perorangan/badan usaha yang melakukan kontrak produksi**

- Nama Perusahaan : .....
- Alamat : .....
- Kota/Kabupaten : .....
- Kode Pos : .....
- Provinsi : .....
- Telepon : .....
- Fax : .....
- Alamat Email : .....
- NPWP : .....
- File NPWP (pdf) : *(upload file pdf)*
- Nomor SIUP : .....
- File SIUP (pdf) : *(upload file pdf)*
- Surat Perjanjian Kerjasama yang dilegalisir Notaris (pdf): *(upload file pdf)*

Data Pabrik:

- Nama : .....
- Alamat : .....
- Kota/Kabupaten : .....
- Kode Pos : .....
- Provinsi : .....
- Negara : .....
- Telepon : .....
- File Sertifikat CPKB atau surat keterangan penerapan CPKB* (pdf): *(upload file pdf)*

2. Data Pimpinan Perusahaan:
   - Nama : .....
   - Alamat : .....
   - Kota/Kabupaten : .....
   - Kode Pos : .....
   - Provinsi : .....
   - Telepon : .....
3. Data Penanggung jawab teknis:
   - Nama : .....
   - Alamat : .....
   - Kota/Kabupaten : .....
   - Kode Pos : .....
   - Provinsi : .....
   - Telepon : .....

Bila semua informasi sudah diisi, klik:

☑ Saya setuju (daftarkan sekarang)

Keterangan:

* 1) sertifikat CPKB atau surat pernyataan penerapan CPKB sesuai dengan bentuk sediaan yang akan dinotifikasi untuk pabrik yang berlokasi di negara ASEAN.

2

2) sertifikat atau surat keterangan yang menyatakan pabrik kosmetika di negara asal telah menerapkan CPKB sesuai dengan bentuk sediaan yang akan dinotifikasi dari pejabat pemerintah yang berwenang atau lembaga yang diakui di negara asal dan dilegalisir oleh Kedutaan Besar/Konsulat Jendral Republik Indonesia setempat untuk pabrik yang berlokasi di luar negara ASEAN.

KEPALA BADAN PENGAWAS OBAT DAN MAKANAN
REPUBLIK INDONESIA,

ttd.

KUSTANTINAH

資料來源：Kriteria dan Tata Cara Pengajuan Notifikasi Kosmetika

圖九、越南化粧品登錄表單

Phụ lục số 01-MP

PHẦN DÀNH CHO CƠ QUAN QUẢN LÝ (FOR OFFICIAL USE)

Ngày nhận (Date acknowledged):

Số công bố (Product Notification No.):

Phiếu công bố có giá trị 05 năm kể từ ngày nhận.

PHIẾU CÔNG BỐ SẢN PHẨM MỸ PHẨM
TEMPLATE FOR NOTIFICATION OF COSMETIC PRODUCT

☑ Đánh dấu vào ô thích hợp *(Tick where applicable)*

THÔNG TIN SẢN PHẨM
PARTICULARS OF PRODUCT

1. Tên nhãn hàng và tên sản phẩm (Name of brand & product) :

1.1 Nhãn hàng (Brand)

1.2 Tên sản phẩm (Product Name)

1.3 Danh sách các dạng hoặc màu (List of Variants or Shade). Tên (Names)

2. Dạng sản phẩm (Product type(s))

1

- ☐ Kem, nhũ tương, sữa, gel hoặc dầu dùng trên da (tay, mặt, chân, ….)
  Creams, emulsions, lotions, gels and oils for skin (hands, face, feet, etc.)
- ☐ Mặt nạ (chỉ trừ sản phẩm làm bong da nguồn gốc hoá học)
  Face masks (with the exception of chemical peeling products)
- ☐ Chất phủ màu (lỏng, nhão, bột)
  Tinted bases (liquids, pastes, powders)
- ☐ Phấn trang điểm, phấn dùng sau khi tắm, bột vệ sinh,…
  Make-up powders, after-bath powder, hygienic powders, etc.
- ☐ Xà phòng tắm, xà phòng khử mùi,…
  Toilet soaps, deodorant soaps, etc
- ☐ Nước hoa, nước thơm dùng vệ sinh,….
  Perfumes, toilet waters and eau de Cologne
- ☐ Sản phẩm dùng để tắm hoặc gội (muối, xà phòng, dầu, gel,…)
  Bath or shower preparations (salts, foams, oils. gels, etc.)
- ☐ Sản phẩm tẩy lông
  Depilatories
- ☐ Sản phẩm khử mùi và chống mùi.
  Deodorants and anti-perspirants
- ☐ Sản phẩm chăm sóc tóc
  Hair care products
  - Nhuộm và tẩy màu tóc
    Hair tints and bleaches
  - Uốn tóc, duỗi tóc, giữ nếp tóc
    Products for waving, straightening and fixing,
  - Các sản phẩm định dạng tóc
    Setting products,
  - Sản phẩm làm sạch (sữa, bột, dầu gội)
    Cleansing products (lotions, powders, shampoos),
  - Sản phẩm cung cấp chất dinh dưỡng cho tóc (sữa, kem, dầu),
    Conditioning products (lotions, creams, oils),
  - Các sản phẩm tạo kiểu tóc (sữa, keo xịt tóc, sáp)
    Hairdressing products (lotions, lacquers, brilliantines)
- ☐ Sản phẩm dùng cạo râu hoặc sau khi cạo râu (kem, xà phòng, sữa,...)
  Shaving product (creams, foams, lotions, etc.)
- ☐ Sản phẩm trang điểm và tẩy trang dùng cho mặt và mắt
  Products for making-up and removing make-up from the face and the eyes
- ☐ Sản phẩm dùng cho môi
  Products intended for application to the lips
- ☐ Sản phẩm để chăm sóc răng và miệng
  Products for care of the teeth and the mouth
- ☐ Sản phẩm dùng để chăm sóc và tô điểm cho móng tay, móng chân
  Products for nail care and make-up
- ☐ Sản phẩm dùng để vệ sinh cơ quan sinh dục ngoài
  Products for external intimate hygiene
- ☐ Sản phẩm chống nắng
  Sunbathing products
- ☐ Sản phẩm làm sạm da mà không cần tắm nắng
  Products for tanning without sun
- ☐ Sản phẩm làm trắng da

Skin whitening products

☐ Sản phẩm chống nhăn da
Anti-wrinkle products

☐ Sản phẩm khác (đề nghị ghi rõ)
Others (please specify)

3. Mục đích sử dụng (Intended use)

_____

_____

4. Dạng trình bày (Product presentation(s))

☐ Dạng đơn lẻ (Single product)

☐ Một nhóm các màu (A range of colours)

☐ Bảng các màu trong một dạng sản phẩm (Palette(s) in a range of one product type)

☐ Các sản phẩm phối hợp trong một bộ sản phẩm (Combination products in a single kit)

☐ Các dạng khác (đề nghị ghi rõ). Others (please specify)

THÔNG TIN Về NHà SảN XUấT/ ĐóNG GóI

(Đề nghị đính kèm danh sách riêng nếu như có nhiều hơn một công ty tham gia sản xuất/ đóng gói để tạo ra một sản phẩm hoàn chỉnh)

PARTICULARS OF MANUFACTURER (S)/ASSEMBLER(S)

(Please attach in a separate sheet if there are more than one manufacturer/assembler)

5. Tên nhà sản xuất (Name of manufacturer) :

Địa chỉ nhà sản xuất (Nước sản xuất) (Address of manufacturer (state country):

C o u n t r y

Tel: Fax:

6. Tên công ty đóng gói (đề nghị đánh dấu vào mục thích hợp. Có thể đánh dấu nhiều hơn 1 ô (Name of assembler (Please tick accordingly. May tick more than one box)):

☐ Đóng gói chính
Primary assembler

☐ Đóng gói thứ cấp
Secondary assembler

3

Địa chỉ của công ty đóng gói (Address of assembler (state country)):

Country

Tel: Fax:

THÔNG TIN VỀ TỔ CHỨC, CÁ NHÂN CHỊU TRÁCH NHIỆM ĐƯA SẢN PHẨM MỸ PHẨM RA THỊ TRƯỜNG

PARTICULARS OF LOCAL COMPANY RESPONSIBLE FOR PLACING THE COSMETIC PRODUCT IN THE MARKET

7. Tên công ty (Name of company):

Địa chỉ công ty (Address of company):

Tel: Fax:

Số giấy phép kinh doanh/Số giấy phép hoạt động

Business Registration Number/License to Operate Number

THÔNG TIN VỀ NGƯỜI ĐẠI DIỆN THEO PHÁP LUẬT CỦA CÔNG TY

PARTICULARS OF PERSON REPRESENTING THE LOCAL COMPANY

8. Họ và tên (Name of person):

Tel: Email:

Chức vụ ở công ty (Designation in the company) :

THÔNG TIN VỀ CÔNG TY NHẬP KHẨU

PARTICULARS OF IMPORTER

9. Tên công ty nhập khẩu/ Name of Importer:

Địa chỉ công ty nhập khẩu/ Address of importer:

Tel: Fax:

DANH SÁCH THÀNH PHẦN
PRODUCT INGREDIENT LIST

10. Đề nghị kiểm tra ô sau đây (Please check the following boxes)

☐ Tôi đã kiểm tra bản sửa đổi từ Phụ lục II đến Phụ lục VII của danh mục các thành phần mỹ phẩm ASEAN như được công bố trên bản sửa đổi gần đây nhất của Hiệp định mỹ phẩm ASEAN. Tôi xin xác nhận rằng sản phẩm được đề cập đến trong bản công bố này không chứa bất cứ một thành phần bị cấm nào và cũng tuân thủ với danh mục hạn chế và các điều kiện quy định trong các phụ lục.

I have examined the latest revisions of the Annexes II to VII of the ASEAN Cosmetic Ingredient Listing as published in the latest amendment of the ASEAN Cosmetic Directive and confirmed that the product in this notification does not contain any prohibited substances and is in compliance with the restrictions and conditions stipulated in the Annexes.

☐ Tôi đảm nhận trách nhiệm trả lời và hợp tác toàn diện với cơ quan có thẩm quyền về bất kỳ hoạt động kiểm soát sau khi bán hàng khi có yêu cầu bởi cơ quan có thẩm quyền.

I undertake to respond to and cooperate fully with the regulatory authority with regard to any subsequent post-marketing activity initiated by the authority.

Danh sách thành phần đầy đủ (product full ingredient list)

(Yêu cầu ghi đầy đủ danh sách tất cả các thành phần và tỉ lệ % của những chất có giới hạn về nồng độ, hàm lượng sử dụng trong mỹ phẩm - To submit ingredient list with percentages of restricted ingredients)

No	Tên đầy đủ thành phần (tên danh pháp quốc tế hoặc sử dụng tên khoa học chuẩn đã được công nhận) *Full Ingredient name (use INCI or approved nomenclature in standard references)*	Tỉ lệ % của những chất có giới hạn về nồng độ, hàm lượng
1		
2		
3		

4		
5		
6		
7		
8		
9		
...		

Cam kết (DECLARATION)

1. Thay mặt cho công ty, tôi xin cam kết sản phẩm được đề cập trong Phiếu công bố này đạt đượcc tất cả các yêu cầu của Hiệp định mỹ phẩm ASEAN và các phụ lục của nó.

   I hereby declare on behalf of my company that the product in the notification meets all the requirements of the ASEAN Cosmetic Directive, its Annexes and Appendices.

2. Tôi xin chịu trách nhiệm tuân thủ các điều khoản sau đây *(I undertake to abide by the following conditions):*

   i. Đảm bảo có sẵn để cung cấp các thông tin kỹ thuật và tính an toàn khi cơ quan có thẩm quyền yêu cầu và có đầy đủ hồ sơ về các sản phẩm đã được phân phối để báo cáo trong trường hợp sản phẩm phải thu hồi.

   Ensure that the product's technical and safety information is made readily available to the regulatory authority concerned ("the Authority") and to keep records of the distribution of the products for product recall purposes;

   ii. Phải thông báo ngay cho cơ quan có thẩm quyền về các tác dụng phụ nghiêm trọng gây chết người hoặc đe doạ tính mạng của sản phẩm bằng điện thoại, fax, thư điện tử hoặc văn bản trước 7 ngày kể từ ngày biết thông tin.

   Notify the Authority of fatal or life threatening serious adverse event[1] as soon as possible by telephone, facsimile transmission, email or in writing, and in any case, no later than 7 calendar days after first knowledge;

   iii. Phải hoàn thành báo cáo tác dụng phụ của sản phẩm (theo mẫu quy định) trong vòng 8 ngày làm việc kể từ ngày thông báo cho cơ quan có thẩm quyền về những tác dụng phụ nghiêm trọng như đã nêu trong mục 2ii nói trên và cung cấp bất cứ thông tin nào theo yêu cầu của cơ quan có thẩm quyền.

   Complete the Adverse Cosmetic Event Report Form[1] within 8 calendar days from the date of my notification to the Authority in para 2ii. above, and to provide any other information as may be requested by the Authority;

   iv. Thông báo ngay cho cơ quan có thẩm quyền về các phản ứng phụ nghiêm trọng nhưng không gây chết người hoặc đe doạ đến tính mạng của sản phẩm và trong bất cứ trường hợp nào, việc báo cáo (sử dụng mẫu báo cáo) về tác dụng phụ phải được tiến hành trước 15 ngày kể từ ngày biết về tác dụng phụ này.

---

[1] Như đã được định nghĩa rõ ràng trong tài liệu hướng dẫn cho các công ty về báo cáo tác dụng phụ của sản phẩm mỹ phẩm.
As defined in the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products
[1] Trình bày trong phụ lục I trong tài liệu hướng dẫn cho các công ty về báo cáo tác dụng phụ của sản phẩm mỹ phẩm.
Set out in Appendix I to the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products

Report to the Authority of all other serious adverse events that are not fatal or life threatening as soon as possible, and in any case, no later than 15 calendar days after first knowledge, using the Adverse Cosmetic Event Report Form;

v. Công bố với cơ quan có thẩm quyền khi có bất cứ sự thay đổi nào trong bản công bố này.

Notify the Authority of any change in the particulars submitted in this notification;

3. Tôi xin cam đoan rằng những thông tin được đưa ra trong bản công bố này là đúng sự thật. Tất cả các tài liệu, các thông tin liên quan đến nội dung công bố sẽ được cung cấp và các tài liệu đính kèm là bản hợp pháp hoặc sao y bản chính.

I declare that the particulars given in this notification are true, all data, and information of relevance in relation to the notification have been supplied and that the documents enclosed are authentic or true copies.

4. Tôi hiểu rằng tôi sẽ có trách nhiệm để đảm bảo tất cả các lô sản phẩm của chúng tôi đều đáp ứng các yêu cầu pháp luật, và tuân thủ tất cả tiêu chuẩn và chỉ tiêu sản phẩm đã được công bố với cơ quan có thẩm quyền.

I understand that I shall be responsible for ensuring that each consignment of my product continues to meet all the legal requirements, and conforms to all the standards and specifications of the product that I have declared to the Authority.

5. Tôi hiểu rằng trong trường hợp có tranh chấp pháp luật, tôi không được quyền sử dụng bản công bố sản phẩm mỹ phẩm đã được cơ quan có thẩm quyền chấp nhận nếu sản phẩm của chúng tôi không đạt được các yêu cầu về tiêu chuẩn, chỉ tiêu mà chúng tôi đã công bố.

I understand that I cannot place reliance on the acceptance of my product notification by the authority in any legal proceedings concerning my product, in the event that my product has failed to conform to any of the standards or specifications that I had previously declared to the Authority.

_____

Tên và chữ ký của người đại diện theo pháp luật của công ty

[Name and Signature of person representing the local company]

_____ _____

Dấu của công ty

[Company stamp]

Ngày *[Date]*

7

資料來源：Quy định về quản lý mỹ phẩm (06/2011/TT-BYT)

三、 產品資訊檔案(PIF)

東協產品資訊檔案管理，各成員國主要是依據東協化粧品指令(ASEAN Cosmetic Directive, 2008)來制定國內法規，與產品資訊檔案相關之條文於第八條 產品資訊及第九條 分析方法中說明，其相關規定如下(參見表四)：

第八條 產品資訊(Product Information)：

(1) 負責化粧品上市的負責公司或人應依照本指令第六條規定在產品標示之地址保留以下資料，以供成員國之主管機關審查。

(2) 所提供之資料應使用一種或多種成員國使用之語言，或主管機關易懂的語言。

(3) 為了達到迅速或適當的醫療目的，成員國可以要求主管機關提供化粧品成分　　之適當且充分的資料，主管機關應確保該資料只使用在上述的醫療目的。

A. 產品成分之定性及定量，香水則為成分名稱、代碼及供應商識別資料。

B. 原料及成品之規格書。

C. 符合「東協化粧品優良製造指引」規定之製造方法，進口或製造化粧品之負責人應具有充分的知識或經驗。

D. 產品及成分、化學結構和暴露量對於人體健康的安全性評估。

E. 現有使用化粧品對人體健康導致不良反應的任何數據。

F. 證明化粧品宣稱功能的支持數據，已證明其合理性。

第九條 分析方法(Method of Analysis)：負責化粧品上市的負責公司或人應向主管機關提供以下資料：

(1) 由製造商提供可檢驗之方法，以確認化粧品成分是否符合檢驗證明書 (Certificate of Analysis, COA)

(2) 化粧品微生物管控及化粧品成分純度之規格，和(或)可確認之檢驗方法。

除指令規範外，東協另有針對「產品資訊檔案指引」，對於指令有更詳細說明並且提出建議之架構，產品資訊檔案可分為四個部分，其內容如下：

第一部分：產品的管理文件及關鍵資訊概述

(1)行政資料：

產品登錄確認書影本；將包含產品的識別，負責將化粧品上市的製造廠、分裝商、輸入商的地址。

如所在成員國有需要，應提供產品所有者的授權書或產品相關的協議文件。

當地主管機關公告要求的任何相關行政文件，如：公司或商業營業登記證明。

(2)產品配方之定性及定量(以國際化粧品成分名稱 INCI 或東協化粧品指令 ACD 認可的命名法，以及成分含量)：

A. 如為香精成分，則應包含成分名稱、識別碼以及供應商識別等。

(3)產品外觀及標示：

A.內外包裝標示(照片或圖片)

B.仿單或說明書。

(4)製造聲明：

A.製造商或公司提出的聲明，須聲明產品之製造符合東協化粧品優良製造規範導則(the ASEAN GMP Guidelines)或任何東協化粧品委員會(ACC)認可等同於 GMP 者。

B.提供產品批號系統。

(5)根據東協化粧品安全評估指引之安全評估(簡述)：

A.安全聲明(簽署的聲明書應包含安全評估員的簽名及資格證明)。

(6)經證實對人體產生之不良反應(簡述)：

(7)產品宣稱支持數據(簡述)：

A.產品功能評估報告，以添加成分推論或實際測試。

第二部分：成分品質資料：此部分提供成分品質相關的完整技術資訊。

(1)成分之規格及檢驗方法：

A.各成分之檢驗規格，包含製程所用之水。

B.可採用之檢驗或鑑別方法。

C.香精或香料應說明成分名稱及識別碼、供應商名稱及地址，符合最新 International Fragrance Association (IFRA)指引之聲明書。

(2)成分安全性資料：可自供應商、東協化粧品科學會(ASEAN Cosmetic Scientific Body, ACSB)、歐盟消費品科學委員會(EU Scientific Committee on Consumer Products, SCCP)或美國化粧品成分評估委員會 US Cosmetic Ingredient Review Board, CIR)等機構取得。

第三部分：產品品質資料：此部分提供產品品質相關的完整技術資訊。

(1)產品配方之定性及定量(以國際化粧品成分名稱 INCI 或東協化粧品指令 ACD 認可的命名法，以及成分含量)：

A.說明配方中每一成分的功能。

(2)製造資訊：

A.包含製造廠、組裝廠或包裝廠之名稱、國家、地址及電話。

B.簡述產品製造流程。

C.詳細製程資訊或品質管制等相關資料必要時主管機關得要求提供。

(3)產品檢驗規格及方法：

A.產品的微生物及成分之化學純度的標準。

B.可確認符合規格之分析方法。

(4)產品安定性報告(產品儲存時間低於三十個月者)：

A.支持保存有效期限的安定性試驗結果或安定性評估。

第四部分：安全性及功能性資料：此部分應提供詳細的產品之安全評估數據，以及產品宣稱功能支持數據。

(1)安全性評估：

A.根據成分、化學結構及暴露量所進行的產品對人體安全評估報告，且應有合格安全評估員之簽署。

B.安全評估員資格證明。

(2)使用產品造成人體健康上之任何不良反應或副作用的最新報告：

A.產品資訊檔案內之不良反應報告應定期更新。

(3)產品宣稱支持數據：

A.由添加成分功效推論或實際測試結果之簽署功效報告。

B.其他佐證宣稱效能之學術文獻，以證明產品特性及效果。

表四、東協之產品資訊檔案管理

法源	1. ASEAN Cosmetic Directive(Art.8 & 9) 2. Guidelines for Product Information File (PIF)
保存人	Responsible Person (company or person)
文件格式	電子檔或紙本
取得位置	包裝標示之地址
語言	主管機關易懂為原則(英語)
保存時間	至少 3 年

出處：ACD-Guidelines for Product Information File (PIF) (2007.6.13)

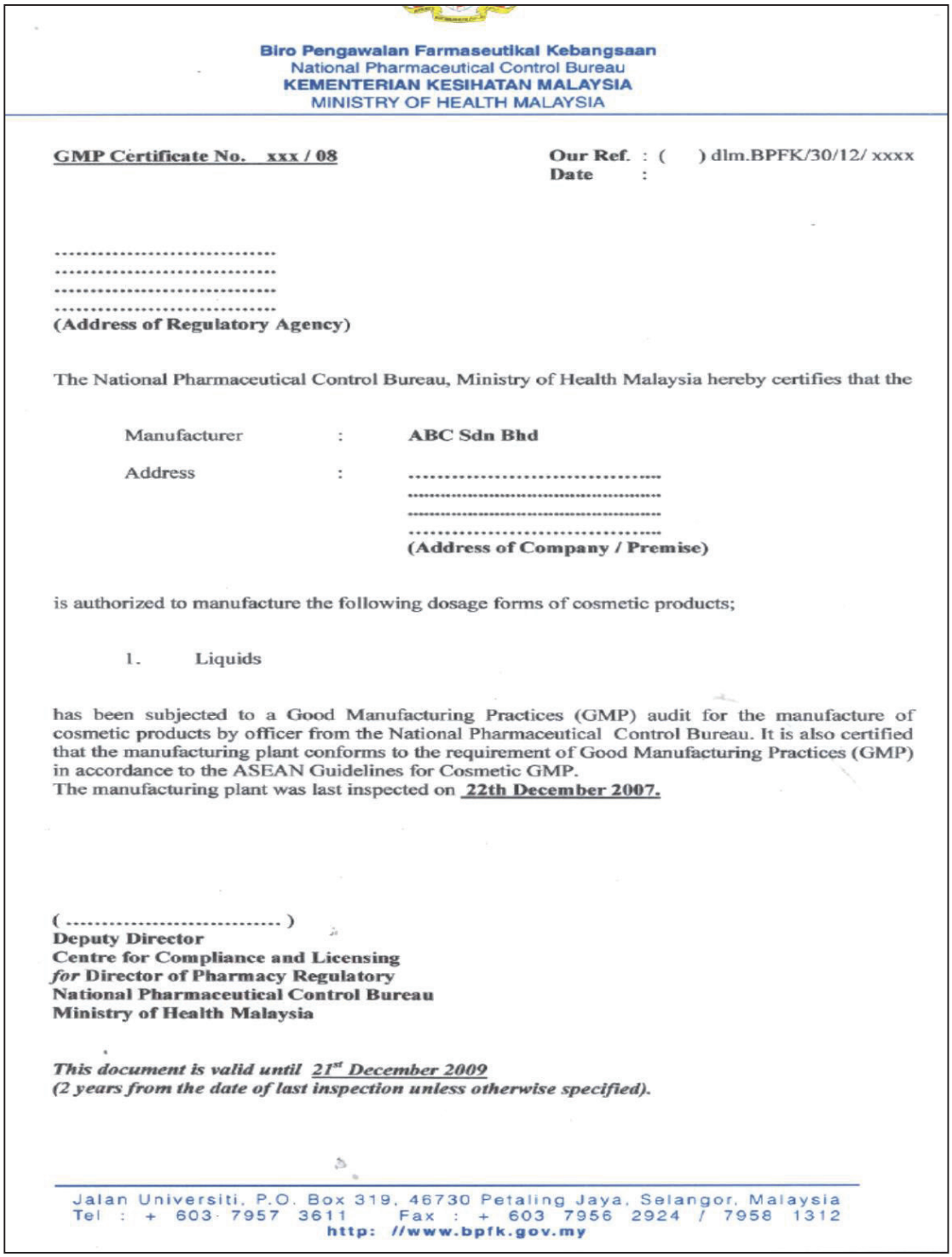
四、 化粧品優良製造(GMP)

東協化粧品優良製造規範導則(The ASEAN GMP Guidelines)公告於東協化粧品指令 Appendix VI 中，並規定化粧品生產工廠需符合 GMP 規範，或其他 ASEAN 認可的工廠品質系統，如：WHO for pharmaceuticals、 PIC/S Australia for pharmaceuticals 、ISO 22716 。凡在東協境內生產與銷售之化粧品，均須符合 GMP 規範，進口產品亦然。此五項等同之標準採認於東協共同簽署化粧品協議時，由各國同意並採認，其中 ISO D/S 22716 目前已是正式公告之版本而非草案版本。東協化粧品 GMP 規定化粧品生產工廠必須針對以下章節執行相關規定，包括品質系統、人員、廠房、設備、衛生、生產、品管、文件、內部稽核、儲存、外包(包括生產與分析)、客戶抱怨、產品召回等十三章節。

東協 ACD 對於化粧品 GMP 的相關法規列於第 Appendix VI 章，目前是採取自我宣告(Self disclaim)的方式由廠商填具切結書(圖十)。在某些東協國家，對於有特殊需求的廠商也提供由政府於驗證通過後發給 GMP 證書的措施，例如：馬來西亞(圖四)、泰國(圖五)、印尼(圖六~九)等。

出處：ACD-Appendix VI (2008)

圖十、馬來西亞 GMP 證書



Biro Pengawalan Farmaseutikal Kebangsaan
National Pharmaceutical Control Bureau
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

GMP Certificate No. xxx / 08

Our Ref. : ( ) dlm.BPFK/30/12/ xxxx
Date :

.....
.....
.....
.....
(Address of Regulatory Agency)

The National Pharmaceutical Control Bureau, Ministry of Health Malaysia hereby certifies that the

Manufacturer : **ABC Sdn Bhd**

Address : .....
.....
.....
.....
(Address of Company / Premise)

is authorized to manufacture the following dosage forms of cosmetic products;

1. Liquids

has been subjected to a Good Manufacturing Practices (GMP) audit for the manufacture of cosmetic products by officer from the National Pharmaceutical Control Bureau. It is also certified that the manufacturing plant conforms to the requirement of Good Manufacturing Practices (GMP) in accordance to the ASEAN Guidelines for Cosmetic GMP.
The manufacturing plant was last inspected on **22th December 2007.**

(.....)
Deputy Director
Centre for Compliance and Licensing
***for* Director of Pharmacy Regulatory**
National Pharmaceutical Control Bureau
Ministry of Health Malaysia

This document is valid until 21st December 2009
(2 years from the date of last inspection unless otherwise specified).

Jalan Universiti, P.O. Box 319, 46730 Petaling Jaya, Selangor, Malaysia
Tel : + 603 7957 3611 Fax : + 603 7956 2924 / 7958 1312
http: //www.bpfk.gov.my

圖十一、泰國 GMP 證書

Food and Drug Administration

Ministry of Public Health, Thailand

GMP CERTIFICATE

Ref. No. 1-5-04-17-0X-00007

Issued on : XX April 2006
(發證日期)

It is hereby certified that

X.Y.Z COSMETIC AND MANUFACTURE CO., LTD.

122,122/1 MOO 5 XXXXX XXXXXXXX 5 ROAD,
OMNOI, KRATHUMBAEN, XXX XXXXXXXX 74130 THAILAND (地址)

is found to conform to the current Cosmetic Good Manufacturing Practice laid down in accordanee with the International Standard Requirements.

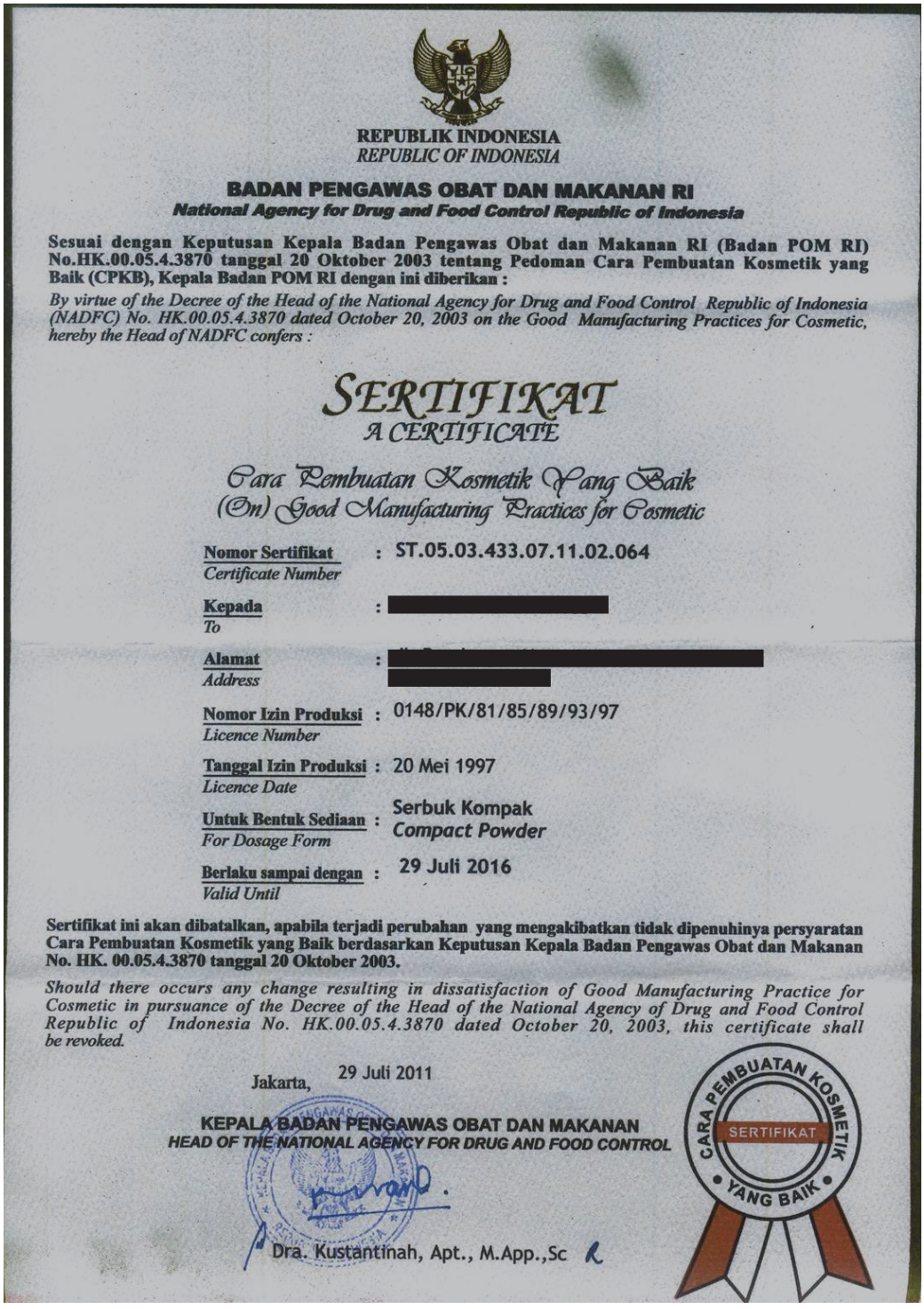
有
證書效期限 :
VALID UNTIL : XX April 2008

Pakdee Pothisiri

(Mr.Pakdee Pothisiri)
Secretary General
Food and Drug Administration

Post-Marketing Inspection Division
Food and Drug Administration, Ministry of Public Health 88/24 Tiwanon Road, Nonthaburi 11000, Thailand
Tel. 66 2590 7273-4 Fax. 66 2591 8468

圖十二、印尼 GMP 證書-粉劑



REPUBLIK INDONESIA
REPUBLIC OF INDONESIA

BADAN PENGAWAS OBAT DAN MAKANAN RI
National Agency for Drug and Food Control Republic of Indonesia

Sesuai dengan Keputusan Kepala Badan Pengawas Obat dan Makanan RI (Badan POM RI) No.HK.00.05.4.3870 tanggal 20 Oktober 2003 tentang Pedoman Cara Pembuatan Kosmetik yang Baik (CPKB), Kepala Badan POM RI dengan ini diberikan :

By virtue of the Decree of the Head of the National Agency for Drug and Food Control Republic of Indonesia (NADFC) No. HK.00.05.4.3870 dated October 20, 2003 on the Good Manufacturing Practices for Cosmetic, hereby the Head of NADFC confers :

SERTIFIKAT
A CERTIFICATE

Cara Pembuatan Kosmetik Yang Baik
(On) Good Manufacturing Practices for Cosmetic

Nomor Sertifikat / *Certificate Number* : ST.05.03.433.07.11.02.064

Kepada / *To* : [redacted]

Alamat / *Address* : [redacted]

Nomor Izin Produksi / *Licence Number* : 0148/PK/81/85/89/93/97

Tanggal Izin Produksi / *Licence Date* : 20 Mei 1997

Untuk Bentuk Sediaan / *For Dosage Form* : Serbuk Kompak / *Compact Powder*

Berlaku sampai dengan / *Valid Until* : 29 Juli 2016

Sertifikat ini akan dibatalkan, apabila terjadi perubahan yang mengakibatkan tidak dipenuhinya persyaratan Cara Pembuatan Kosmetik yang Baik berdasarkan Keputusan Kepala Badan Pengawas Obat dan Makanan No. HK. 00.05.4.3870 tanggal 20 Oktober 2003.

Should there occurs any change resulting in dissatisfaction of Good Manufacturing Practice for Cosmetic in pursuance of the Decree of the Head of the National Agency of Drug and Food Control Republic of Indonesia No. HK.00.05.4.3870 dated October 20, 2003, this certificate shall be revoked.

Jakarta, 29 Juli 2011

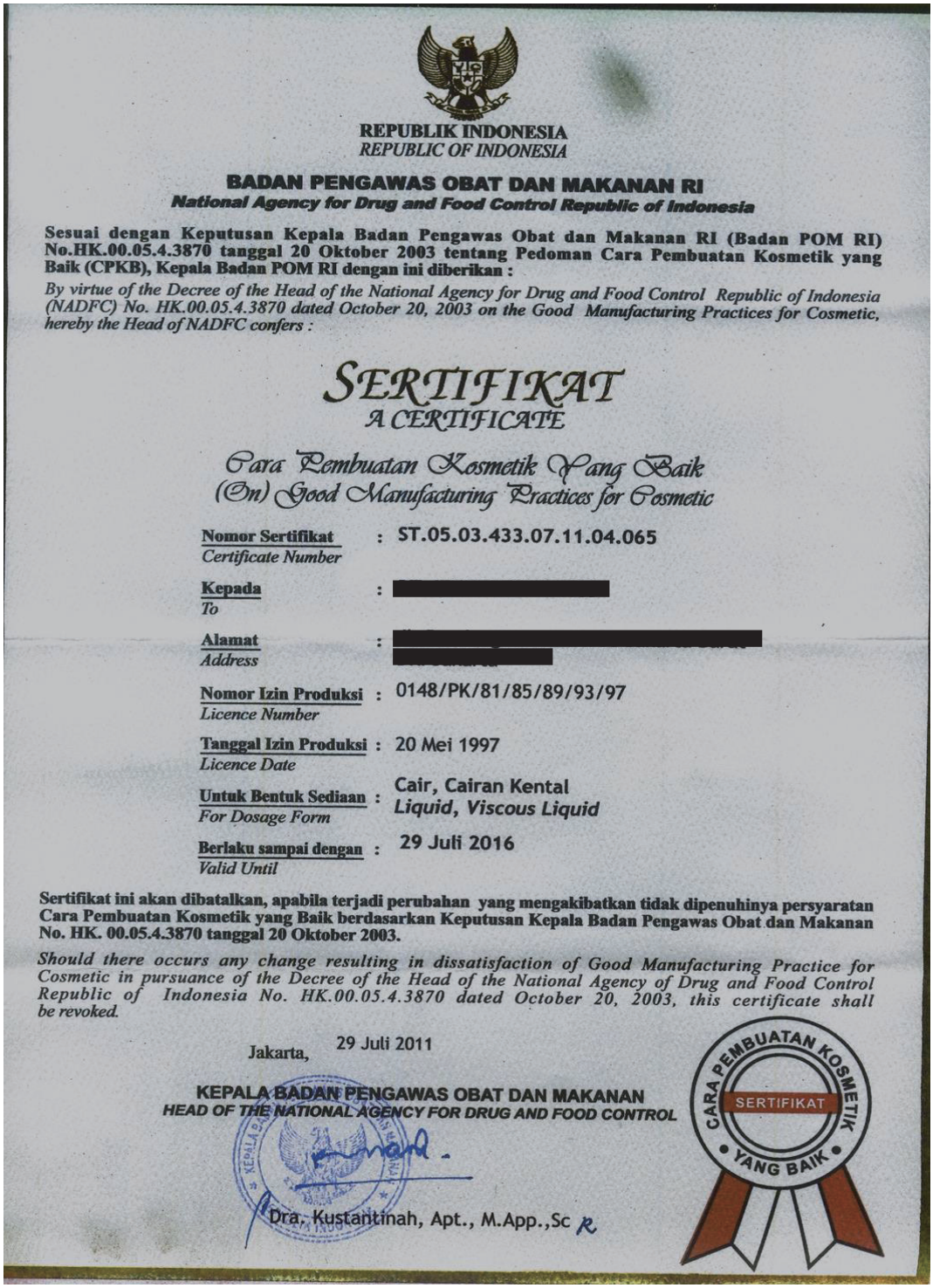
KEPALA BADAN PENGAWAS OBAT DAN MAKANAN
HEAD OF THE NATIONAL AGENCY FOR DRUG AND FOOD CONTROL

Dra. Kustantinah, Apt., M.App.,Sc

CARA PEMBUATAN KOSMETIK YANG BAIK
SERTIFIKAT

(感謝 台南市化粧品公會前理事長林培火先生提供)

圖十三、印尼 GMP 證書-液劑



REPUBLIK INDONESIA
REPUBLIC OF INDONESIA

BADAN PENGAWAS OBAT DAN MAKANAN RI
National Agency for Drug and Food Control Republic of Indonesia

Sesuai dengan Keputusan Kepala Badan Pengawas Obat dan Makanan RI (Badan POM RI) No.HK.00.05.4.3870 tanggal 20 Oktober 2003 tentang Pedoman Cara Pembuatan Kosmetik yang Baik (CPKB), Kepala Badan POM RI dengan ini diberikan :

By virtue of the Decree of the Head of the National Agency for Drug and Food Control Republic of Indonesia (NADFC) No. HK.00.05.4.3870 dated October 20, 2003 on the Good Manufacturing Practices for Cosmetic, hereby the Head of NADFC confers :

SERTIFIKAT
A CERTIFICATE

Cara Pembuatan Kosmetik Yang Baik
(On) Good Manufacturing Practices for Cosmetic

Nomor Sertifikat / *Certificate Number* : ST.05.03.433.07.11.04.065

Kepada / *To* : [redacted]

Alamat / *Address* : [redacted]

Nomor Izin Produksi / *Licence Number* : 0148/PK/81/85/89/93/97

Tanggal Izin Produksi / *Licence Date* : 20 Mei 1997

Untuk Bentuk Sediaan / *For Dosage Form* : Cair, Cairan Kental / *Liquid, Viscous Liquid*

Berlaku sampai dengan / *Valid Until* : 29 Juli 2016

Sertifikat ini akan dibatalkan, apabila terjadi perubahan yang mengakibatkan tidak dipenuhinya persyaratan Cara Pembuatan Kosmetik yang Baik berdasarkan Keputusan Kepala Badan Pengawas Obat dan Makanan No. HK. 00.05.4.3870 tanggal 20 Oktober 2003.

Should there occurs any change resulting in dissatisfaction of Good Manufacturing Practice for Cosmetic in pursuance of the Decree of the Head of the National Agency of Drug and Food Control Republic of Indonesia No. HK.00.05.4.3870 dated October 20, 2003, this certificate shall be revoked.

Jakarta, 29 Juli 2011

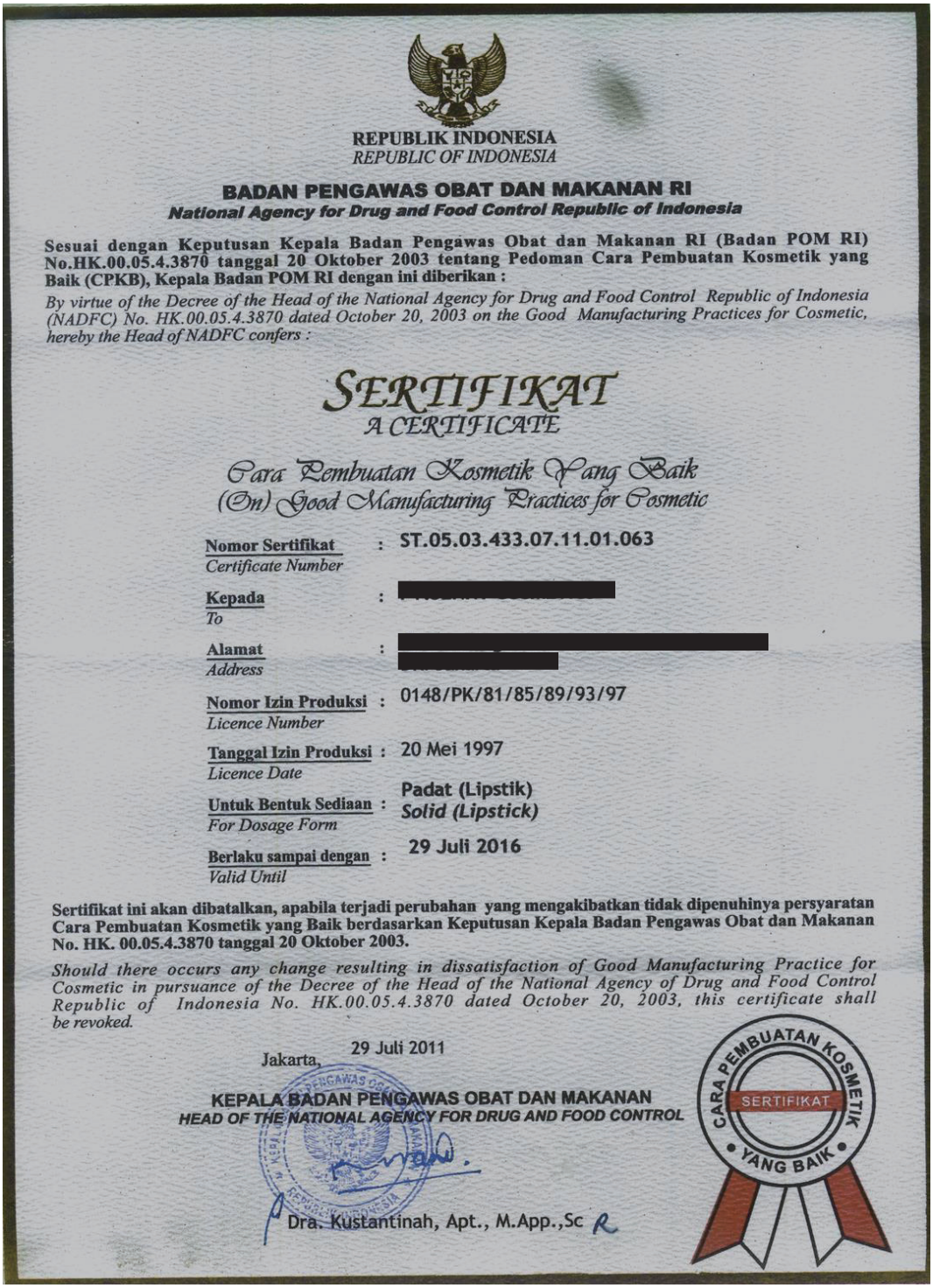
KEPALA BADAN PENGAWAS OBAT DAN MAKANAN
HEAD OF THE NATIONAL AGENCY FOR DRUG AND FOOD CONTROL

Dra. Kustantinah, Apt., M.App.,Sc

CARA PEMBUATAN KOSMETIK YANG BAIK
SERTIFIKAT

(感謝 台南市化粧品公會前理事長林培火先生提供)

圖十四、印尼 GMP 證書-膏劑



REPUBLIK INDONESIA
REPUBLIC OF INDONESIA

BADAN PENGAWAS OBAT DAN MAKANAN RI
National Agency for Drug and Food Control Republic of Indonesia

Sesuai dengan Keputusan Kepala Badan Pengawas Obat dan Makanan RI (Badan POM RI) No.HK.00.05.4.3870 tanggal 20 Oktober 2003 tentang Pedoman Cara Pembuatan Kosmetik yang Baik (CPKB), Kepala Badan POM RI dengan ini diberikan :

By virtue of the Decree of the Head of the National Agency for Drug and Food Control Republic of Indonesia (NADFC) No. HK.00.05.4.3870 dated October 20, 2003 on the Good Manufacturing Practices for Cosmetic, hereby the Head of NADFC confers :

SERTIFIKAT
A CERTIFICATE

Cara Pembuatan Kosmetik Yang Baik
(On) Good Manufacturing Practices for Cosmetic

Nomor Sertifikat *Certificate Number*	:	ST.05.03.433.07.11.01.063
Kepada *To*	:	[redacted]
Alamat *Address*	:	[redacted]
Nomor Izin Produksi *Licence Number*	:	0148/PK/81/85/89/93/97
Tanggal Izin Produksi *Licence Date*	:	20 Mei 1997
Untuk Bentuk Sediaan *For Dosage Form*	:	Padat (Lipstik) *Solid (Lipstick)*
Berlaku sampai dengan *Valid Until*	:	29 Juli 2016

Sertifikat ini akan dibatalkan, apabila terjadi perubahan yang mengakibatkan tidak dipenuhinya persyaratan Cara Pembuatan Kosmetik yang Baik berdasarkan Keputusan Kepala Badan Pengawas Obat dan Makanan No. HK. 00.05.4.3870 tanggal 20 Oktober 2003.

Should there occurs any change resulting in dissatisfaction of Good Manufacturing Practice for Cosmetic in pursuance of the Decree of the Head of the National Agency of Drug and Food Control Republic of Indonesia No. HK.00.05.4.3870 dated October 20, 2003, this certificate shall be revoked.

Jakarta, 29 Juli 2011

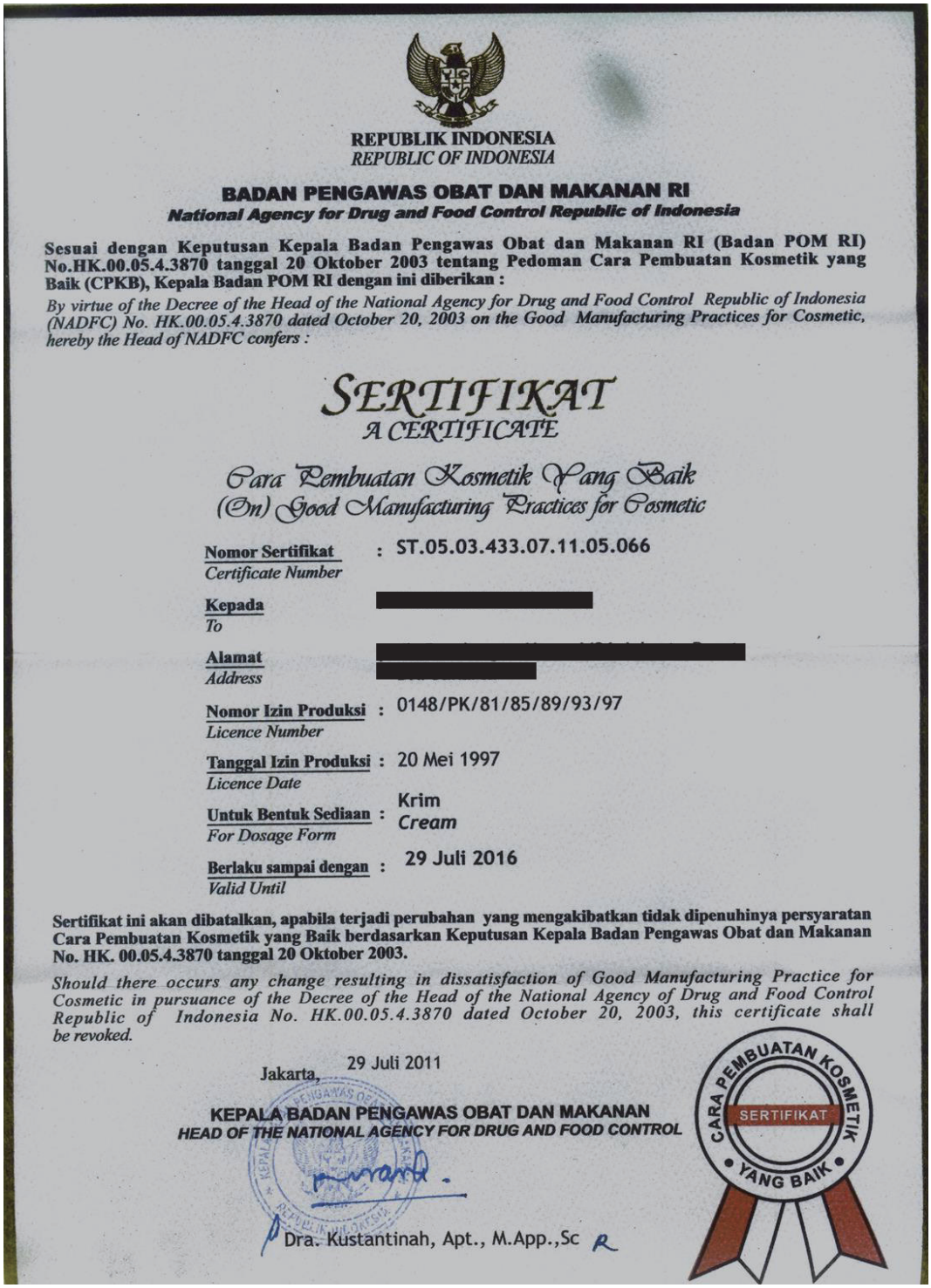
KEPALA BADAN PENGAWAS OBAT DAN MAKANAN
HEAD OF THE NATIONAL AGENCY FOR DRUG AND FOOD CONTROL

Dra. Kustantinah, Apt., M.App.,Sc

CARA PEMBUATAN KOSMETIK SERTIFIKAT YANG BAIK

(感謝 台南市化粧品公會前理事長林培火先生提供)

圖十五、印尼 GMP 證書-乳劑



REPUBLIK INDONESIA
REPUBLIC OF INDONESIA

BADAN PENGAWAS OBAT DAN MAKANAN RI
National Agency for Drug and Food Control Republic of Indonesia

Sesuai dengan Keputusan Kepala Badan Pengawas Obat dan Makanan RI (Badan POM RI) No.HK.00.05.4.3870 tanggal 20 Oktober 2003 tentang Pedoman Cara Pembuatan Kosmetik yang Baik (CPKB), Kepala Badan POM RI dengan ini diberikan :

By virtue of the Decree of the Head of the National Agency for Drug and Food Control Republic of Indonesia (NADFC) No. HK.00.05.4.3870 dated October 20, 2003 on the Good Manufacturing Practices for Cosmetic, hereby the Head of NADFC confers :

SERTIFIKAT
A CERTIFICATE

Cara Pembuatan Kosmetik Yang Baik
(On) Good Manufacturing Practices for Cosmetic

Nomor Sertifikat / *Certificate Number* : ST.05.03.433.07.11.05.066

Kepada / *To* : [redacted]

Alamat / *Address* : [redacted]

Nomor Izin Produksi / *Licence Number* : 0148/PK/81/85/89/93/97

Tanggal Izin Produksi / *Licence Date* : 20 Mei 1997

Untuk Bentuk Sediaan / *For Dosage Form* : Krim / *Cream*

Berlaku sampai dengan / *Valid Until* : 29 Juli 2016

Sertifikat ini akan dibatalkan, apabila terjadi perubahan yang mengakibatkan tidak dipenuhinya persyaratan Cara Pembuatan Kosmetik yang Baik berdasarkan Keputusan Kepala Badan Pengawas Obat dan Makanan No. HK. 00.05.4.3870 tanggal 20 Oktober 2003.

Should there occurs any change resulting in dissatisfaction of Good Manufacturing Practice for Cosmetic in pursuance of the Decree of the Head of the National Agency of Drug and Food Control Republic of Indonesia No. HK.00.05.4.3870 dated October 20, 2003, this certificate shall be revoked.

Jakarta, 29 Juli 2011

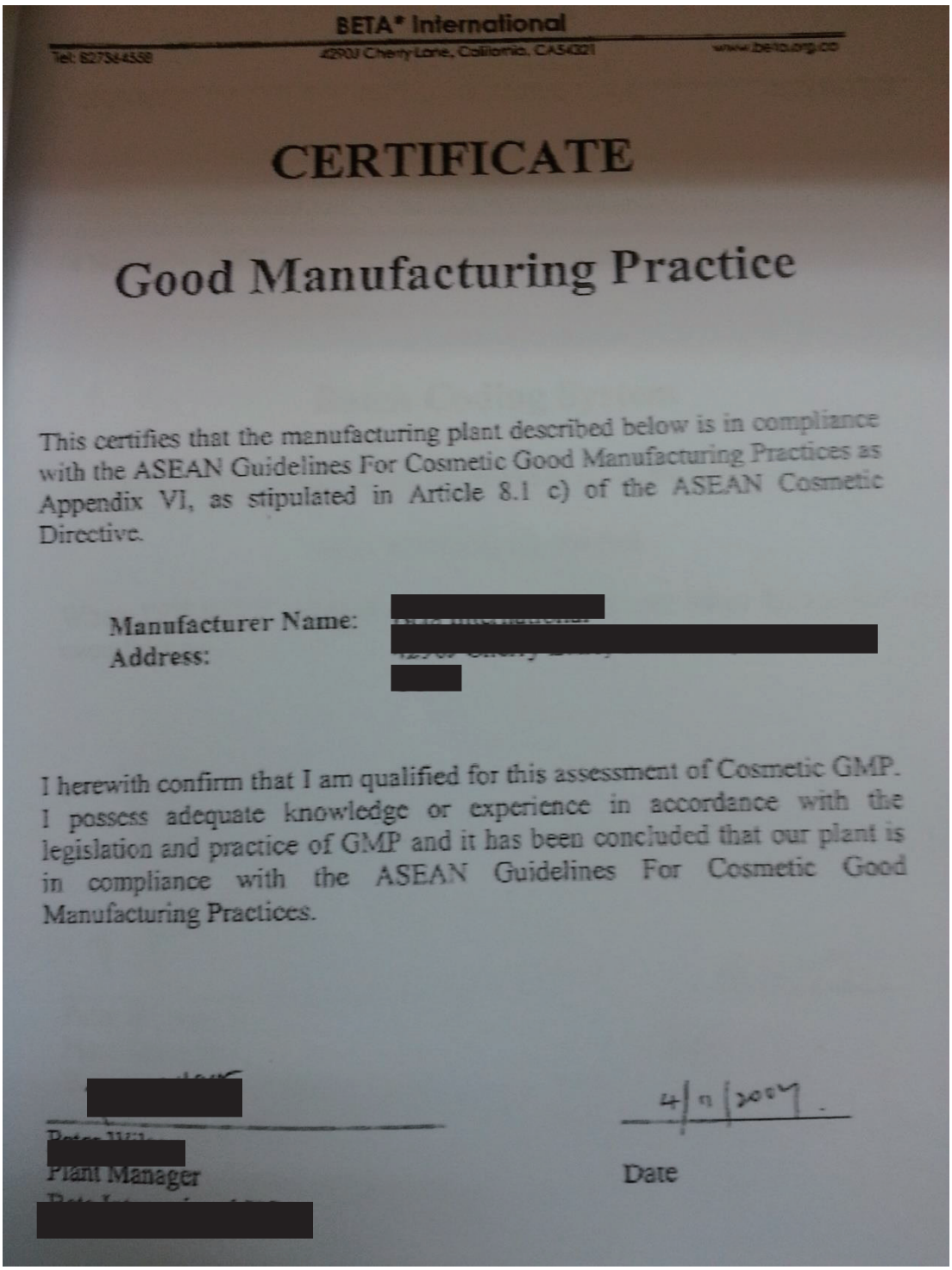
KEPALA BADAN PENGAWAS OBAT DAN MAKANAN
HEAD OF THE NATIONAL AGENCY FOR DRUG AND FOOD CONTROL

Dra. Kustantinah, Apt., M.App.,Sc

CARA PEMBUATAN KOSMETIK YANG BAIK
SERTIFIKAT

(感謝 台南市化粧品公會前理事長林培火先生提供)

圖十六、GMP 自我宣告廠商切結書



BETA® International

Tel: 827564558 4290J Cherry Lane, California, CA54321 www.beta.org.ca

CERTIFICATE

Good Manufacturing Practice

This certifies that the manufacturing plant described below is in compliance with the ASEAN Guidelines For Cosmetic Good Manufacturing Practices as Appendix VI, as stipulated in Article 8.1 c) of the ASEAN Cosmetic Directive.

Manufacturer Name: [redacted]
Address: [redacted]

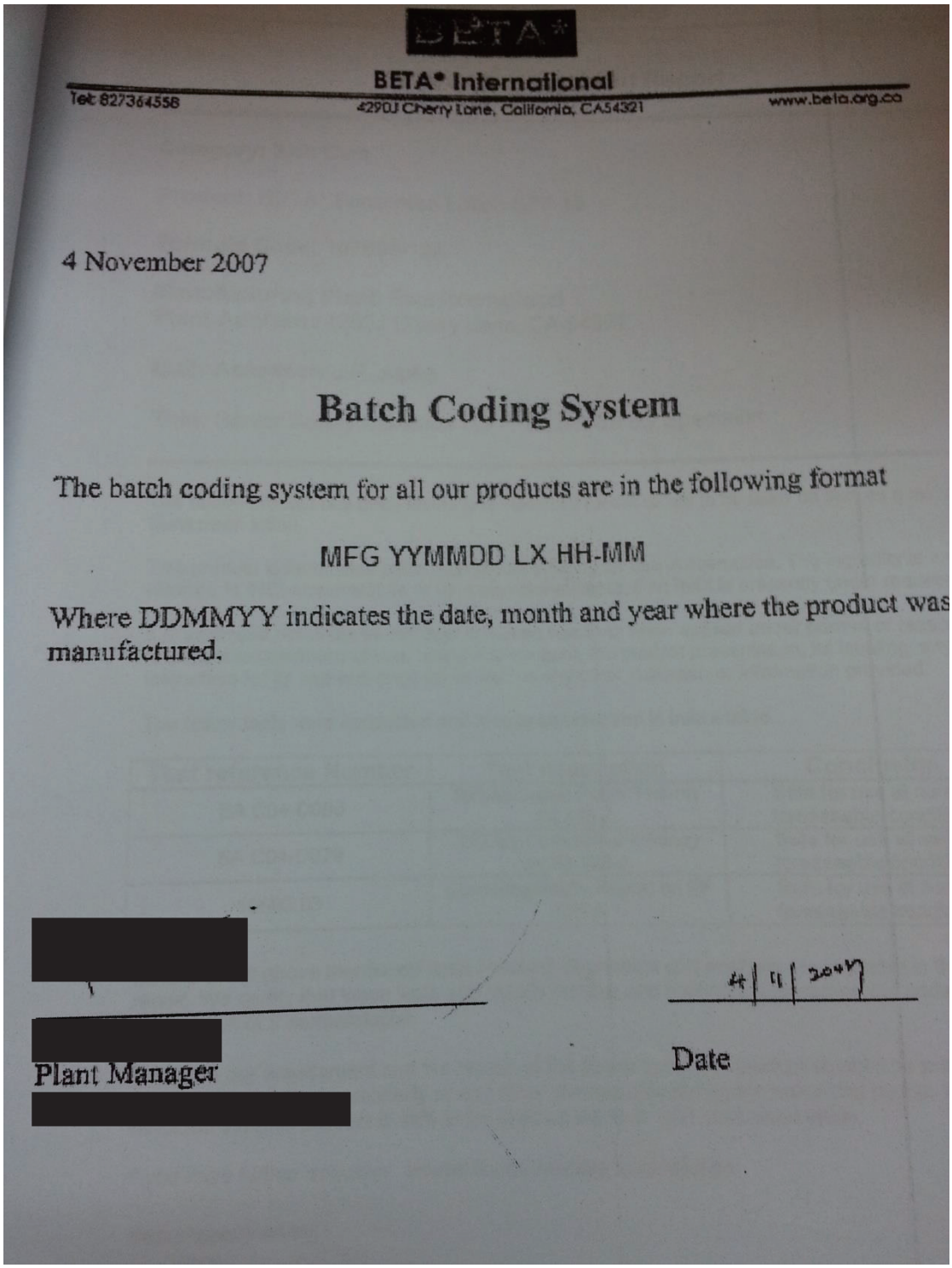
I herewith confirm that I am qualified for this assessment of Cosmetic GMP. I possess adequate knowledge or experience in accordance with the legislation and practice of GMP and it has been concluded that our plant is in compliance with the ASEAN Guidelines For Cosmetic Good Manufacturing Practices.

[redacted]

[redacted]
Plant Manager
[redacted]

4/11/2004

Date



BETA*

BETA* International

Tel: 827364558 | 4290J Cherry Lane, California, CA54321 | www.beta.org.co

4 November 2007

Batch Coding System

The batch coding system for all our products are in the following format

MFG YYMMDD LX HH-MM

Where DDMMYY indicates the date, month and year where the product was manufactured.

[redacted]

[redacted]

Plant Manager

[redacted]

4/11/2047

Date

五、 化粧品標示規定

化粧品外包裝或內包裝(如無外包裝)上應註明以下規定，並文字需清析可辨識、易讀且不易塗改，另需英文及(或)國家語言及(或)消費者所能理解之語言標示：

1. 化粧品名稱與功能(除非產品本身已明顯表示)
2. 化粧品使用說明(除非產品名稱與呈現已明顯表示)
3. 全成份清單
4. 製造商所在國家
5. 產品負責人或公司名稱及住址
6. 包裝時之容量(以重量或體積表示)
7. 生產商批號
8. 生產日期或產品有效日期(如：年/月)
9. 使用注意事項(特別是列在指令內之成份)
10. 若容器或包裝尺寸、形狀或性質不適合上述規定的標示，可使用手冊、標籤、吊牌、顯示板或熱縮塑膠膜等。但小包裝上至少須註明：產品名稱和生產商批號。

法規出處：ASEAN Cosmetics Association, ASEAN Cosmetic Directive - APPENDIX II

六、 原料相關規定

1.化粧品禁用物質

ASEAN 化粧品指令之附錄二–第一部分(Annex II - Part 1) November 2012

2.化粧品限用物質

ASEAN 化粧品指令之附錄三–第一、二部分(Annex III - Part 1,2) November 2012,

3.化粧品中允許使用之色素

ASEAN 化粧品指令之附錄四-第一部分(Annex IV-Part 1) November 2012

4.指令範圍以外的物質

ASEAN 化粧品指令之附錄五(Annex V) 02 December 2009

5.化粧品中允許含有之防腐劑

ASEAN 化粧品指令之附錄六(Annex VI) November 2012

6.化粧品中允許使用之紫外線吸收劑

ASEAN 化粧品指令之附錄七(Annex VII) November 2012

法規出處：ASEAN Cosmetics Association, ASEAN Cosmetic Directive -Technical Documents
http://aseancosmetics.org/default/asean-cosmetics-directive/technical-documents

七、 衛生安全標準

(一)化粧品中微生物容許量

	三歲以下兒童用、眼部周圍用及使用於接觸黏膜部位之化粧品	其他產品
總生菌數 (細菌、酵母菌和黴菌)	≤ 500 cfu/g	≤ 1000 cfu/g
綠膿桿菌 ***(P. aeruginosa)***	-ve per 0.1g or 0.1ml test sample	-ve per 0.1g or 0.1ml test sample
金黃色葡萄球菌 ***(S. aureus)***	-ve per 0.1g or 0.1ml test sample	-ve per 0.1g or 0.1ml test sample
白色念珠菌 ***(C. albicans)***	-ve per 0.1g or 0.1ml test sample	-ve per 0.1g or 0.1ml test sample

法規出處：ASEAN Guidelines on Microbiological Limit in Cosmetic Products (June 2007)

(二)化粧品重金屬限量

重金屬	檢出限量(μg/g)
砷(As)	2.5
鎘(Cd)	1
鉛(Pb)	10
汞(Hg)	0.5

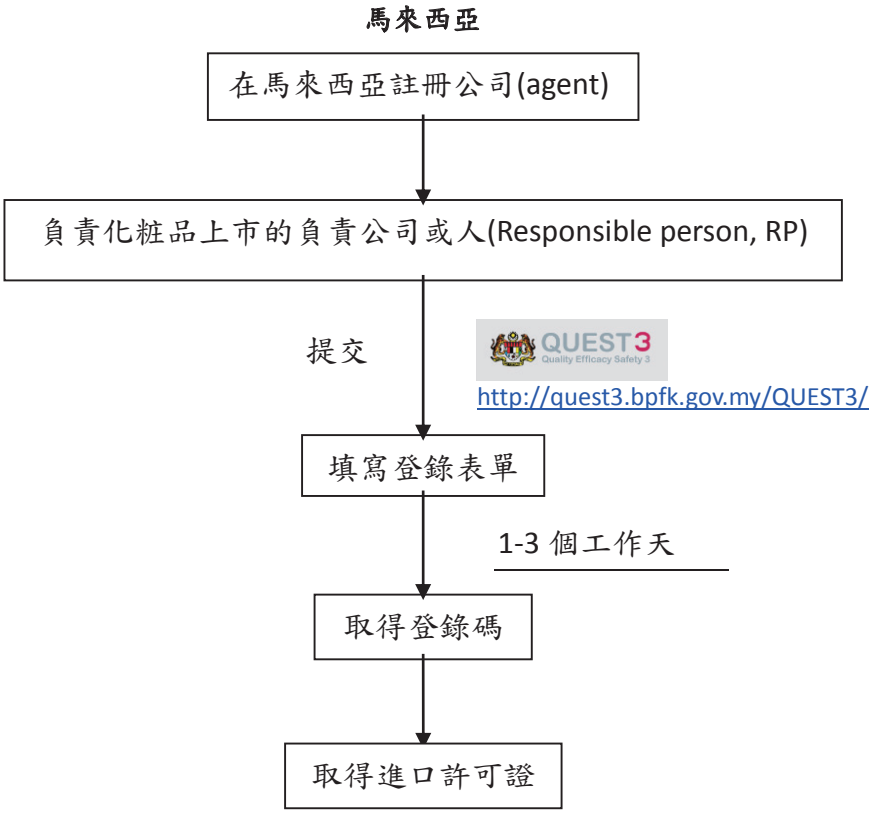
根據東協化粧品指令(ACD)中技術文件之附錄二–第一部分化粧品禁用物質清單明列砷(As)、鎘(Cd)、鉛(Pb)和汞(Hg)為化粧品禁用物質。

若重金屬含量低於檢出限量，則須呈報此「低於檢出限量」；若高於檢出限量，則須呈報此重金屬含量。

法規出處：ASEAN Cosmetics Association, Product Safety Evaluation (PSE) Harmonized Testing Methods-Heavy Metals(2/12/05)

第二章化粧品出口相關規定與流程

壹、出口流程



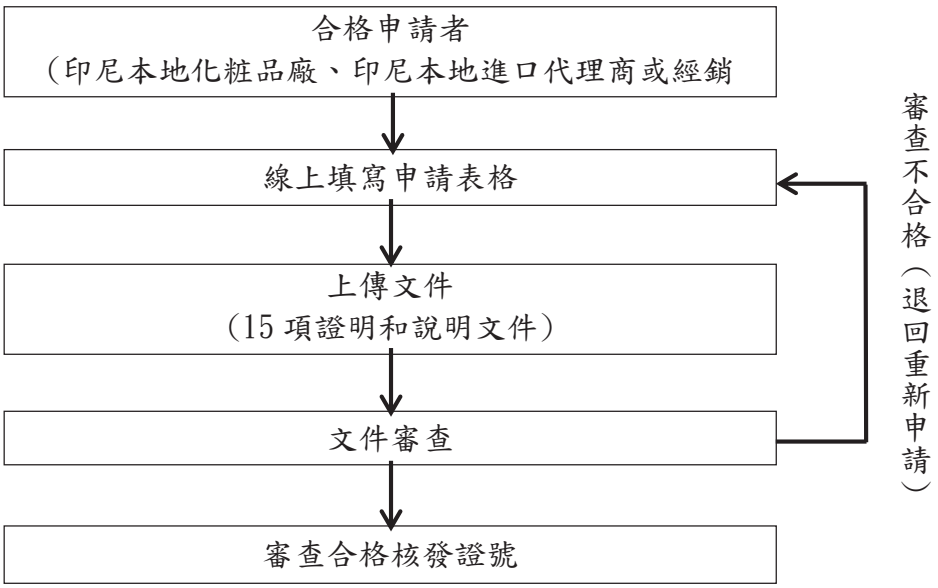
注意事項：

1.若申請者不是該產品的所有者，在提交登錄表單時，必須附有一份該產品所有者的委託授權書。

2.若為一家海外公司欲進口化粧品，則必須委任當地代理人(在馬來西亞的註冊公司)，負責產品登錄的所有事宜。

出處：日本貿易振興機構-マレーシアにおける化粧品の輸入制度(2011 年 12 月)

印尼



BPOM 申請流程圖

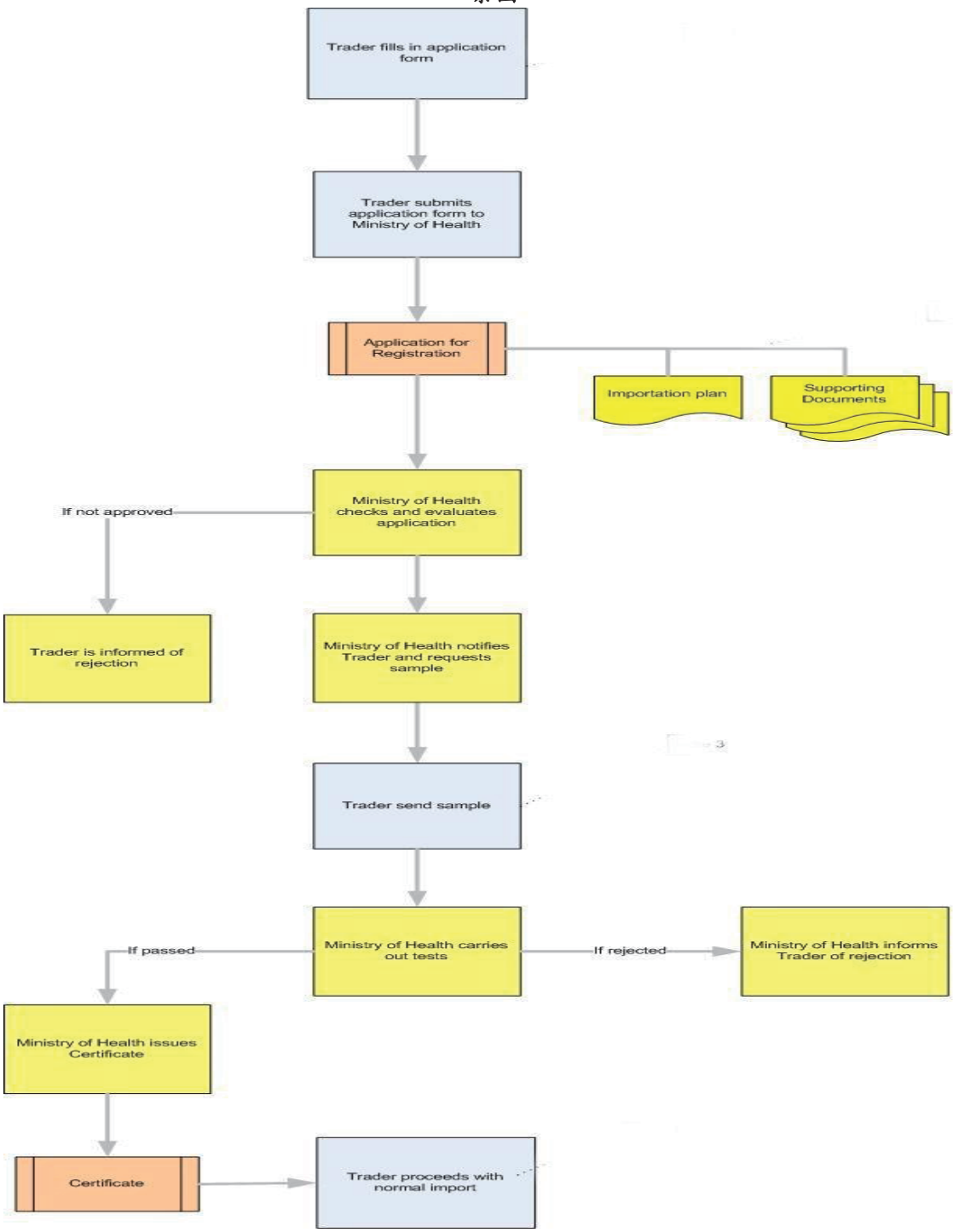
十五項證明和說明文件

文件編號	項目
1	自由銷售證明(需印尼辦事處官印)
2	代理授權書(5 年期效，需印尼辦事處官印)
3	產品成分表
4	成分分析表
5	生產流程(包含主要成分製程)
6	包裝材質說明書
7	完成品分析說明、完成品檢驗分析報告
8	完成品安定性檢驗分析報告
9	產品批號意義說明
10	產品曾經銷售之國家(註明銷售時間)
11	GMP 廠證明(衛生福利部核發之證明，需印尼辦事處官印)
12	所有產品成分之文獻資料(可以期刊文獻資料證明)
13	外部機構檢驗報告(例如 SGS)
14	膠囊產品分析報告(非膠囊品不需提供)
15	產品描述

註：原出口化粧品至印尼須具備化粧品工廠 GMP 認證，惟當地化粧品業者以中小企業為主，難以配合 GMP 制度與作業，實施多年來成效不彰，目前該國已不強制實施 GMP，業者仍可檢附相關文件申請衛字號。

出處：印尼保健食品和美容保養品商機研究(2013)，經濟部國貿局

寮國



進口化粧品流程圖

資料來源：Registration and Import of Drugs, Cosmetics and Traditional Medicines (2014)

表五、東協主要國家進出口相關內容

國家	網址
馬來西亞	http://portal.bpfk.gov.my/index.cfm?&menuid=123
新加坡	http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/cosmetic_products/faq.html
菲律賓	http://www.fda.gov.ph/industry-corner/downloadables/197-asean-cosmetic-harmonization
印尼	http://perkosmi.com/?s=IMPORT
寮國	http://www.laotradeportal.gov.la/
泰國	http://newsser.fda.moph.go.th

貳、稅率

國家	負責單位	網址
馬來西亞	Royal Malaysian Customs Department	http://www.customs.gov.my/
新加坡	Singapore Customs	http://www.customs.gov.sg/
菲律賓	Tariff Commission	http://www.tariffcommission.gov.ph/
印尼	Directorate General of Customs and Excise (DGCE)	http://www.beacukai.go.id/wwwbcgoid/index.html?page=apps/browse-tarif-dan-lartas.html
汶萊	Ministry of Finance	http://www.mof.gov.bn
越南	Vietnam Customs	http://www.customs.gov.vn/English/Lists/CustomsFormalities/Importer.aspx
寮國	Lao Customs	http://laocustoms.laopdr.net/
緬甸	Myanmar Customs Department	http://www.myanmarcustoms.gov.mm
柬埔寨	General Deparment of Customs and Excise of Cambodia (GDCE)	http://www.customs.gov.kh/dutyrateimports.html
泰國	Customs Department	http://igtf.customs.go.th/igtf/en/main_frame.jsp

圖十七、印尼稅率

33.03-33.05

POS/SUBPOSH EADING/SUBH EADING	URAIAN BARANG	DESCRIPTION OF GOODS	BEA MASUK IMPORT DUTY		PAJUK TAX		LARANGAN/PE MBATASAN PROHIBITION/R ESTRICTION	KETERANGAN REMARKS
			UMUM GENERAL (%)	CEPT (%)	PPN VAT (%)	PPnBM SALESTAX ON LUXURY GOODS (%)		
3303.00.00.00	**Parfum dan cairan pewangi.**	**Perfumes and toilet waters.**	10	0	10	20*)	Izin	BPOM
33.04	**Preparat kecantikan atau rias dan preparat untuk perawatan kulit (selain obat-obatan), ter masuk preparat penutup atau pelindung kulit terhadap sinar matahari; preparat manikur atau pedikur.**	**Beauty or make-up preparations and preparations for the care of the skin (other than medicaments), including sunscreen or sun tan preparations; manicure or pedicure preparations.**						
3304.10.00.00	-Preparat rias bibir	-Lip make-up preparations	10	0	10	-		
3304.20.00.00	-Preparat rias mata	-Eye make-up preparations	10	0	10	-		
3304.30.00.00	-Preparat manikur atau pedikur	-Manicure or pedicure preparation	10	0	10	-		
	-Lain-lain :	-Other :						
3304.91.00.00	--Bubuk, dipadatkan maupun tidak	--Powders, whether or not compressed	10	0	10	-		
3304.99	--Lain-lain :	--Other :						
3304.99.10.00	---Krim dan losion untuk wajah dan kulit	---Face and skin creams and lotions	10	0	10	-		
3304.99.20.00	---Krim anti jerawat	---Anti-acne creams	10	0	10	-		
3304.99.90.00	---Lain-lain	---Other	10	0	10	-		
33.05	**Preparat digunakan untuk rambut.**	**Preparations for use on the hair.**						
3305.10.00.00	-Sampo	-Shampoos	10	0	10	-		
3305.20.00.00	-Preparat pengeriting atau pelurus rambut secara permanen	-Preparations for permanent waving or straightening	10	0	10	-		
3305.30.00.00	-Lak rambut	-Hair lacquers	10	0	10	-		
3305.90.00.00	-Lain-lain	-Other	10	0	10	-		

BTBMI 2007

(感謝 台南市化粧品公會前理事長林培火先生提供)

33.06-33.07

POS/SUBPOSHEADING/SUBHEADING	URAIAN BARANG	DESCRIPTION OF GOODS	BEA MASUK IMPORT DUTY		PAJUK TAX		LARANGAN/PEMBATASAN PROHIBITION/RESTRICTION	KETERANGAN REMARKS
			UMUM GENERAL (%)	CEPT (%)	PPN VAT (%)	PPnBM SALESTAX ON LUXURY GOODS (%)		
33.06	**Preparat kesehatan mulut atau gigi, termasuk pasta dan bubuk penguat gigi buatan; benang untuk pembersih sela gigi (dental floss),dalam kemasan tersendiri untuk penjualan eceran.**	**Preparations for oral or dental hygiene, including denture fixative pastes and powders; yarn used to clean between the teeth (dental floss), in individual retail packages.**						
3306.1	-Odol gigi :	-Dentifrices :						
3306.10.10.00	--Pasta dan bubuk profilaksis	--Prophylactic pastes and powders	10	0	10	-		
3306.10.90.00	-Lain-lain :	-Other :	10	0	10	-		
3306.20.00.00	-Benang pembersih sela gigi (dental floss)	-Yarn used to clean between the teeth (dental floss)	5	0	10	-		
3306.90.00.00	-Lain-lain :	-Other :	10	0	10			
33.07	**Preparat yang digunakan sebelum mencukur, sewaktu mencukur, atau sesudah mencukur, deodoran, preparat mandi, preparat perontok bulu dan preparat wewangian, kosmetika atau rias lainnya, tidak dirinci atau termasuk pos lain; preparat penghilang bau ruangan, diberi wewangian atau mengandung desinfektan maupun tidak**	**Pre-shave, shaving or after-shave preparations, personal deodorants, bath preparation, depilatories and other perfumery, cosmetic or toilet preparations, not elsewhere specified or included; prepared room deodorisers, whether or not perfumed or having desinfectant properties.**						
3307.10.00.00	-Preparat yang digunakan sebelum mencukur, sewaktu mencukur atau sesudah mencukur	-Pre-shave, shaving or after-shave preparations	10	0	10	-		
3307.20.00.00	-Deodoran dan antiperspirant	-Personal deodorants and antiperspirants	10	0	10	-		
3307.30.00.00	-Garam pewangi dan preparat lainnya untuk mandi	-Perfumed bath salts and other bath preparations	10	0	10	-		
	-Preparat pewangi atau penghilang bau E25ruangan, termasuk preparat bau-bauan yang digunakan selama ritual keagamaan :	-Preparations for perfuming or deodorizing rooms, including odoriferous preparations used during religious rites :						

BTBMI 2007

(感謝 台南市化粧品公會前理事長林培火先生提供)

第三章 清真 HALAL 化粧品認證

壹、清真組織及範圍

世界清真 Halal 產品唯一國際認證組織為 1999 年成立之「世界清真食品理事會」(World Halal Food Council, WHFC),旨在聯合全球哈拉認證機關,建置哈拉認證與管理之統一規則與標準,目前仍為鬆散之組織,國際間相互認證不需透過 WHFC 取得,相互認證機制之平台尚未建立,僅由兩國友好之 Halal 認證機構,透過認證交流後,相互承認彼此之認證標誌,惟隨著哈拉產品市場之逐漸成長,該協會將逐漸佔有重要地位。中國回教協會並已於 2007 年 11 月加入。2011 年 5 月合組正式成立『台灣清真產業品質保證推廣協會』(THIDA),該協會已整合文化清真寺清真認證團隊,並與中國回教協會協議就清真認證事務分工合作,凡加工食品、生鮮蔬果類之清真認證,均由該協會負責辦理發證;凡國內餐旅業、屠宰業、肉品供應等服務國內教親之認證事務,則由中國回教協會負責辦理發證。

『台灣清真產業品質保證推廣協會』清真證書已獲馬來西亞、印尼、新加坡等國清真驗證單位書面認可。清真驗證事務係近一、二十年來新出現之國際需求,而以馬來西亞、印尼、新加坡等三國較積極推動。

東協主要清真產品認證(Halal Certification)

國家	清真產品認證主管機關
臺灣	中國回教協會(授權單位:台北清真寺和台中清真寺) 台灣清真產業品質保證推廣協會
馬來西亞	伊斯蘭事務發展部 Jabatan Kemajuan Islam Malaysia (JAKIM)
泰國	泰國伊斯蘭中央委員會 The Central Islamic Committee of Thailand (CICOT)
新加坡	新加坡伊斯蘭教理事會 Majlis Ulama Islam Singapura (MUIS)
菲律賓	總統府轄下回教事務辦公室
印尼	宗教學者理事會 Majelis Ulama Indonesia(MUI)

『台灣清真產業品質保證推廣協會』目前已獲書面認可之國外官方機構，及加入為會員之國際組織如下：

1. 馬來西亞：伊斯蘭事務發展部 (JabatanKamajuan Islam Malaysia—JAKIM, Department of Islamic Development Malaysia)，獲其認可之國外清真驗證單位 71 個/45 國(2013/2/15)。

   網站：http://www.islam.gov.my/

2. 印尼：宗教學者理事會 (MajelisUlama Indonesia—MUI, Indonesian Council of Ulama)，獲其認可之國外清真驗證單位 45 個/20 國(2011/12/31)。

   網站：http://www.mui.or.id/

3. 新加坡：新加坡伊斯蘭教理事會(Majlis Ugama Islam Singpura—MUIS, Islamic Religious Council of Singapore)。

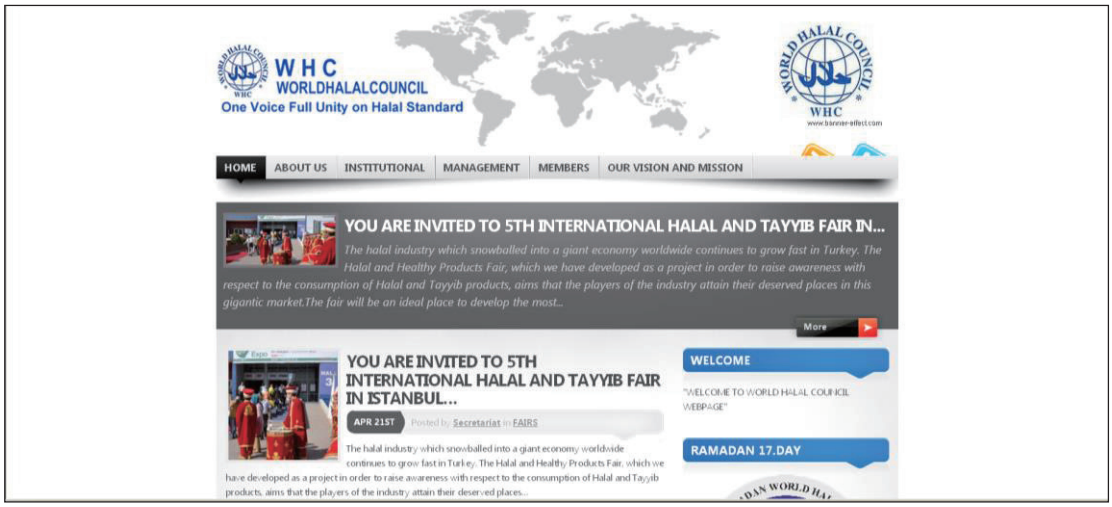
網站：http://www.muis.gov.sg/cms/index.aspx

4. 國際清真品保聯盟(International Halal Integrity Alliance – IHI)：總部設於馬來西亞吉隆坡，會員約 20 個。

網站：http://www.ihialliance.org/home.php

5. 世界清真食品理事會(World Halal Food Council—WHFC)：總部設於印尼雅加達，會員約 35 個。

網站：http://www.worldhalalcouncil.com/



貳、驗證申請程序

1. **廠商洽詢：**向台灣清真產業品質保證推廣協會(以下簡稱協會)認可之各地清真寺（以下簡稱各寺）洽詢申請事宜，索取申請書。
2. **提出申請：**填寫申請書表，並檢送所須文件（如「二、條件與規定」)。
3. **文件審查：**由協會協辦單位進行文件初審及覆審，並通知申請廠商提供補件或改正，直至符合教法要求，由文件審核人員做成文件覆審報告轉送協會。
4. **勘查現場：**文件經覆審完畢，協會將請協辦單位承辦人員聯絡申請廠商，由廠商安排協會與各寺驗證人員赴生產現場實際查勘。勘查內容包括確認原料與添加物及其倉儲、產品製程、包裝、設備清洗以及成品倉儲，並確認生產現場無任何供奉、祭祀之設置以及其他伊斯蘭教法所禁止之產品。勘廠完畢後由稽核人員做成勘廠報告，與文件初、覆審報告合併為申請案報告。
5. **審查會議：**由教法及技術顧問、文件審核人員、勘廠稽核人員開會審查各申請案，決議是否通過，並將結果通知申請廠商。
6. **驗證簽約：**申請案審核通過後，雙方約定簽約日期，協會將安排公證人見證合約之簽訂並發給證書。
7. **後續輔導：**在合約簽訂後六個月內，通過驗證之廠商必須成立一公司內部之清真品保小組，組員並須通過協會之清真品保訓練課程。合約期間協會與各寺將派員訪廠作不定期查驗以確保合約有效執行。
8. **期滿續約：**領證廠商應於合約期滿前至少一個月主動提出申請續約，以利合約延續；協會得於合約期滿前兩個月寄發續約通知。

出處：台灣清真產業品質保證推廣協會-清真食用品-美妝品(Release 2.1)

參、清真驗證條件與規定

1. 伊斯蘭 HALAL 食(用)品概述

1.1. 自古以來人類對食飲的問題，什麼可食飲，什麼不可食飲，各有見解。伊斯蘭教對飲食的規定係來自造物主。阿拉伯文中，「HALAL」意為合法或美好，「HARAM」意為非法或禁止，合法與非法均係針對伊斯蘭教法而言。概略言之，一般植物皆可食，但會使人麻醉、精神萎靡、危害身體健康者，或轉化為酒精類者為非法；水產大體皆合法，但部分兩棲類（如青蛙、蠑螈）以及爬蟲類（如龜、鱉等）為非法；至於陸棲動物，禁食自死物、血液、豬、狗以及猛禽與猛獸等；此外，合法之陸棲動物尚需經穆斯林宰殺；經祭拜之任何食物飲料皆屬禁食。

1.2. 申請伊斯蘭 HALAL 食(用)品驗證之產品，不得含有上述禁食之任何成份，或禁食成份之衍生物，並須區隔或防止其生產設備器具受到污染。

1.3. 目前國際清真驗證規定，凡生產清真食用品的工廠或代工廠，不得於同一產線生產任何含有豬成份或其衍生物之產品。簡言之，清真產品的生產線不得與任何含有豬成份或其衍生物之成份的產品共用生產線[1]。同一廠房內若生產任何含有豬成份或其衍生物之成份的產品，如欲產製清真產品，恐難通過驗證，除非與生產清真產品的產線有實體的牆面區隔，包含原物料、成品之倉儲及備料等皆須有所區隔。

2. 申請驗證須知

2.1. 協會為社團法人組織，辦理伊斯蘭食 (用) 品驗證事務之宗旨，係對國內食(用)品廠商提供服務，當在可能範圍內協助，並輔導廠商取得驗證。

2.2. 申請驗證分為新申請、申請續約、變更品項等三類，各類申請案均請填寫協會專用申請書並惠付申請工本費。**新申請**係指申請者針對某(幾)項產品初次提出申請「伊斯蘭 HALAL 清真食(用)品證」(以下簡稱「清真食(用)品證」)；**申請續約**係指已與協會簽約且領有食(用)品證之廠商，於其合約之效期屆滿至少一個月以前，針對相同產品提出申請續約(請閱 9.**申請續約**)；**申請變更品項**係指已領證廠商在合約期間針對其合約產品作任何變更，包括變更品名、成份、原料來源 (特別是供應商或製造商之異

[1]伊斯蘭教法上定義的「交叉汙染」並非一般的機器設備清潔流程可以去除。

動)、代工廠，以及增加或刪除品項等。

2.3. 辦理驗證所需時間依個案而定。文件審核階段，端視廠商配合之快慢及所提供之資料文件是否符合需要而定，一般至少需三週以上，請確實遵照本須知辦理，以利審核作業。文件是否齊備，檢送文件所用產品、成份名稱是否一致，產品各項成份及添加物是否合乎伊斯蘭教法，相關證明文件是否齊備、並符合效期、而其內容無疑慮，是否須由廠商補提文件或特定檢驗報告等等，均影響審核所需時間。至於勘廠與簽約階段端視貴我雙方之配合，所須時間通常較少。廠商如有特殊時效需求，請於申請時告知，協會得視情況以特案方式處理。

2.4. **申請者同意遞交該會之所有文件由協會保管留存，若須留底，請於寄送協會前自行影印留存。所有文件及申請工本費一經送交協會，概不退還。**
協會承諾對申請者所提供之文件資料妥善管理，並盡保密之義務。

2.5. 檢送基本文件

2.5.1 確認詳閱並願完全遵守協會伊斯蘭 HALAL 食(用)品驗證方案之「條件與規定」

2.5.2 申請書(含附件一及附件二)

2.5.3 原料清單列表（附件三）

2.5.4 公司營利事業登記證影本或變更登記事項卡影本

2.5.5 工廠登記證影本

2.5.6 工廠平面圖

2.5.7 產品產製流程圖及詳細說明

2.5.8 生產設備清潔、消毒作業程序

2.5.9 產品包裝設計圖及外觀標示

2.5.10 光碟(包含附件一、附件二、附件三及產品包裝設計圖)

2.5.11 申請工本費收據影本

2.5.12 其它文件(請說明，例如 HACCP, ISO, GMP 或其他)。

3. 驗證條件

3.1. 協會簽發伊斯蘭 HALAL 清真食(用)品證，係對國內外所有穆斯林消費者宣告，經協會驗證之產品為符合伊斯蘭教法之食(用)品，可以放心食用，乃是承擔一項嚴肅的宗教責任，因此協會辦理驗證態度嚴謹審慎。申請驗證之廠商（以下簡稱申請者）與協會雙方，必須以誠實互信之原則為合作基礎。為保護申請者之權益，協會對申請者填報之資料均作密件處理。

3.2. 申請者必須同意完全遵守本「條件與規定」；一經協會收到申請書，即表示申請者已詳閱並願完全遵守本「條件與規定」。

3.3. 本表所填資料須為最後之確定資料，自送件起，至申請案核准、公證簽約後之三個月內，將不接受增加或變更品項。

3.4. 通過審查並與協會簽約獲發清真食（用）品證之廠商，應確實履行合約之規定，如有任何違約情事，協會將立即收回並註銷該清真食（用）品證（驗證廠商且須放棄一切印有 HALAL 清真標記之包裝及標籤並寄來協會繳銷），違約者並須依約無條件給付協會懲罰性違約金（依合約所定金額），並同意放棄法院之優先抗辯權。本協會並得向穆斯林或一般大眾或國外清真認證單位公佈違約情事及違約廠商已喪失協會認證之事實。

3.5. 為確保協會證書獲得國際認可，協會除須符合國外清真驗證單位之清真規範外，並須定期向每個單位寄發協會驗證之廠商名單、不續約名單及違約廠商名單。

3.6. 協會對於所發清真食（用）品證相關事宜之認定即為最終決定。

4. 填寫申請書

4.1. 申請書填寫不全或文件不齊之申請案，恕不受理；申請書與文件請以打字處理，請勿手寫，以避免難以辨識；申請書格式不可自行更改，各欄所有空格均須填寫，不可留空；

4.2. 申請者送件前請確認完全遵照本「條件與規定」填寫申請書，並已檢齊所須文件，以免延誤時效；申請書與文件請以郵寄或快遞方式送達各寺或協會，恕不接受傳真申請。

4.3. 檢送之所有文件均須為正式文件：所有文件，請加蓋公司正式印信；由

其他任何第三方公司(含申請者)出具之文件，均須使用印有該公司銜之正式信紙，並加蓋該公司之正式印信以及申請者之公司印信。此外如需補充其它文件，當以協會告知為準。

4.4. 申請驗證之產品，如經多於一家工廠製造(製程分段)，每家工廠之資料均須填入申請書，並須由各廠提供其工廠登記證、所製造部分之生產流程圖與詳細說明、及設備清洗作業程序；亦請說明各廠所製(半)成品之銜接細節。

4.5. 填寫**附件一：「產品及成份表」**：

4.5.1 本表以產品為主，欲申請驗證之所有產品均須填入，每項產品佔一格，請每項編列一序號，並可分類(A1,A2,A3,…；B1, B2, B3…)。

4.5.2 每項產品均須填寫中英文品名，且須與成品外包裝之品名相符；如有外銷用特殊品名，亦須條列並加註說明。

4.5.3 各項產品所含之所有成份之中、英文名稱均須詳實填報（填入成份欄），不可遺漏，即使依法令無需於包裝上標示之成份、添加物或加工助劑，亦請填列，以便判別是否合於清真規範。各項成份之名稱須與相關證明文件之名稱一致，以利核對。

4.5.4 如某項成份並非原物料或非原狀（如加工品、萃取物…），請另提供組成該成份之各項成份及原物料品名；如該成份並非由貴公司（工廠）自行產製，請檢附原製造商或加工廠提供之文件（國外亦然）。此外如需其他文件，當依本協會告知為準。

4.5.5 包裝規格欄內請列明產品之包裝方式、容量、數量、包材等；「包裝外觀標示」包含貼標、包裝袋（或盒）圖樣等足以顯示成品包裝之外觀以及包裝上之文字，請寄 A4 印本以利存檔。

4.6. 填寫附件二：「不申請驗證之產品及成份表」：

4.6.1 為評估並排除交叉汙染[2]之可能性及疑慮，申請廠商（含已領證廠商）所有不欲申請清真驗證之產品皆須列於附件二，填列方式同附件一；序號請依序填入(Y1,Y2,Y3,Y4…)。若公司全產品皆已提出申請清真驗證，則請於附件二的欄位中填寫「無」。

[2]請參見**「伊斯蘭教法之交叉汙染」**說明。

4.6.2 「共線」係指共用生產設備。凡任何不申請驗證之產品（附件二）與任何驗證產品（附件一）共同使用任何一件或多件生產設備、工具或器皿，請一律於「共線」欄中打✓。

4.7. 如某項成份本身係加工製品，內含油脂、菌種、或動物成份等添加物，請提供成份、使用之酵素名稱、培養基成分等，必要時提供製程，以說明其**原物料**成份（請勿提供化學成份或性狀分析）；如為萃取物，請提供萃取過程並說明所使用之溶劑(solvent)；並請檢附貴公司與供應商之採購合約或進貨單及其 HALAL 食（用）品證影本；必要時，得要求申請廠商提供產品之油脂、乙醇或 DNA 等檢驗報告，檢驗之項目依協會告知為準。

4.8. 所有提供 Halal 證（須在效期內）的原物料，必須同時檢附最近一次的進口報單（價格可以遮住）。

4.9. 所提供之證明文件皆須為正式文件（印有公司銜），**不得塗改**；如為外文文件請適當加註中文或附中文譯本，並請簽章以示負責；分析、檢驗報告或證明文件之簽發日期應為最近三個月之內。

4.10. 生產設備之清潔、消毒作業程序，需清楚說明清洗作業之程序及所使用之清潔劑、消毒劑品名及成份。

4.11. 申請時請將**現有包裝標示**送審。**產品中、英文名稱須明確，不可多項產品對應同一產品名稱。**簽約發證後，驗證廠商欲將包裝標示做任何變更前（包括加印 HALAL Logo 或標籤），均須**事先**經由協會確認及取得書面許可。

4.12. 填寫**附件三：**「原料及添加物明細表」：

4.12.1 本表以產品原料、添加物以及加工助劑為主，列於附件一及附件二之所有產品原料(成份) 、添加物以及加工助劑均須填入本附件（附件三）。

4.12.2 為確保驗證產品在合約期間之產製符合清真品質保證之要求，附件三須列為合約之附件一併公證。在合約期間，廠商欲進行任何與表上所載相異之變動，皆需於變動發生之前向本協會提出「申請變更」，待本協會確認申請者所做之變更不影響產品

之清真狀態之後，始可變更。否則視同違約。

4.12.3 「製造商」、「供應商」以及「產地」欄請確實填寫，「製造商」欄請勿填入供應商或貿易商的名稱。

4.12.4 「添加該原料之認證產品序號」欄，請填入含有該項原料之所有產品序號（附件一及附件二）。

4.12.5 待協會確認表中內容無誤後，請廠商備妥本表一式三份，表末須由填表人（同時為申請廠商之公司內部清真事務負責人）以及公司負責人或經理簽名並蓋章後寄交協會。

5. 文件初審與覆審

通知申請者補件起一個月內若無回應，協會將主動聯絡申請者詢問進度。若補件取得有困難，請主動與協會聯絡，協會當就所知提供建議以協助，如自通知補件起兩個月內無回應，協會將予主動結案，倘日後有意申請，請重新提出申請。

6. 勘查現場

6.1. 文件審核作業完成後，由申請者安排陪同協會（含各寺驗證人員）赴生產現場實際查勘；協會與各寺驗證人員前往勘廠之往返交通費，由申請者負擔（實報實銷）。

6.2. 申請者向協會申請伊斯蘭 HALAL 清真食(用)品證，必須對協會完全坦誠，亦係申請者向協會展現坦誠及有意遵守清真規定之決心。協會勘廠之目的在於確認申請案文件之陳述，並釐清任何疑慮，決非刺探機密。倘申請者以商業機密或者 know-how 等任何理由拒絕協會勘驗人員勘查工廠的特定區域，則審查無法完成，並招致疑慮，申請案將無法通過。若委由代工廠生產，申請者有責任於協會前往勘廠前先與代工廠溝通，確定代工廠願意全力配合協會稽核人員進行勘廠。

6.3. 勘查現場當天，應以生產線上正在生產申請驗證之產品為原則，若因生產排程難以配合，則至少要正在生產使用相同產線（產製程序與申請驗證產品相同）的產品。若原料倉內無備料，請事先告知，以免影響勘驗結果。

6.4. 勘驗項目包括確認原料與添加物及其倉儲、製程、設備清洗、包裝、成

品與倉儲，確認生產現場無交叉汙染之虞，並確認生產現場無任何供奉、祭祀之設置。

7. 審核結果與簽約發證

7.1. 文件審查及現場勘查結束後，協會將邀請該會教法及技術委員會委員、文件審核人員、勘廠稽核人員開會審查申請案，決議是否通過，並將結果以電話、傳真或信函方通知申請廠商。

7.2. 通過審核之申請案，協會將擇期約請申請者與公證人，簽立合約，並發給「伊斯蘭 HALAL 清真食(用)品證」；簽約時申請者應繳納公證費用並給付驗證捐款。自核准通知日起**二週**內未簽約之廠商，視同放棄申請案；日後如欲領證，須重新申請。

7.3. 申請者須於公證簽約前提供協會「稽核同意書」一份，經由公司負責人、工廠（代工廠）主管簽名之同意書，同意協會稽察人員於合約期間得隨時至驗證產品之工廠或代工廠進行勘查，申請者不得以任何理由拒絕。

7.4. 「伊斯蘭 HALAL 清真食(用)品證」為經協會審查通過後，核發予廠商之證書，以證明該廠商承諾遵守合約產製符合伊斯蘭教法規定之伊斯蘭清真食(用)品。

7.5. 簽發予廠商持用之「伊斯蘭 HALAL 清真食(用)品證」係屬於協會授權之文書，合約期滿，不論是否續約均須交還協會；如有違約情事，協會得隨時要求立即交還。

7.6. 驗證廠商應負責妥善保管「伊斯蘭 HALAL 清真食(用)品證」，在任何情況下，該食(用)品證不得轉讓或借予他人使用。如有需要，可將證書影本提供客戶僅作證明之用，影本須加蓋貴公司正式印信，且作成記錄備查，並須對客戶或任何第三者之不當使用該證書影本或其負全部法律責任。

7.7. 如證書遺失，除須立即通報本協會外，並須登報聲明作廢，再檢附刊登遺失啟示之報紙向協會申請補發。

8. 後續輔導

為確保合約之有效執行，廠商應配合辦理下列各項：

8.1. 廠商應在合約簽訂後六個月內，成立公司內部之清真品質保證小組，並指定專人擔任該小組召集人，負責公司內部一切有關清真品保之業務，

該召集人須同時負責與協會之一切連絡。

8.2. 清真品保小組至少必須由下列人員組成：公司負責人或其代表、採購部門、製造部門及品保部門工作人員各一位（主管尤佳）。

8.3. 上款（8.2）所列清真品保小組成員必須參加並通過協會舉辦之教育訓練課程，獲發清真品保員證書。建立該小組，並使其成員領有此項證書為申請續約的條件之一。

8.4. 廠商應指定專人負責清真產品品質保證事宜，此位清真品保人員須同時負責與協會之一切連絡。

8.5. 為確保合約之有效執行，在合約期間協會將派員做不定期、無預告之抽檢，驗證廠商必須完全配合，並提供所須之相關資料，且負擔協會稽核人員之交通費(實際報銷)；每年抽檢次數由協會視情況而定。

8.6. 協會將不定期規劃清真產品教育訓練課程，增加業界員工對清真產品之認知。協會另將不定期舉辦清真食(用)品驗證座談會，邀請業者分享經驗。協會並將提供已領證廠商國內以及國際大型清真食用品展覽訊息。

9. 申請續約

9.1. 協會基於輔導協助之善意，將於效期屆滿前兩個月寄發續約通知，作為提醒；如未收到通知，廠商仍應主動申請續約。

9.2. 協會核發食(用)品證與簽約之效期一般為一年，期滿得申請續約，本協會得視情況同意簽發效期至多兩年。

9.3. 續約之審核包括廠商履約情況，並需參考配合國際清真驗證之最新標準及清真科技研發之成果，必要時需重新審核驗證產品之成份、製程等各項，以確保協會清真驗證符合最新國際 Halal 驗證標準。

9.4. 有意續約之廠商，仍請按規定填寫申請書，檢送(寄)所須文件。**申請續約時所遞送之資料須為最新資料，協會不接受續約廠商以前一年之申請資料做為續約文件**。合約期滿後提出申請者，視同新申請，協會無法保證續約能在舊約期滿前核准。

9.5. 無意續約之廠商，應於約滿前一週將「伊斯蘭 HALAL 清真食(用)品證」寄還協會。如市面上仍有流通之產品時，請切結品名、生產日期、批號及數量備查。

10. 變更品項

10.1. 「變更品項」係指領有協會清真食(用)品證之廠商，在合約期間需改變驗證產品之品名、成份(包括原料製造商或供應商之變動)、包裝、代工廠，或增加新品，或刪除某項產品。

10.2. 除非另簽新約，否則至申請案核准、公證簽約後之三個月內，協會將不接受變更或增加品項。

10.3. 申請變更品項，請填寫申請書，檢送相關文件，並給付申請工本費。

11. 其它規定

11.1. 如有國內外穆斯林或外界人士向協會或其它單位檢舉或抱怨，驗證廠商知悉後應立即負責答覆與處理，並向協會提出書面說明。

11.2. 驗證廠商在任何情況下均應善盡維護協會名譽及驗證公信力之責任，以法律或合法之方式對抗任何直接或間接發生之指控、損害、費用等。

11.3. 驗證廠商有責任保持廠區之清真狀態，而確保無交叉汙染之虞。對於未申請清真驗證之產品，或新研發生產之產品，即使不在清真驗證產品之列，申請者亦有責任提供該產品之成份、製程等文件，以釐清無交叉汙染之可能性。

11.4. 無論新研發之產品是否欲申請納入清真驗證，新研發之產品若與已通過驗證之產品使用共同或部分共同之生產線，為避免共線之交叉汙染影響已通過驗證之產品的清真狀態，於新研發之產品正式生產前，需檢附產品成分文件，待協會確認產品成分無伊斯蘭教法所禁止之成份之後，始可生產上市[3]。

11.5. 驗證廠商印製發行或變更任何有關驗證產品之包裝、廣告、文宣文件所載內容，均須合乎協會之認可(而無伊斯蘭不宜之圖文)，並須事先徵得協會同意，方可發行或變更。

11.6. 協會得隨時修改本「方案」，恕不另行通知。請上協會網站下載，或電郵協會索取最新版本。

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[3]新研發之產品若未在正式生產前取得協會核可，而致發生交叉汙染影響已驗證產品之清真狀態，最嚴重之情況下協會可解除與廠商之合約，即刻註銷並收回伊斯蘭 HALAL 清真食（用）品證。

出處：台灣清真產業品質保證推廣協會-清真食用品-美妝品(Release 2.1)

肆、認證申請書

社團法人台灣清真產業品質保證推廣協會
「伊斯蘭 HALAL 食(用)品」認證申請書-美妝品

一、 公司名稱 (中文)：_____

(英文)：_____

統一編號：_____

負責人：_____

地址：_____

公司電話：_____ 傳真：_____

聯絡人：_____分機：_____手機：_____

電子郵件：_____

二、 工廠名稱[4]： _____

工廠登記證字號： _____

地址： _____

電話： _____

三、 申請認證之產品，請填寫附件一：「**申請認證產品及成份表**」。

四、 不申請認證之產品，請填寫附件二：「**所有不申請驗證之產品及成份表**」。

五、 申請認證之產品是否有含藥化妝品？□是□否若是，請附上衛生福利部許可證。

六、 申請附件或確認(請勾選)：

1. ☐本申請書(含附件一及附件二) ☐新申請 ☐續約(舊證書號碼：_____)
2. ☐原料清單列表（附件三）
3. ☐公司營利事業登記證影本或變更登記事項卡影本
4. ☐工廠登記證影本
5. ☐工廠平面圖
6. ☐產品產製流程圖及詳細說明
7. ☐生產設備清潔、消毒作業程序
8. ☐產品包裝設計圖及外觀標示
9. ☐光碟(包含附件一、附件二、附件三及產品包裝設計圖)
10. ☐申請文審費收據影本
11. 其它文件(例如 HACCP, ISO, GMP 或其他，請說明)：_____

☐確認詳閱並願完全遵守本會伊斯蘭 HALAL 食(用)品驗證方案之「條件與規定」(打勾)

七、 申請人簽章：_____申請日期：_____

[4]如經多家工廠製造，請詳列各廠資料。

出處：台灣清真產業品質保證推廣協會-http://thida.org/ (Release 2.1)

附件一：申請認證產品及成份表-美妝品

日期：_____

請詳填申請 HALAL 認證之各項產品與成份(所有各項成份均須詳填，不可遺漏)，並加蓋公司印信：

序號	產品中文名稱	產品英文名稱	包裝規格	原料成份中英文名稱(包含所有添加物與加工助劑)
A1				
A2				
A3				
A4				

註：序號請依序分類填入(A1,A2,A3,…B1, B2, B3,…)；多項產品可合填一表，如一頁不敷使用，請影印本表加頁填寫。

附件二：所有不申請驗證之產品及成份表-美妝品

為釐清交叉污染疑慮，務請詳填不申請驗證之所有產品與其成份，與驗證產品合用生產線者，請於「**共線**」欄打✓。每頁請加蓋公司印信：

序號	產品中文名稱	產品英文名稱	共線	原料成份中英文名稱(包含所有添加物與加工助劑)
Y1				
Y2				
Y3				
Y4				

註：序號請依序填入(Y1,Y2,Y3,Y4…)；多項產品可合填一表，如一頁不敷使用，請影印本表加頁填寫

附件三：原料及添加物明細表-美妝品

請羅列附件一及附件二所申請之產品原料、添加物、加工助劑。若具有 HALAL 認證者，請檢附效期內之證書，並附上進口報單。

序號	原料名稱 (中英文)	添加該原料之產品序號(A1, A4,…Y1, Y6…)	製造商(原名)及產地	供應商	Halal 證書 發證單位及效期	其他文件 (問卷、COA、許可證等)
1			製造商： 產地：		請填 Halal 證發證單位及效期	
2			製造商： 產地：			
3			製造商： 產地：			
4			製造商： 產地：			
5			製造商： 產地：			
6			製造商： 產地：			
7			製造商： 產地：			
8			製造商： 產地：			

註：多項產品可合填一表，如一頁不敷使用，請影印本表加頁填寫。

出處：台灣清真產業品質保證推廣協會-http://thida.org/ (Release 2.2)

第四章 Q&A

Q1: 若打算出口化粧品至東協任何成員國該如何做？

ANS： 負責將產品放入市場之公司或人員大部分必須為當地註冊公司或當地人，而此責任人應使用該銷售國的主管機關所規定之化粧品登錄表單通知該主管機關，得到許可後，產品才可以銷售。並須確保預備上市之化粧品符合東協化粧品指令的每項規定。

Q2: 若產品已完成登錄於東協之任一成員國 ,該產品是否能豁免登錄其他東協成員國?

ANS： 否；若您打算將產品投入三個東協之成員國的市場，將必須分別向三個國家之主管機關做產品登錄。

Q3:若工廠或代工廠沒有工廠登記證，可以申請清真認證嗎？

ANS： 台灣清真產業品質保證推廣協會要求清真認證產品之產製須符合政府衛生、安全等相關規定，故若產品的加工場所無工廠登記證，協會難接受申請。

Q4: 申請清真認證需要多久時間才可以拿到證書？

ANS： 這個問題基本上沒有一個標準答案，因為需時長短，端賴廠商之配合以及申請品項之成份是否複雜而定，一般來說如果成份單純，廠商配合補件效率高，最快的情形可望 3~4 星期完成，此外情況則因個案而異。

Q5: 申請清真認證有哪些相關費用？

ANS： 台灣清真產業品質保證推廣協會為社團法人，係非營利組織，針對會員提供服務。詳細請洽詢台灣清真產業品質保證推廣協會，Tel: +886-2-2367-5231、2367-5421。

Q6: 清真認證之證書效期是多久？

ANS： 對於首次領證的廠商 ,台灣清真產業品質保證推廣協會一律簽發一年效期

之證書，以便於廠商評估外銷之績效，協會亦可評估廠商履約情形。次年續約時，協會得視廠商情況，核發至多兩年效期之證書。國外清真證書效期一般多為一至二年，極少數為三年。

Q7: 申請清真認證的產品如由代工廠製作，是否仍須詳填附件一與附件二？如代工廠透露原料成分有困難，該怎麼辦？

ANS： 清真驗證係一宗教性認證，無論申請者自有工廠或委外代工，均須透露原料成份，以便台灣清真產業品質保證推廣協會判別其中有無不合伊斯蘭教法之成份，而釐清交叉汙染之疑慮，否則無法辦理。

Q8: 台灣清真產業品質保證推廣協會發證之適用區域?

ANS： 據了解係由台灣清真協會向馬來西亞總部提出擴大適用區域申請後，總部人員會到台灣查核其認證標準與作業，適時擴大認證地區。

資料來源：台灣清真產業品質保證推廣協會-申請清真認證之相關問題；ASEAN Cosmetics Association-Notification

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