東協保健品法規技術統一規範之現況–A

Health Supplement Regulatory Harmonization in ASEAN – Part A

AAHSA

ASEAN Alliance of
Health Supplement Associations

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東協保健品協會聯盟

8 September 2020

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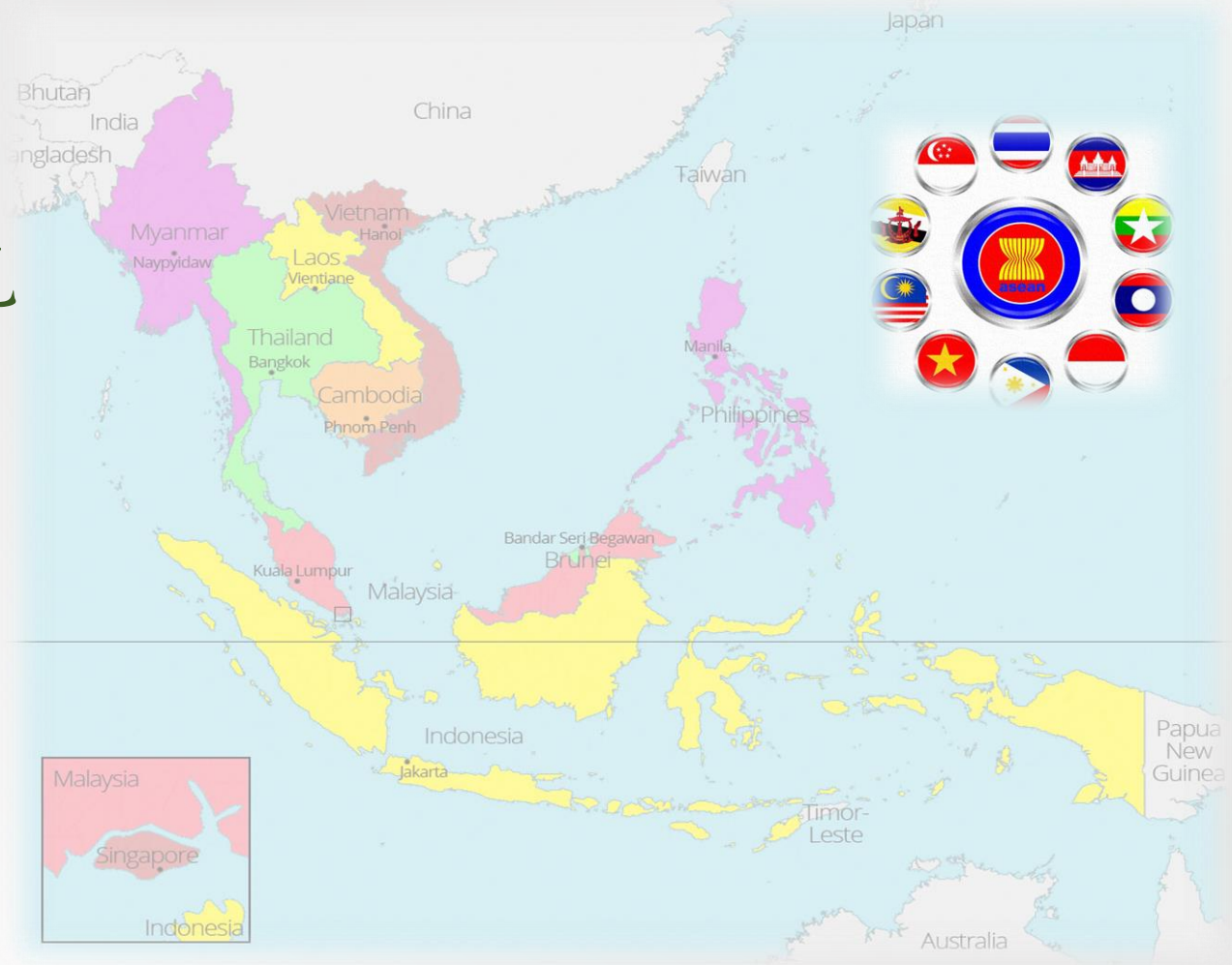
ASEAN Alliance of Health Supplement Associations

內容大綱

1. 東協保健品協會聯盟簡介
2. 縱觀現行東協國家保健品法規
3. 未來東協保健品法規十項技術規範



1. 東協保健品協會聯盟簡介

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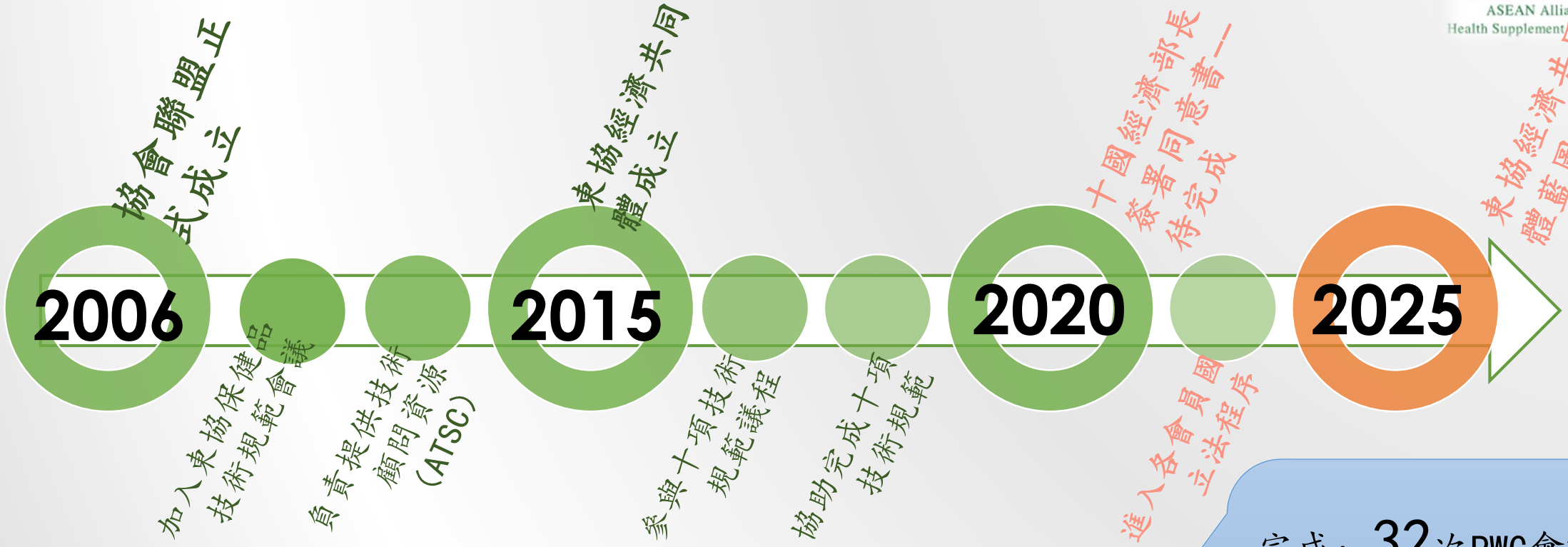


2006 新加坡


2016 新加坡

2019 吉隆坡

完成：32次PWG會議
36次ATSC會議

統一：10項技術規範

1. 東協保健品協會聯盟簡介

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宗旨

- 促進優質產品的貿易，使消費者受益。
- 在東協保健品法規技術統一規範的会议進程中，代表產業進行協調。
- 在統一規範的協調過程中提供法規、科學、技術及市调數據。
- 協助成立和強化東協各國保健品協會。
- 組織區域性活動。
- 協助強化其他區域對東協保健產業的認識。

1. 東協保健品協會聯盟簡介

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七個協會會員

- 汶来保健化妆品协會
  Health and Cosmetics Association (HCA)
- 印尼保健品協會
  Asosiasi Pengusaha Suplemen Kesehatan Indonesia (APSKI)
- 馬來西亞膳食補充品協會
  Malaysian Dietary Supplement Association (MADSA)
- 菲律賓保健品協會
  Health and Dietary Supplements Association of The Philippines (HADSAP)
- 新加坡保健品協會
  Health Supplements Industry Association of Singapore (HSIAS)
- 泰國保健品協會
  Health Food and Supplements Association (HFSA)
- 越南功能性食品協會
  Vietnam Association of Functional Foods (VAFF)

四個產業會員

- 安利
  Amway
- 全美世界有限公司集團
  Best World International Pte Ltd
- 帝斯曼營養品
  DSM Nutritional Products
- 三得利食品飲料亞洲有限公司
  Suntory Beverage & Food Asia Ltd

1. 東協保健品協會聯盟簡介

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新加坡總理李顯龍在東協第50屆於新加坡舉行的經濟部長會議開幕致詞中提到，預計到了2030年，東協將成為繼美國、中國和歐盟之後的世界

第四大經濟體。

新加坡商業評論，2018年8月30日

The ASEAN is predicted to become the **4th**-largest economy in the world by 2030 after the United States, China, and the European Union, Singapore PM Lee said in his speech at the opening ceremony of the 50th ASEAN Economic Ministers Meeting held in Singapore.

Business Review Singapore, 30 Aug 2018

1. 東協保健品協會聯盟簡介

隨著人们生活方式和健身習慣發生變化，預計未來幾年亞太地區將看到
營養保健品和功能性食品行業的巨大增長機會。

聯合市場研究公司（Allied Market Research）的一份報告指出，
由於消費者逐漸意識到膳食補充劑、植物性食品和功能性食品的保健益處，

其**複合年增長率(CAGR)**估計可高达7.33％。

Innova Market Insights發現，2015年全球新上市的保健品16%來自亞洲，
高於2013年的11%

The Asia Pacific region is expected to see huge opportunity for growth over the next few years as the nutraceutical and functional food industry sees shifts in lifestyle trends and fitness habits. A report from Allied Market Research indicates consumers are increasingly aware of the health benefits to be found in dietary supplements, botanicals and functional foods, resulting in an estimated 7.33 percent CAGR. Innova Market Insights found 16 percent of global supplement launches in 2015 came from Asia, up from 11 percent in 2013.

Source：

ASEAN Market Overview Nov 20, 2017 https://www.vitafoodsinsights.com/market-trends/asean-market-overview

1. 東協保健品協會聯盟簡介

東協三大共同體（ASEAN Community）：

- ✓ 東協政治安全共同體
- ✓ 東協經濟共同體
- ✓ 東協社會文化共同體

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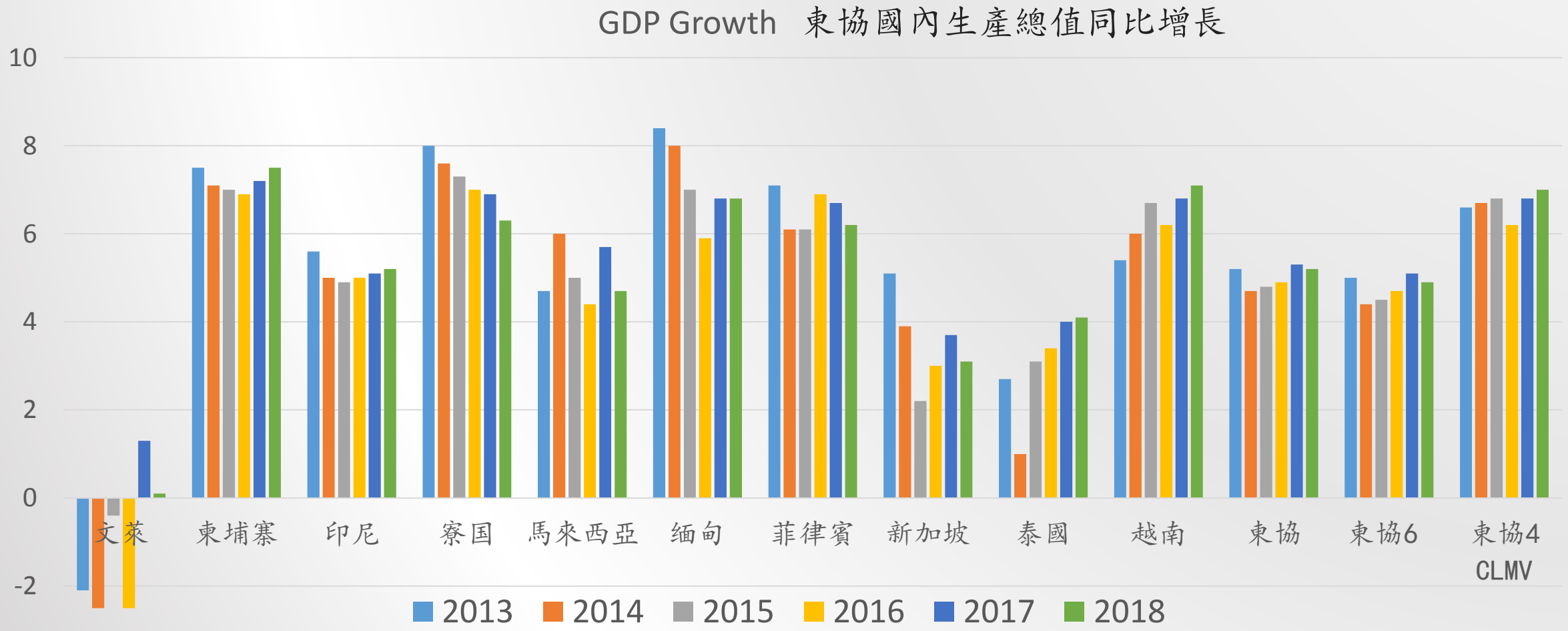
東協經濟增長

ASSOCIATION OF SOUTHEAST ASIAN NATIONS



-4 百分比，GDP根據以不變價格的本國貨幣計算

資料來源： https://data.aseanstats.org/indicator/AST.STC.TBL.6

1. 東協保健品協會聯盟簡介

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東協保健品2018年市值調查：
69.2億美元！


WRCBtv

HOME NEWS WEATHER

PRESS RELEASE

Top Trends in ASEAN Dietary Supplements Market Size 2020 - Industry Revenue and Upcoming Demand

ASEAN Dietary Supplements Market Size, Share, Growth, Revenue, Global Industry A
| Fortune Business Insights™

Friday, February 28th 2020, 7:25 AM EST

As per the new Fortune Business Insights™ report, titled ***"ASEANDietary Supplements Market Si***
Analysis, By Type (Vitamins, Minerals, Enzymes, Fatty Acids, Proteins, and Others), Form (Tabl
Liquid), and Regional Forecasts, 2019 2026", the market value stood at**USD 6.92 billion in 2018.**
The**ASEAN Dietary Supplements Market Size**is set to reachUSD 10.60 billion by 2026, exhibiting
forecast period. Increasing prevalence of lifestyle-induced disorders, or Non-Communicable Dis
and cancer, will be a key factor driving the food supplements market growth. Estimates comput
Organization (WHO) state that close to 8 million people die every year in Southeast Asia due to
the total deaths in the region in a given year.


FORTUNE BUSINESS INSIGHTS

HOME INDUSTRIES SERVICES INSIGHTS ABO

Food & Beverages / Southeast Asia Dietary Supplements Market

"Market I
Your Succ

Southeast Asia Dietary Supplements Market Size, Share & Industry Analysis, By Type (Vitamins, Minerals, Enzymes, Fatty Acids, Proteins, and Others), Form (Tablets and Capsules, Powder, and Liquid), and Regional Forecasts, 2019 – 2026

Region : Global | Format: PDF | Report ID: FBI101943 Share

Summary | Table of Content | Market Segmentation | Methodology | Infographics | Request Sample PDF

KEY MARKET INSIGHTS

Listen to Audio Version

The Southeast Asia dietary supplements market size was valued at USD 6.92 Billion in 2018 and is projected to reach USD 10.60 Billion by 2026, exhibiting a CAGR of 5.60% during the forecast period (2019-2026).

資料來源：
https://www.wrcbtv.com/story/41831317/top-trends-in-asean-dietary-supplements-market-size-2020-industry-revenue-and-upcoming-demand
https://www.fortunebusinessinsights.com/industry-reports/southeast-asia-dietary-supplements-market-101943

1. 東協保健品協會聯盟簡介

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東協2025經濟共同體藍圖

ASSOCIATION OF SOUTHEAST ASIAN NATIONS

預估在2025年前完成

部長簽署同意書

進入各會員國立法程序

會員國依法監管執行

已完成

2. 縱觀現行東協國家保健品法規

東協各國保健品分類、監管部門及相關法規

國家	新加坡	汶来	馬來西亞	印尼	越南	菲律賓	泰國	寮国	柬埔寨	緬甸
分類	保健品 Health Supplement			膳食補充品 Food Sup	功能性食品 Func Food	膳食補充品 Dietary Supplement				保健品 Health Sup
監管部门	HSA 衛生部 衛生科學局	BDMCA 衛生部 醫藥管理局	NPRA 衛生部 藥事管理局	BPOM 衛生部 藥物食品管理署	FDA 衛生部 藥物食品管理署	FDA 衛生部 食品藥物管理署	FDA 公共衛生部 食品藥物管理署	FDD 衛生部 食品藥物管理署	DDF 衛生部 藥物食品管理署	FDA 衛生部 藥物食品管理署
相關法規	保健品安全與品質規定指引	藥事法 Medicine Order, 2007	藥事法 SALE OF DRUGS ACT 1952 (REVISED - 1989)	藥物食品法 Article 68 of Presidential Decree No. 103 in 2001	食品安全法 Food safety Law	食品安全法 FOOD SAFETY ACT OF 2013	食品法 Food Act BE 2522	食品安全法 Food safety Law 2013	食品安全法 Food safety Law	食品安全法 National Food Law
是否已开始採用東協保健品技術規範?	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
需要註冊嗎?	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
法規链接	https://www.hsa.gov.sg/health-supplements/overview	http://www.moh.gov.bn/SitePages/Traditional%20Medicine%20and%20Health%20Supplement.aspx	https://www.npra.gov.my/images/00NPRA/health-supplements/appendix4HS.pdf	www.pom.go.id/new/	https://dav.gov.vn/en	https://www.officialgazette.gov.ph/2015/02/20/implementing-rules-and-regulations-of-republic-act-no-10611/	http://food.fda.moph.go.th/law/index.php	http://www.fdd.gov.la/showContent_en.php?contID=15	https://www.ddfcambodia.com/	https://www.fda.gov.mm/?cat=15

2. 縱觀現行東協國家保健品法規

東協主要國家保健食品市場及上市申請相關法規

1) 越南保健食品市場及上市申請相關法規

2) 泰國保健食品市場及上市申請相關法規

3) 印尼保健食品市場及上市申請相關法規

4) 馬來西亞保健食品市場及上市申請相關法規

5) 菲律賓保健食品市場及上市申請相關法規

以上資料來源:經濟部國際貿易局 https://www.trade.gov.tw/Pages/List.aspx?nodeID=4176

6) 新加坡保健品上市相關法規 https://www.hsa.gov.sg/health-supplements/overview

7) 汶来保健品上市相關法規
http://www.moh.gov.bn/Shared%20Documents/Traditional%20Medicines/1.1%20Guideline%20for%20Importation%20andor%20sale%20of%20TMHS.pdf

8) 寮国保健品上市申請相關法規http://www.fdd.gov.la/showContent_en.php?contID=15

9) 柬埔寨保健品上市申請相關法規

10) 缅甸保健品上市申請相關法規

2. 縱觀現行東協國家保健品法規- 越南

一、主管機關	越南衛生部食品安全局(Vietnam Food Administration, Ministry of Health)
二、法源依據	(一)越南政府於2018年2月2日頒布之第15/2018/ND-CP號議定(「食品安全法施行細則」) (二)越南衛生部於2014年11月24日頒布之第43/2014/TT-BYT號公告(「功能性食品管理規定」)
三、進口程序	(一)產品宣告(product declaration)(請參考第15/2018/ND-CP號議定第7條): 1. 產品宣告表(declaration form)→附錄I, Form No.02; 2. 由出口國主管機關核發之自由銷售證明(Certificate of Free Sale, CFS)、出口證明(Certificate of Exportation)或衛生證明(Health Certificate)(須經領事認證); 3. 在進行宣告前12個月內, 由指定實驗室或符合ISO17025標準實驗室所作之食品安全資訊表(food safety data sheet)(正本或經認證影本); 該食品安全資訊表須載明由越南衛生部依國際規範風險管理原則訂定之安全指標; 4. 產品或成分效果之科學證據文件(正本或經認證影本); 若採用成分效果之科學證據, 每日劑量須大於或等於該文件內容之15%。 5. 自2019年7月1日起, 膳食補充品(dietary supplements)須檢附GMP證明或其他同等效力證明。
	(二)產品宣告註冊程序(procedures for registration of product declaration) (請參考第15/2018/ND-CP號議定第8條): 1. 由供應商向越南衛生部辦理相關註冊程序。 2. 越南衛生部在收到完備申請文件之情況下, 將於21個工作天內進行審核並核發產品宣告註冊證書(Certificate of Registered Product Declaration)→附錄I, Form No.03
	(三)食品安全證書(Certificate of Food Safety)(請參考第15/2018/ND-CP號議定第11、12、28條): 1. 所有食品製造商及銷售商均須取得食品安全證書, 除有第12條第1項之例外情形, 包括第(k)款食品業(food business)已取得下列認證: GMP、HACCP、ISO22000、IFS、BRC、FSSC22000或其他同等證明。 2. 膳食補充品之製造商須遵守本法第28條之相關食品安全規範, 包括採用符合標準之品管系統、員工、工廠設施, 以及成立品管部門及備齊製造過程、品管及配銷之相關文件供查驗等。 3. 越南衛生部應就膳食補充品應用GMP標準提供指導。

2. 縱觀現行東協國家保健品法規-泰國

一、主管機關	泰國衛生部食品藥物管理署
二、法源依據	食品法Food Act BE 2522 No. 293, 294, 309, 405 核可作為膳食補充品原料之植物成分清單 氨基酸劑量表 維生素劑量表
三、進口程序	（申請人須為在泰國已註冊登記之進口商）申請進口單位聯絡人：025907320 Ms Nattana 一、進口商須至泰國食品藥物管理局申請進口倉儲場地，並準備以下資料： (一)申請進口食品進入泰國許可證 (二)申請人的身分證影本 (三)公司營業登記 (四)公司營業執照 (五)進口場地的照片(彩色) (六)戶籍謄本影本 (七)進口倉儲場地的格局 (八)申請進口食品進入泰國確認書(如附件)「檔案下載」泰國申請進口保健食品許可流程及相關法規.pdf 二、收到進口場地許可後，申請進入E-submission系統進口商須透過E-submission系統申請進口許可。 三、泰國FDA建議進口商應於申請前先聯絡FDA，告知產品配方，確認該產品是否屬於保健食品。FDA聯絡人：0968606316 Ms Pimchanok
	E-submission： (1) 配方及成份 (2) 台灣FDA許可證 (3) 工廠生產著證明 (4) 有效原料成分規格 (5) 額外文件，依情況所需

2. 縱觀現行東協國家保健品法規-印尼

一、主管機關	印尼食品藥物管理局(BPOM） NADFC，The National Agency of Drug & Food Control
二、法源依據	1. BPOM 2001年第HK 00.05.4.03960號令(保健食品不得含有Aristolochia SP Plant成分) 2. BPOM 2001年第HK 00.05.4.03961號令(保健食品不得含有Ephedra Plant成分) 3. BPOM 2005年第HK.00.05.41.1381號令(保健食品的註冊程序) 4. BPOM 2007年第HK.00.05.42.6575號令(保健食品不得含有Benzilpiperazin成分) 5. BPOM 2019年第16號條例(保健食品的監管) 6. BPOM 2019年第17號條例(保健食品的品質要求) 7. BPOM 2020年第11號條例(保健食品註冊的條件與管理)
三、進口程序	1. 保健食品在印尼銷售必須先向印尼食品與藥物管理局(BPOM)申請上市許可，進口品在獲得上市許可後才可申請進口許可。 2. 外國保健食品無法自行申請上市許可，必須經由印尼本地代理商申請。 3. 印尼對其國內的保健食品申請上市許可，要求由政府直接核發或政府授權機構核發的GMP證明，故對進口品申請上市許可，亦要求出示該國政府直接核發或政府授權機構核發的GMP證明。 4. 印尼食品與藥物管理局(BPOM)負責管理(1)食品(不含未加工生鮮產品)、(2)藥品、(3)化妝品、(4)傳統草藥(traditional medicine)、(5)保健食品(Food Supplement)等五類產品，保健食品僅為其中的一類。此五類產品要在印尼販售都必須先獲得BPOM的上市許可，且外國商品在獲得上市許後要進口時必須先向BPOM申請進口許可。 5. BPOM亦監控上述五類產品在市場上販售的品質，以確保商品符合官方要求，且無害於印尼人民健康，BPOM對此五類產品的上市、進口、監管有各別的規定與要求
	1. BPOM申請可以先在線上填寫申請表格，備妥產品相關證明文件後上傳，待BPOM完成檢驗與確認後即核發上市許可編號。 2. 許可效期：上市許可效期為5年，期效屆滿後可重新申請換發。 3. 申請時間：申請時間依官方預估約1個月，惟根據臺商經驗，單一產品申請上市許可常常耗時半年甚至是1年以上，原因在於當地行政作業流程緩慢，且不會主動通知廠商受審文件是否缺漏，導致廠商必須重複申請數次才能拿到上市許可。
	1. GMP證明：印尼保健食品申請上市許可時要求GMP證明(由政府核發或政府授權機構核發)，由於我國已取消食品GMP制度，改由民間機構自行核發TQF(Taiwan Quality Food)認證，無法與印尼制度接軌，印尼食品藥物管理局(BPOM)諮詢處表示，可彈性接受我國TQF證明加上PIC/S Site Master File以代替GMP證明。 2. 印尼保健食品未被歸類在藥品下，保健食品與藥品在監管上係兩種彼此獨立的產品。

2. 縱觀現行東協國家保健品法規-馬來西亞

一、主管機關	馬來西亞衛生部藥品管制局（National Pharmaceutical Regulatory Agency, NPRA）NPRA)，主司馬國國內各類藥品以及化粧品之登記、審查、品管、監督與法規管理的單位。 NPRA 亦為保健食品(Health Supplements) 之主管機關。 (另馬來西亞衛生部所屬的食品安全及品質局（Food Safety and Quality Division, 依據相關法規負責食品安全、衛生與品質相關的規劃、督導與執行之工作事項。)
二、法源依據	
三、進口程序	(一) 我國保健食品業者自 2017 年 11 月 1 日起，可於食藥署「食品衛生安全管理認證及驗證資訊系統」填妥相關表件並檢附所需證明文件，提出驗證申請 。業者在通過全廠二級品管驗證及食品擴充驗證方案後，可取得「二級品管驗證證明書」及「食品擴充方案驗證」之證明文件，續向食藥署申請核發符合馬國「營養補充食品外銷核備函」，流程約需 6 個月。取得我食藥署核備函後，業者需再向馬方提出查驗登記申請，取得上市文件約需 7 個月。 (二) 馬來西亞 NPRA 表示，我國保健食品出口商可委由馬國代理商或至馬國成立公司 提出申請，檢附前述核備函與其他必要文件向NPRA 重新申請（ resubmit)，第一階段初審（ 可約 1 個月內完成，之後申請人於繳付費用後，第二階段審核 evaluation）約需時 6 個月，最後 NPRA 將通知審核結果，如通過將核發產品登記號碼供申請人產品上市使用。 附件: 「檔案下載」馬來西亞保健食品市場法規及證照申請說明.pdf

2. 縱觀現行東協國家保健品法規-菲律賓

一、主管機關	菲律賓衛生部食品藥物管理署
二、法源依據	(一) 由於東協傳統藥物及保健品法案尚未通過，菲國未列有獨立之「 保健食品 」 分類，故此保健食品目前適用菲國食品相關法規。
三、進口程序	(一) 菲國上市及進出口之保健食品均須至菲國衛生部 FDA 之電子註冊系統 (Electronic Registration) 登記 ， 取得產品註冊證 Certificate of Product Registration. 登記流程、電子許可步驟與產品註冊及經營許可證分別規範於菲國FDA第 2016 014號通告、第 2016 004號通告及 2014 0029號行政命令。 (二) 菲國FDA針對食品標示另訂有第 2014 0030號 行政命令及 1999年第2號通告，要求所有保健食品均須標示「 No Approved Therapeutic Claim 」 。
	三) 檢附上述相關法規如附件。 附件: 「檔案下載」菲律賓保健食品市場法規及證照申請說明.pdf 「檔案下載」菲律賓保健食品市場法規及證照申請說明附件1.pdf 「檔案下載」菲律賓保健食品市場法規及證照申請說明附件2.pdf 「檔案下載」菲律賓保健食品市場法規及證照申請說明附件3.pdf 「檔案下載」菲律賓保健食品市場法規及證照申請說明附件4.pdf 「檔案下載」菲律賓保健食品市場法規及證照申請說明附件5.pdf

2. 縱觀現行東協國家保健品法規-汶来

一、主管機關	衛生部食品藥物管理署
二、法源依據	A. Medicines Order, 2007 B. Poison Act (Cap.144) & The Poisons Rule C. Misuse of Drugs Act (Cap.27) & The Misuse of Drugs Regulation D. ASEAN Annexes on Traditional medicines (TM) and Health supplements (HS) E. British Pharmacopoeia (2013)
三、進口程序	every importation of TMHS must go through Brunei Darussalam National Single Window (BDNSW) for endorsement. To facilitate the importation, you are encouraged to submit the application for importation and/or sale of TMHS to the TMHS Unit prior to its importation.
	http://www.moh.gov.bn/Shared%20Documents/Traditional%20Medicines/1.1%20Guideline%20for%20Importation%20andor%20sale%20of%20TMHS.pdf

3. 未來東協保健品法規十項技術規範

“保健品 Health Supplements”

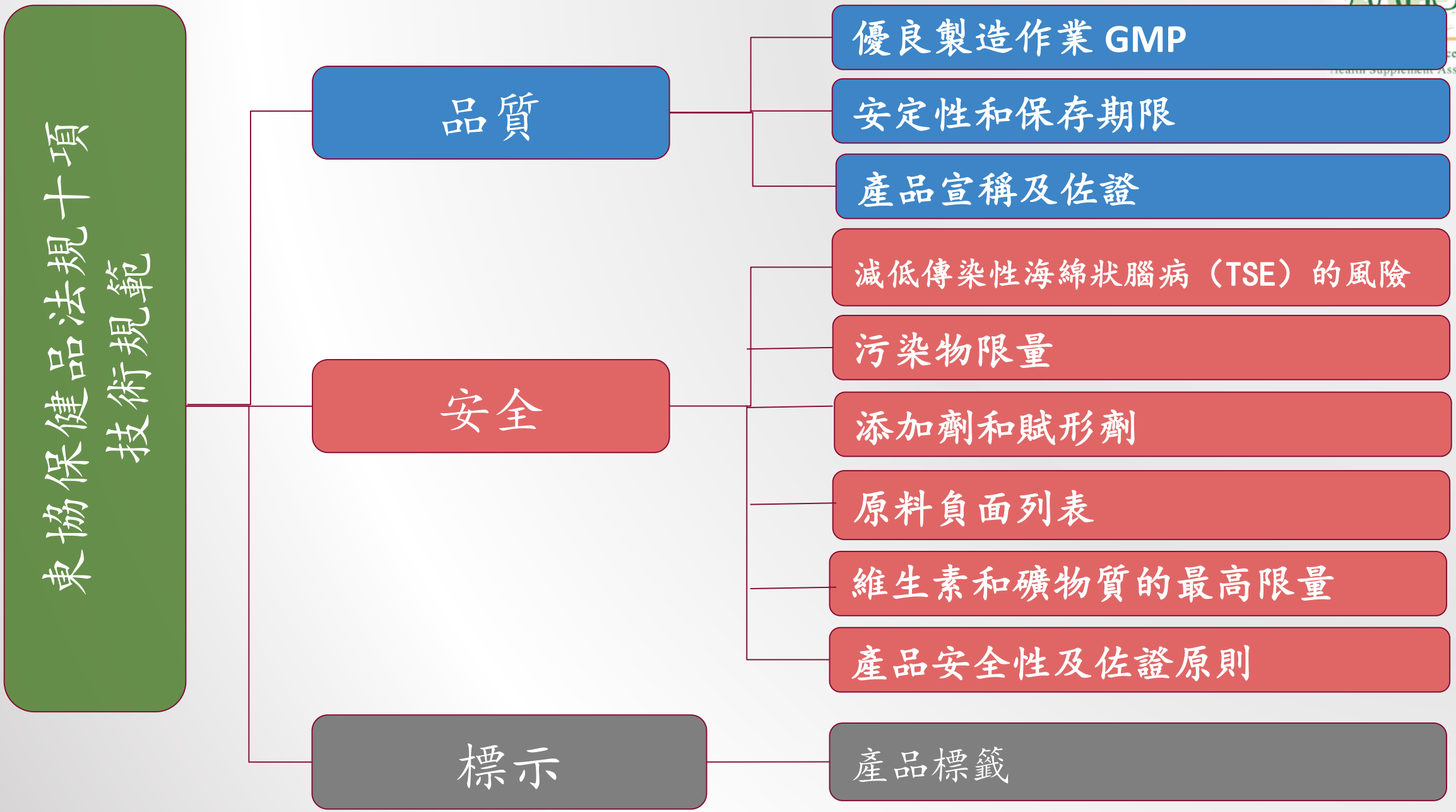
定义	用於補充飲食並維持、增強和改善人體健康功能的任何產品
成分	包含一種或多種，或以下各項的組合： i. 維生素、礦物質、氨基酸、脂肪酸、酵素、益生菌和其他生物活性物質 ii. 衍生自動物、礦物和植物天然來源之物質，包括提取物、分離物、濃縮物、代謝物 iii. （i）和（ii）中提到的成分之合成來源
產品形態	劑型形式，以小單位劑量（例如膠囊、片劑、散劑、液體）服用，不得包括任何無菌製劑（即注射劑、眼藥水）。

Purpose	any product that is used to supplement a diet and to maintain, enhance and improve the healthy function of human body
Composition/ Ingredient	contains one or more, or a combination of: i. Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and other bioactive substances ii. Substances derived from natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates, metabolite iii. Synthetic sources of ingredients mentioned in (i) and (ii)
Product Format/ Form	presented in dosage forms, administer in small unit doses (e.g. capsules, tablets, powder, liquids), shall not include any sterile preparations (i.e. injectable, eyedrops).

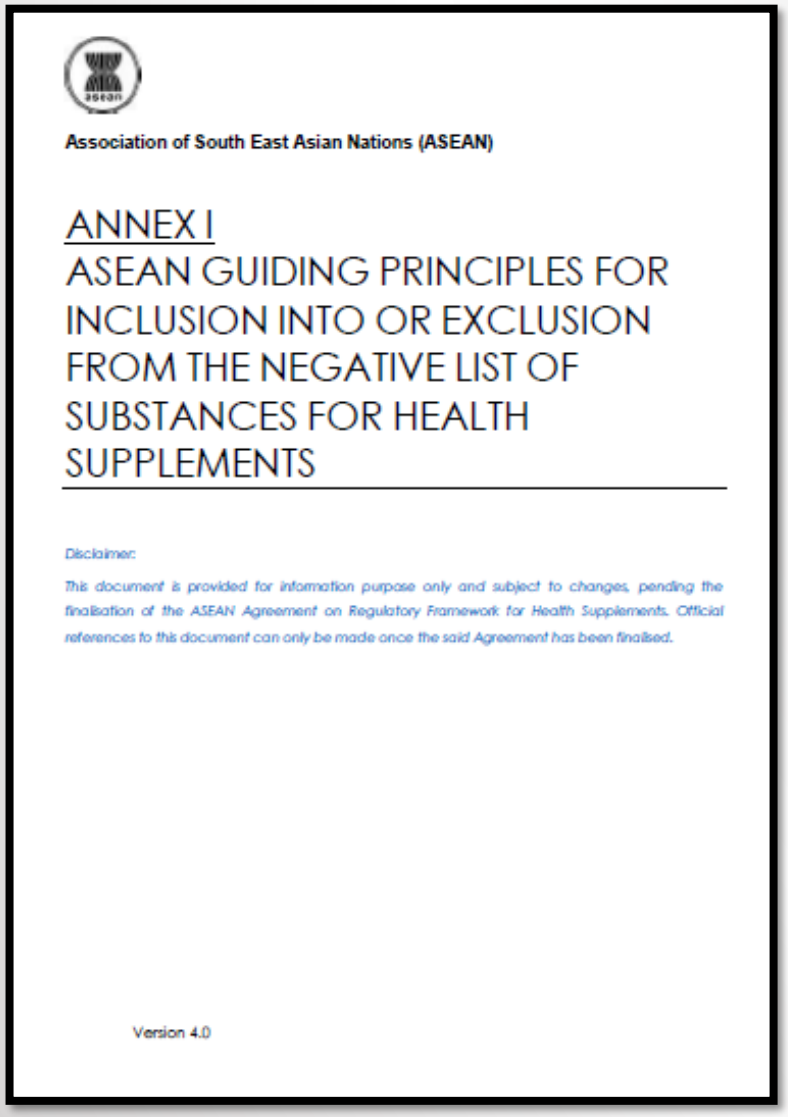
3. 未來東協保健品法規十項技術規範

附件	東協保健品技術規範	有無對應的台湾法规?	差距?
1	原料負面列表 Negative List of Substances	No	
2	添加劑和賦形劑 Additives and Excipients	Yes - 食品添加劑法規，藥典	
3	污染物限量 Limits of Contaminants	Yes - 食品法規	
4	减低傳染性海綿狀腦病（TSE）的風險 Minimising the Risk of Transmissible Spongiform Encephalopathies (TSE)	No	
5	安定性和保存期限 Stability and Shelf-Life	Yes – 健康食品法規	
6	產品安全及佐證原則 Safety and Substantiation	Yes – 健康食品法規	
7	產品宣稱及佐證 Claims and Claims Substantiation	No	
8	優良製造作業 GMP	營養保健食品業者GMP指引	
9	產品標籤 Labeling Requirements	Yes - 食品法規	
10	维生素和矿物质最高限量 Maximum Levels of Vits & Mins	Yes – 食品添加劑法規	

3. 未來東協保健品法規十項技術規範



3. 未來東協保健品法規十項技術規範–
附件1 原料負面列表



Association of South East Asian Nations (ASEAN)

ANNEX I
ASEAN GUIDING PRINCIPLES FOR INCLUSION INTO OR EXCLUSION FROM THE NEGATIVE LIST OF SUBSTANCES FOR HEALTH SUPPLEMENTS

Disclaimer:

This document is provided for information purpose only and subject to changes, pending the finalisation of the ASEAN Agreement on Regulatory Framework for Health Supplements. Official references to this document can only be made once the said Agreement has been finalised.

Version 4.0

重點提示：

- 此負面列表中之物質指經科學證明有安全隱憂，對人體健康有害
- 此原料負面列表不包括下列附件中的物質：添加劑和賦形劑，維生素和礦物質最高限量，污染物限量；以及所有會員國現行的野生動植物保護法所禁止的物質。
- 會員國可依據審查標準要求增列有害物質，列入的理由例如物質的毒性作用，如急性，亞急性，慢性，特定毒性，並提供參考文獻（例如配方，專論/科學報告）
- **配方中絕對不可含有此表中之物質！**

3. 未來東協保健品法規十項技術規範–
附件1 原料負面列表

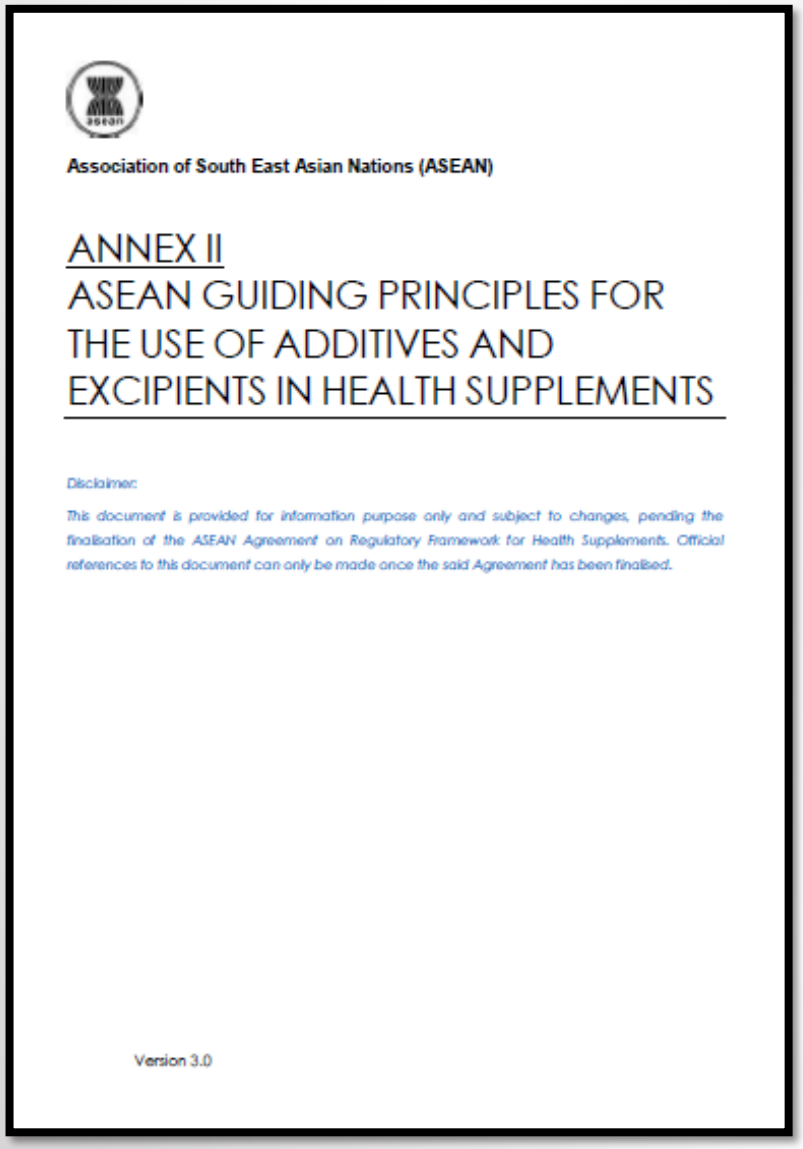
ASEAN Alliance of Health Supplement Associations

Appendix 1 NEGATIVE LIST OF SUBSTANCES FOR HEALTH SUPPLEMENTS

Scientific Name	Common name(s)	Harmful Animal/ Plant Part(s)	Name of Harmful Compound or Compound Class	Ban Status in HS
***Abrus precatorius* L.**	Indian Licorice, Precatory bean, Jequerity, Mutual love Bean (China), Kudri Mani (Tamil), Guru Ginja (Telegu)	Seed	Abrin, which consists of abrus agglutinin, and toxic lectins abrins	Banned
***Aconitum spp.* containing aconite alkaloids**	Monkshood, Aconite	Whole plant	Aconite alkaloids	Banned
***Adonis vernalis* L.**	Pheasant's eye	Whole plant	Cardiac glycosides, (e.g. adonitoxin)	Banned
Animals parts containing hormones	-	Parts that may contain hormones: Pituitary gland, Thyroid gland, Parathyroid glands, Adrenal glands, Pancreas, Thymus gland, Ovary, Testes, Placenta	Growth hormone, prolactin, adrenocortico-tropic hormone, Thyroid-stimulating hormone, Follicle-stimulating hormone, luteinizing hormone, oxytocin, antidiuretic hormone, thyroid hormone, calcitonin, parathyroid hormone, mineralocorti-coids,	Banned

3. 未來東協保健品法規十項技術規範–

附件2 添加劑和賦形劑



Association of South East Asian Nations (ASEAN)

ANNEX II
ASEAN GUIDING PRINCIPLES FOR THE USE OF ADDITIVES AND EXCIPIENTS IN HEALTH SUPPLEMENTS

Disclaimer:

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Version 3.0

重點提示:

指導原則:

1. 使用添加劑和賦形劑的理由
2. 添加劑和賦形劑安全性
3. 確認添加劑和賦形劑的種類，規格和純度
4. 良好生產規範（GMP）使用原則--最少用量
5. 限制性添加劑和賦形劑列表—可參考最新版

CODEX GSFA，药用赋形剂手册，药典

6. 確定在保健品中使用添加劑和賦形劑的程序

一定要先確認！

3. 未來東協保健品法規十項技術規範–

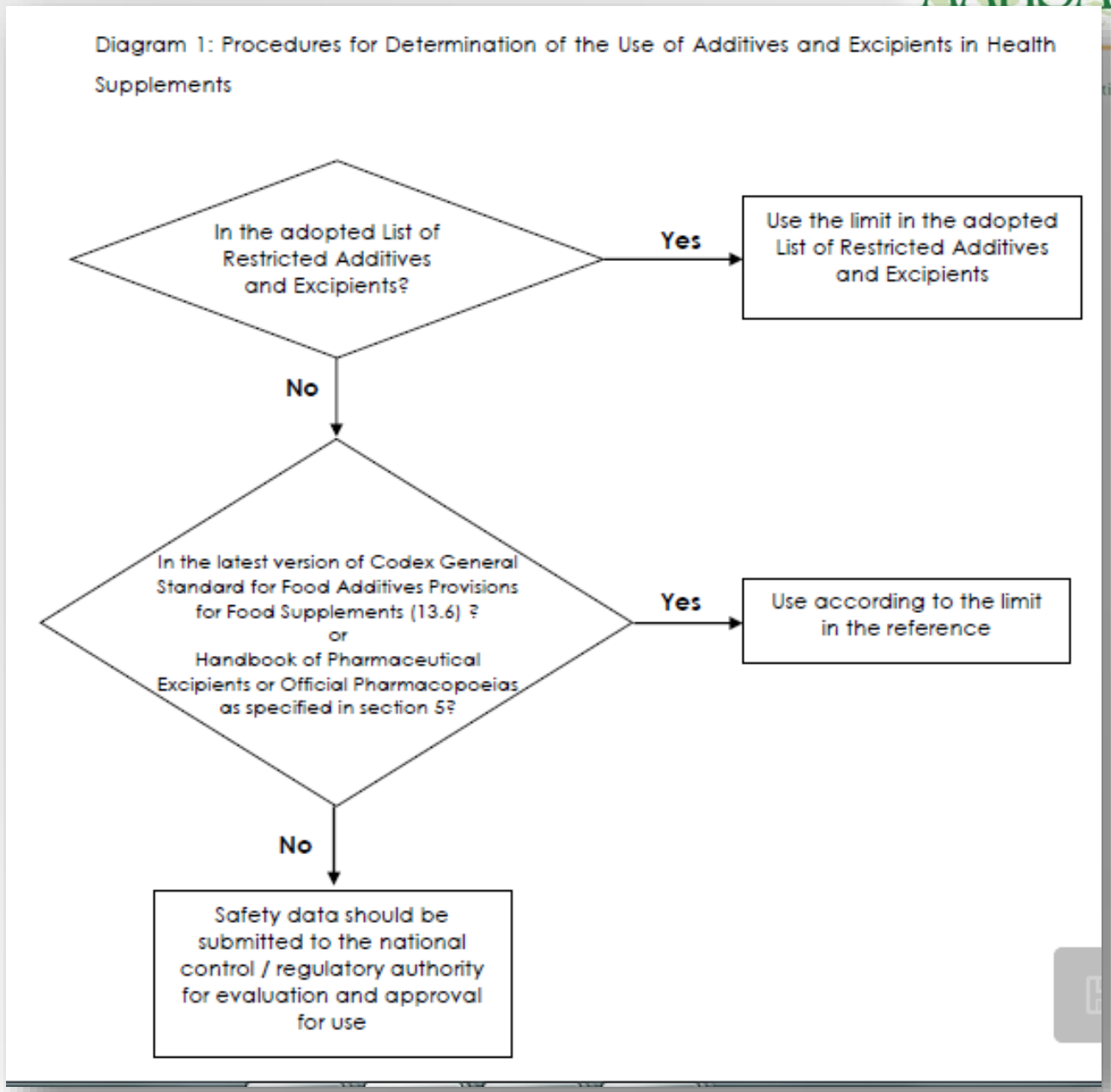
附件2 添加劑和賦形劑

確定在保健品中使用添加劑和賦形劑的程序：

添加劑和賦形劑列表和用量限制

CODEX GSFA 13.6，藥用賦形劑手冊，藥典

安全文獻，報告



3. 未來東協保健品法規十項技術規範–
附件2 添加劑和賦形劑

AAHSA
ASEAN Alliance of Health Supplement Associations

Appendix 1 The List of Restricted Additives and Excipients for Health Supplements

Item	Common name	INS No./ CAS No.	
Coloring agent			
1	Allura Red AC	129	- Cl - Cl - FD
2	Brilliant Blue FCF	133	- Cl - Cl - FD
3	Caramel III – Ammonia process	150c	- Ar
4	Caramel IV - Sulphite Ammonia Process	150d	- Su
5	Carmines	120	- C - Cl - Cl - C

10 of 29 | Version 2.0

FAO/WHO Food Standards ENGLISH | FRANÇAIS | ESPAÑOL

CODEX alimentarius

GSFA Online

Updated up to the 42nd Session of the Codex Alimentar

FOOD ADDITIVE INDEX

This page contains an index of individual food additives

Clicking on an individual food additive or food additive
food additive.

Clicking on "Show synonyms" will display food additive s

Jump to:
A B C D E F G H I K L
Z

A

- Acesulfame potassium (950)
- Acetic acid, glacial (260)
- Acetic and fatty acid esters of glycerol (472a)
- Acetylated distarch adipate (1422)
- Acetylated distarch phosphate (1414)
- Acetylated oxidized starch (1451)
- Acid-treated starch (1401)
- Adipic acid (355)
- Advantame (969)

Pharm

Raymond C Row

British Approved

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The current issue and full text archive of this journal is available at www.emeraldinsight.com/0007-070X.htm

Food additive control: a survey among selected consumers and manufacturers

Food additive control

353

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Revised 8 August 2012
Accepted 13 August 2012

Abstract

Purpose – The aim of this paper is to explore consumer knowledge, attitudes and practices relating to food additives and to investigate manufacturers' attitudes and practices pertaining to food additives and their control.

Design/methodology/approach – Questionnaire administered face-to-face interviews were conducted with 180 consumers from the population working at the University of Mauritius while an interview guide was used for in-depth interviews with 12 manufacturers.

Findings – The results showed that 65 per cent of all respondents never checked food labels for additives. Overall, the respondents had poor knowledge on food additives. A significant relationship was established between level of education and knowledge rating based on percentage correct answers to food additive questions ($p < 0.05$). The mean percentage correct answers for consumers with different educational levels increased in the following order: primary education; secondary education; tertiary education ($p < 0.05$). The responses relating to attitudinal statements reflected indecision and certain misconceptions. In-depth interviews with local food manufacturers revealed positive attitudes and practices towards food additives. Several problems relating to additive control were mentioned, such as outdated regulations and weak enforcement.

Research limitations/implications – Given the sample sizes, the consumer research should not be extrapolated to the Mauritian population while the exploratory manufacturer study should not be generalised to the whole food industry.

Originality/value – These findings provide a factual basis for further investigations, review of current food legislation and development of education strategies for consumers, all aiming towards enhancing the effectiveness of the national food control system in Mauritius.

Keywords Attitudes, Knowledge, Practices, Consumers, Food additives, Manufacturers

Paper type Research paper

1. Introduction

The role of food additives in maintaining food supply worldwide has become more prominent in recent years (US Department of Agriculture, 2008). They are essential tools in the manufacture of many food items to ensure safety and quality, extend shelf-life and enhance consumer appeal (Ilback and Busk, 2000). However, consumers tend to look upon their presence in foods suspiciously and many seek to avoid them

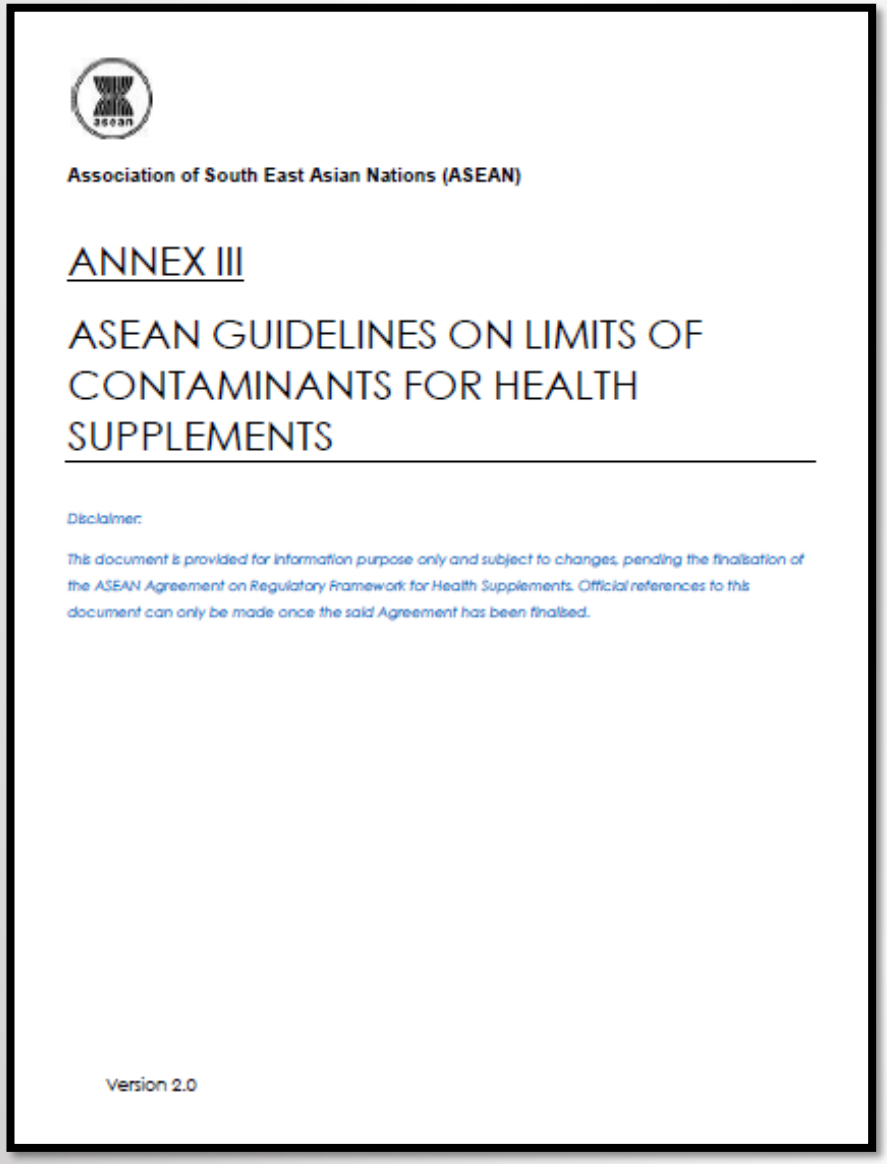
The University of Mauritius is acknowledged for its support of this research along with the valuable contribution of all consumers and participating food industries.

British Food Journal
Vol. 116 No. 2, 2014
pp. 353-372

0007-070X
DOI 10.1108/BFJ-05-2012-0125

3. 未來東協保健品法規十項技術規範–

附件3 污染物限量



Association of South East Asian Nations (ASEAN)

ANNEX III

ASEAN GUIDELINES ON LIMITS OF CONTAMINANTS FOR HEALTH SUPPLEMENTS

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Version 2.0

重點提示:

三種污染物限制:

1. 重金屬　2. 微生物　3. 農藥殘留

1. 重金屬限量

重金屬	鉛 Lead	砷 Arsenic	汞 Mercury	鎘 Cadmium
限量	NMT 10.0 mg/kg or 10.0 mg/L (10.0ppm)	NMT 5.0 mg/kg or 5.0 mg/L (5.0ppm)*	NMT 0.5 mg/kg or 0.5 mg/L (0.5ppm)	NMT 0.3 mg/kg or 0.3 mg/L (0.3ppm)
		*菲律賓: 0.3 mg/kg or 0.3 mg/L (0.3 ppm)		
台灣健康食品限量	≤ 20ppm	≤ 2ppm	無規定	無規定

3. 未來東協保健品法規十項技術規範–

附件3 污染物限量

2. 微生物限量：

✓ 根據英國藥典2013版，得以逐年更新或增加。

✓ 依劑型，原料及製程不同而分為6類產品。

Route of Administration	Acceptable criteria for microbiological quality		
	TAMC (CFU/g or CFU/mL)	TYMC (CFU/g or CFU/mL)	Specified Microorganisms
For Oral Use			
A. Health supplement products containing material of plant origin, with or without excipients, intended for the preparation of infusions and decoctions using boiling water (for example herbal teas, with or without added flavourings)	NMT 5×10^7	NMT 5×10^5	- NMT 10^3 CFU of *Escherichia coli* in 1g or 1mL - Absence of *Salmonella* in 25g or 25mL
B. Health supplement products containing materials of plant origin, with or without excipients, where the method of processing (for example, extraction) or pre-treatment reduces the levels of organisms to below those stated for this category	NMT 5×10^4	NMT 5×10^2	- NMT 10^2 CFU of bile-tolerant gram-negative bacteria in 1g or 1mL - Absence of *Escherichia coli* in 1g or 1mL - Absence of *Salmonella* in 25g or 25mL

3. 未來東協保健品法規十項技術規範–
附件3 污染物限量

C. Health supplement products containing materials of plant origin, with or without excipients, where it can be demonstrated that the method of processing (for example, extraction with low strength ethanol or water that is not boiling or low temperature concentration) or, of pre-treatment, would not reduce the level of organisms sufficiently to reach the criteria required under B	NMT 5×10^5	NMT 5×10^4	- NMT 10^4 CFU of bile-tolerant gram-negative bacteria in 1g or 1mL - Absence of *Escherichia coli* in 1g or 1mL - Absence of *Salmonella* in 25g or 25mL
D. Health supplement products containing materials of natural (animal, plant or mineral) origin for which antimicrobial pre-treatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 10^3 CFU/gram or CFU/mL	NMT 2×10^4	NMT 2×10^2	- NMT 10^3 CFU of bile-tolerant gram-negative bacteria in 1g or 1mL - Absence of *Salmonella* in 10g or 10mL - Absence of *Escherichia coli* in 1g or 1mL - Absence of *Staphylococcus aureus* in 1g or 1mL

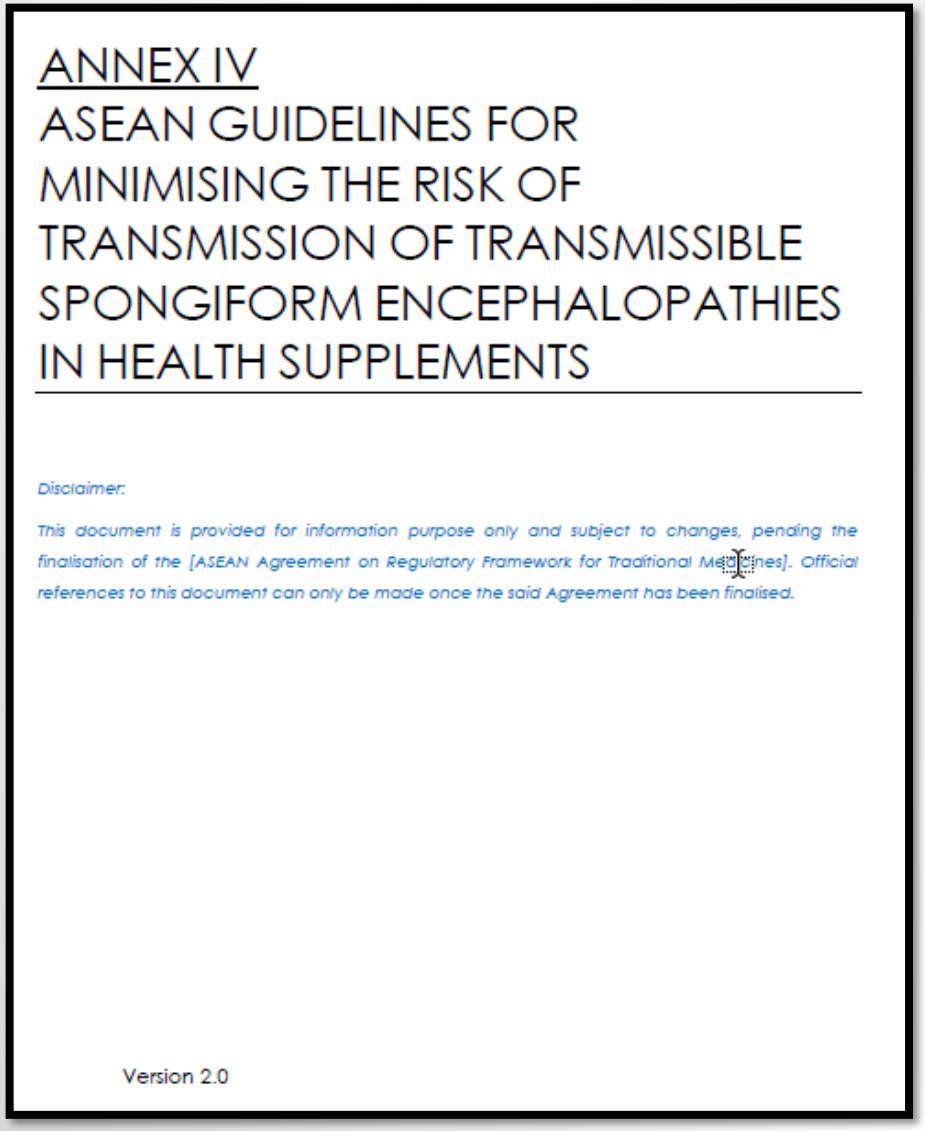
2. 微生物限量：

E. Aqueous preparations which does not fall under category A, B, C or D	NMT 2×10^2	NMT 2 x 10	- Absence of *Escherichia coli* in 1g or 1mL
F. Non-aqueous preparations which does not fall under category A, B, C or D	NMT 2×10^3	NMT 2×10^2	- Absence of *Escherichia coli* in 1g or 1mL

3. 農藥殘留管理原則：

- ✓ 廠商自主管理
- ✓ 原料源頭管控(GAP)
- ✓ GMP廠家嚴格把關農殘超標原料

3. 未來東協保健品法規十項技術規範–
附件4 減低傳染性海綿狀腦病（TSE）的風險



ANNEX IV

ASEAN GUIDELINES FOR MINIMISING THE RISK OF TRANSMISSION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES IN HEALTH SUPPLEMENTS

Disclaimer:

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Version 2.0

重點提示：

傳染性海綿狀腦病（TSE）的風險主要來自遭到感染的反芻動物來源原料，例如牛骨製成之膠囊，膠原蛋白等。

1. 風險管理
2. 避免使用來自BSE高風險區的原料
3. 原料廠商提供来源聲明書
4. 保健品生產廠家自我風險評估表

3. 未來東協保健品法規十項技術規範–
附件4 減低傳染性海綿狀腦病（TSE）的風險

ASEAN Alliance of Health Supplement Associations

APPENDIX 3 SAMPLE OF TSE DECLARATION FORM

TSE Submission Form
Brand & Product Name:
Kit Name:

Ingredient	Quantity	Animal Species	Tissue Used	Infectivity Category	Country of Origin	Reasons for Using

I hereby undertake that the above-mentioned product imported / manufactured (delete where appropriate) by my company complies with the A
Risk of Transmission of Transmissible Spongiform Encephalo
hold evidence to demonstrate that the product is prepare

- from ruminant-derived materials without any risk of
authority in the country of origin has endorsed that the
herds

-by manufacturing process with adequate measures taken to prevent cross-contamination between different tissues from different categories of infectivity

- by a manufacturing process that has shown experimentally to minimise the TSE transmissible agent, if the above product contains tallow and/or gelatin derived from ruminant-derived materials (including those for making capsule shells)

I shall retain all the necessary evidence at all times and would supply the evidence to the regulatory authority if required to do so. I shall report any changes in the TSE status of the ruminant-derived materials of the above product to the regulatory authority as soon as possible.

I hereby declare that the information on this form is current and correct.

I undertake the responsibility to check and ensure compliance to the latest ASEAN Guidelines for Minimising the Risk of Transmission of Transmissible Spongiform Encephalopathies in Health Supplements.

Name: ..... Designation: .....

Company Name: .....

Tel: ..... Fax: .....

Manufacturer Name: .....Date: .....

Company Stamp: ..... Signature: .....

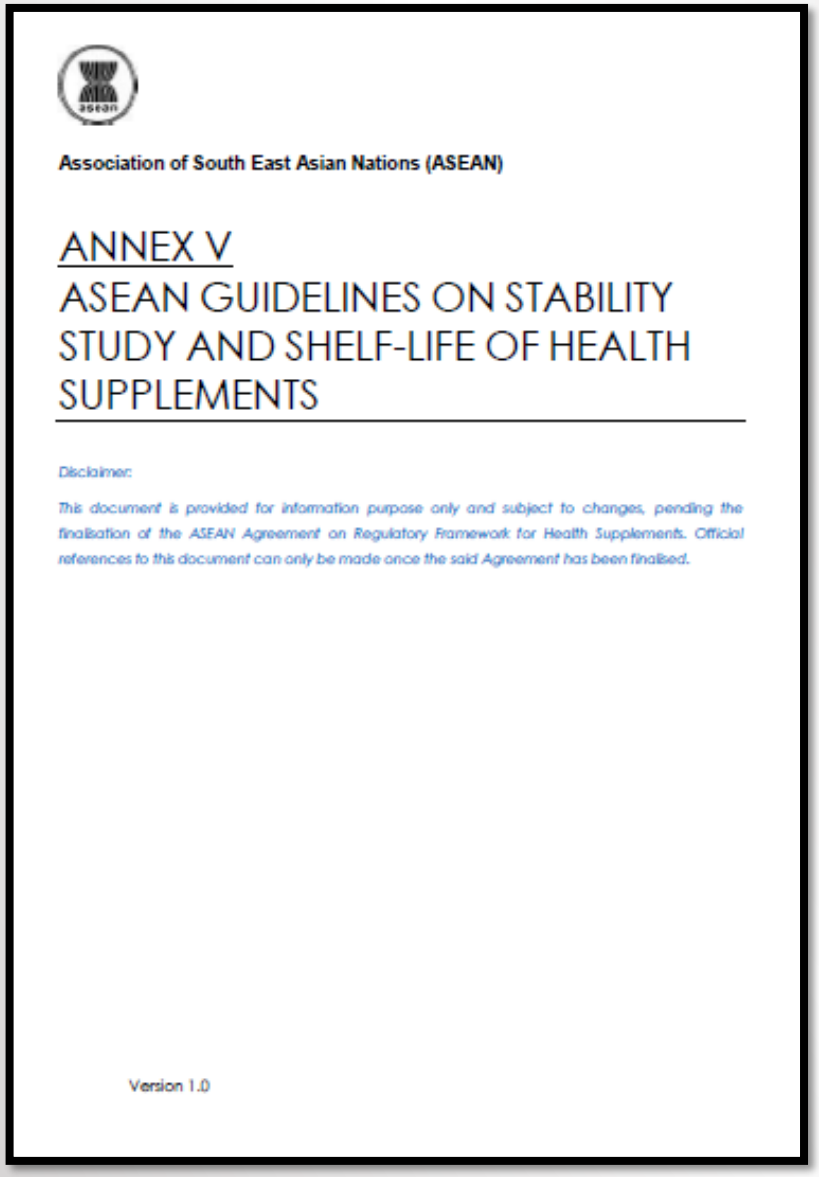
原料廠商提供
来源聲明書

APPENDIX 4 SAMPLE OF CHECKLIST FOR SELF-ASSESSMENT

Check if available	Document	Enclosure number
	1. Source of Animal	
☐	Updated notification of BSE cases in country where each animal material is sourced, where applicable	
☐	Justification for using animal materials from BSE (if applicable)	
☐	Documentary proof issued by health authorities to show that the raw materials used are source herds	
	2. Nature of animal tissue used in manufacturing	
☐	Detailed information on the nature and quantity of each animal-derived material: • Used in the manufacturing process (whether or not this is present in the final products) • Present in the final product formulation	
☐	Letter of confirmation or assurance from the raw materials supplier and/or manufacturer that: • Considerations to reduce cross contamination between different tissues have been taken when obtaining the raw materials	
	3. Manufacturing process(es)	
☐	Letter of confirmation or assurance from the manufacturer that: • Considerations to TSE inactivation / reduction methods have been taken when developing manufacturing methods • If claims have been made to inactivate TSE agents during manufacturing process, then the necessary documentary proof are held in possession and will be made available to the regulatory authority if needed • Quality assurance system is taken into consideration in developing and implementing the manufacturing processes	

保健品生產廠家自我
風險評估表

3. 未來東協保健品法規十項技術規範–
附件5 安定性和保存期限



Association of South East Asian Nations (ASEAN)

ANNEX V
ASEAN GUIDELINES ON STABILITY STUDY AND SHELF-LIFE OF HEALTH SUPPLEMENTS

Disclaimer:

This document is provided for information purpose only and subject to changes, pending the finalisation of the ASEAN Agreement on Regulatory Framework for Health Supplements. Official references to this document can only be made once the said Agreement has been finalised.

Version 1.0

重點提示:

安定性試驗設計須考慮以下因素:

1. 根據產品的性質來決定
2. 批次選擇: 至少2批
3. 規格/測試參數: 物理, 化學和微生物特性
4. 測試頻率: 加速試驗, 實時試驗
5. 儲存條件: 溫度, 濕度
6. 容器封閉系統: 材質, 透水性, 透氣性
7. 評估: 全方位系統性評估表
8. 標籤: 儲存條件, 保存期限

3. 未來東協保健品法規十項技術規範–
附件5 安定性和保存期限

ASEAN Alliance of Health Supplement Associations

規格/測試參數：物理，化學和微生物特性

Testing Parameters / HS Dosage Form	Organoleptic characteristics	Assay	Hardness/ friability	Dissolution /Disintegration	Water content	Viscosity	pH	Microbial content	Granules/Particle Size	Resuspendability
Oral powder	√	√			√			√		
Hard capsule	√	√		√	√			√		
Soft capsule	√	√		√				√		
Coated and Uncoated Tablet	√	√	√	√	√			√		
Coated and Uncoated Pill/Pellet	√	√		√	√			√		
Suspension	√	√				√	√	√	√	√
Solution	√	√				√	√	√		
Emulsion	√	√				√	√	√		
Granules	√	√			√			√	√	

測試頻率

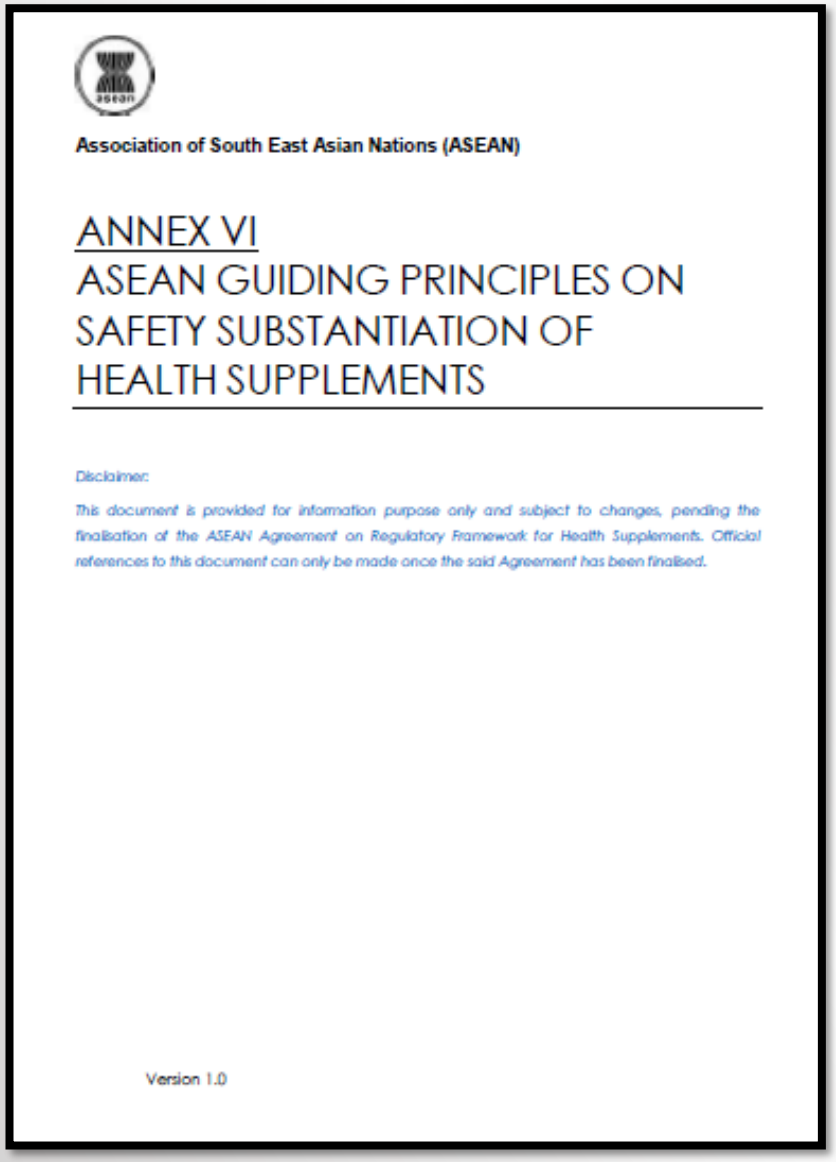
試驗	測試頻率
實時	0，3，6，9，12，18，24 月，每年
加速	0，3，6 月

儲存條件:溫度，濕度

Table 2 Common storage conditions

TYPE OF CONTAINER CLOSURE SYSTEM / STUDY	STORAGE CONDITION
Products in primary containers permeable to water vapour	30°C ± 2°C/75% RH ± 5% RH
Products in primary containers impermeable to water vapour	30°C ± 2°C
Accelerated studies	40°C ± 2°C/75% RH ± 5% RH

3. 未來東協保健品法規十項技術規範–
附件6 產品安全及佐證原則



Association of South East Asian Nations (ASEAN)

ANNEX VI
ASEAN GUIDING PRINCIPLES ON SAFETY SUBSTANTIATION OF HEALTH SUPPLEMENTS

Disclaimer:

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Version 1.0

重點提示：

產品安全指導原則：以下情況必須提供數據證明產品的安全性

（a）含新成分的產品。

（b）成分新的純化，提取或製造方法的產品。

（c）現有產品但以新組合，新劑量，新服用法，或使用特殊或新目標人群（例如孕婦，乳婦，兒童）。

（d）存在安全隱憂的現有產品。

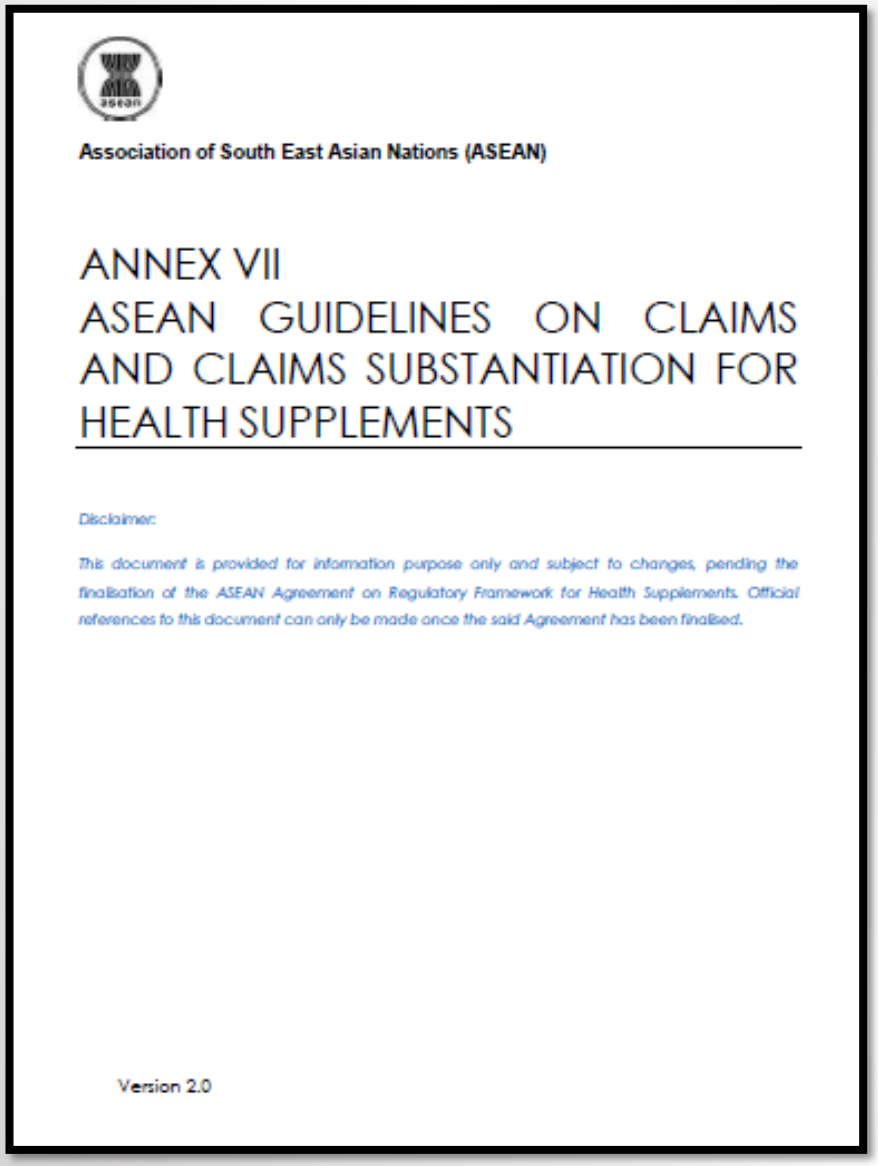
證明產品安全性的條件：

（a）食用歷史依據

（b）科學實驗依據：WHO或OECD指南，急性，亞慢性和/或慢性毒性試驗，其他毒性試驗如致畸性，致癌性和/或致突變性試驗。

3. 未來東協保健品法規十項技術規範–

附件7 產品宣稱及佐證



Association of South East Asian Nations (ASEAN)

ANNEX VII
ASEAN GUIDELINES ON CLAIMS AND CLAIMS SUBSTANTIATION FOR HEALTH SUPPLEMENTS

Disclaimer:

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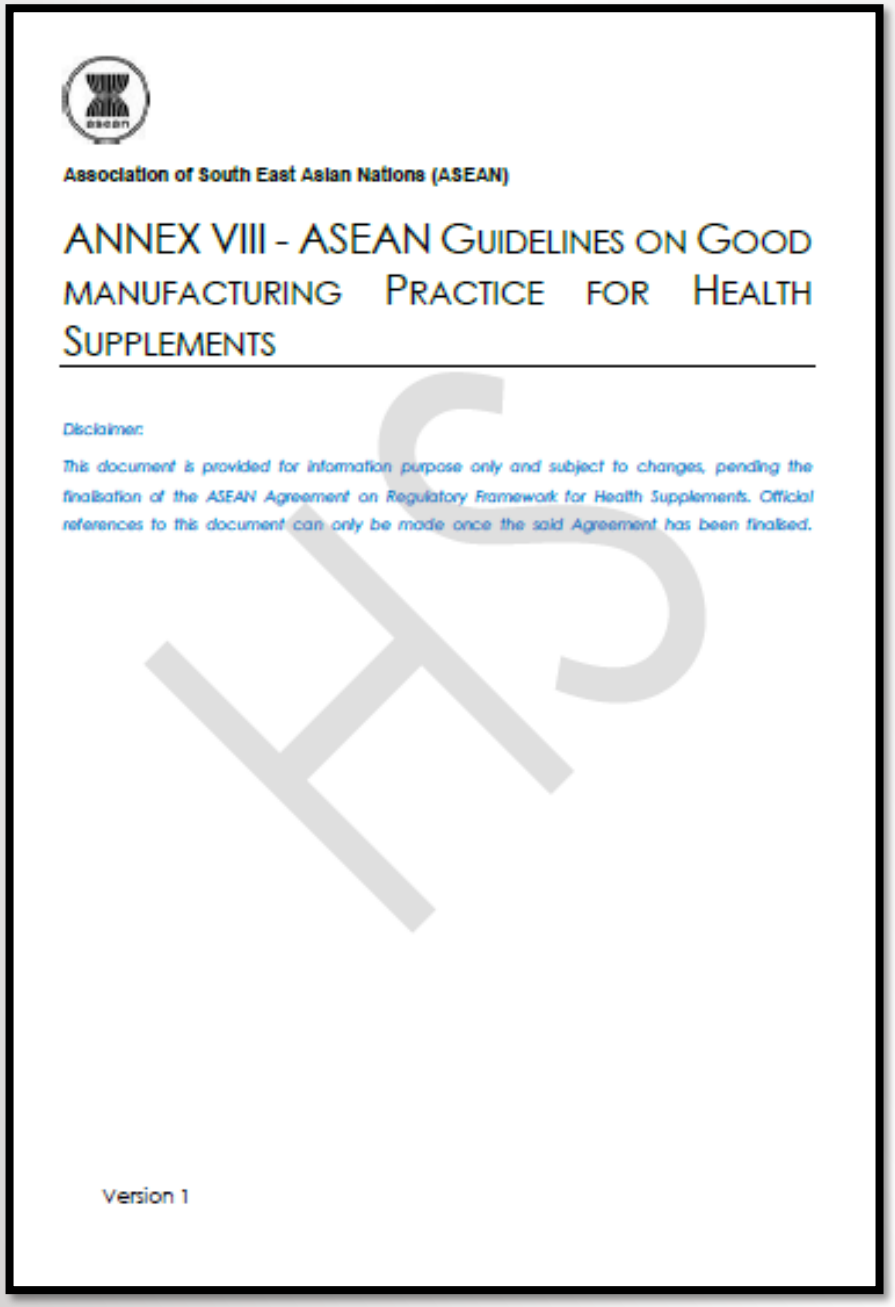
Version 2.0

重點提示：

產品宣称	佐证程度	数据资料标准	资料
一般产品宣称或营养宣称	一般	e. g. 15% Codex NRV	参考书
功能宣称	中	国际或先进国家认可的营养或身体功能宣称	1＋1
降低疾病风险宣称	高	功能机制有持续的证据支持	人体试验＋1

3. 未來東協保健品法規十項技術規範– 附件8 GMP



Association of South East Asian Nations (ASEAN)

ANNEX VIII - ASEAN GUIDELINES ON GOOD MANUFACTURING PRACTICE FOR HEALTH SUPPLEMENTS

Disclaimer:

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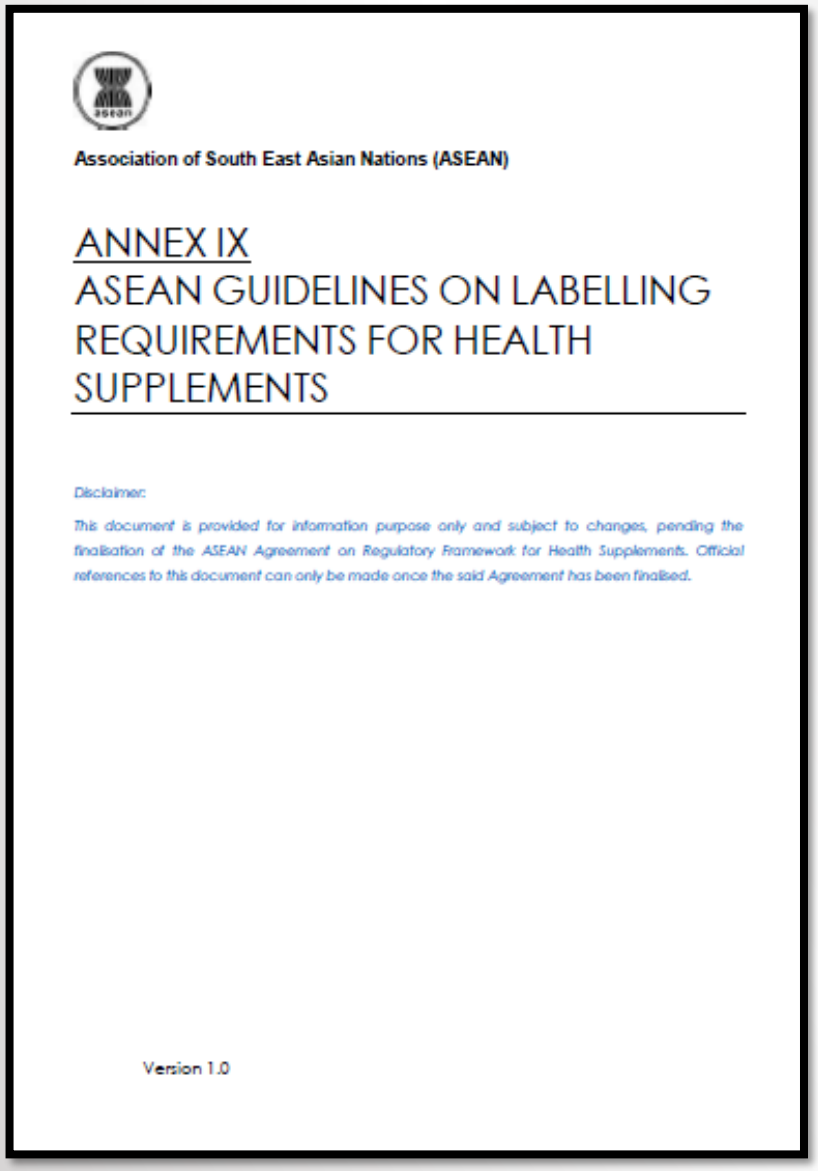
Version 1

3. 未來東協保健品法規十項技術規範– 附件8 GMP

Chapter	ASEAN GMP	營養保健食品業者優良製造作業指引	差距?
1	QUALITY MANAGEMENT	品質管理	
2	PERSONNEL	人員	
3	PREMISES AND EQUIPMENT	廠房設施與設備	
4	SANITATION AND HYGIENE	衛生管理	
5	DOCUMENTATION	文件	
6	PRODUCTION	製造作業	
7	QUALITY CONTROL	品質管制	
8	CONTRACT MANUFACTURE AND ANALYSIS	委託製造與檢驗	
9	COMPLAINTS AND PRODUCT RECALLS	客訴和產品回收	
10	SELF-INSPECTION	自我檢查	

3. 未來東協保健品法規十項技術規範–

附件9 產品標籤



Association of South East Asian Nations (ASEAN)

ANNEX IX
ASEAN GUIDELINES ON LABELLING REQUIREMENTS FOR HEALTH SUPPLEMENTS

Disclaimer:

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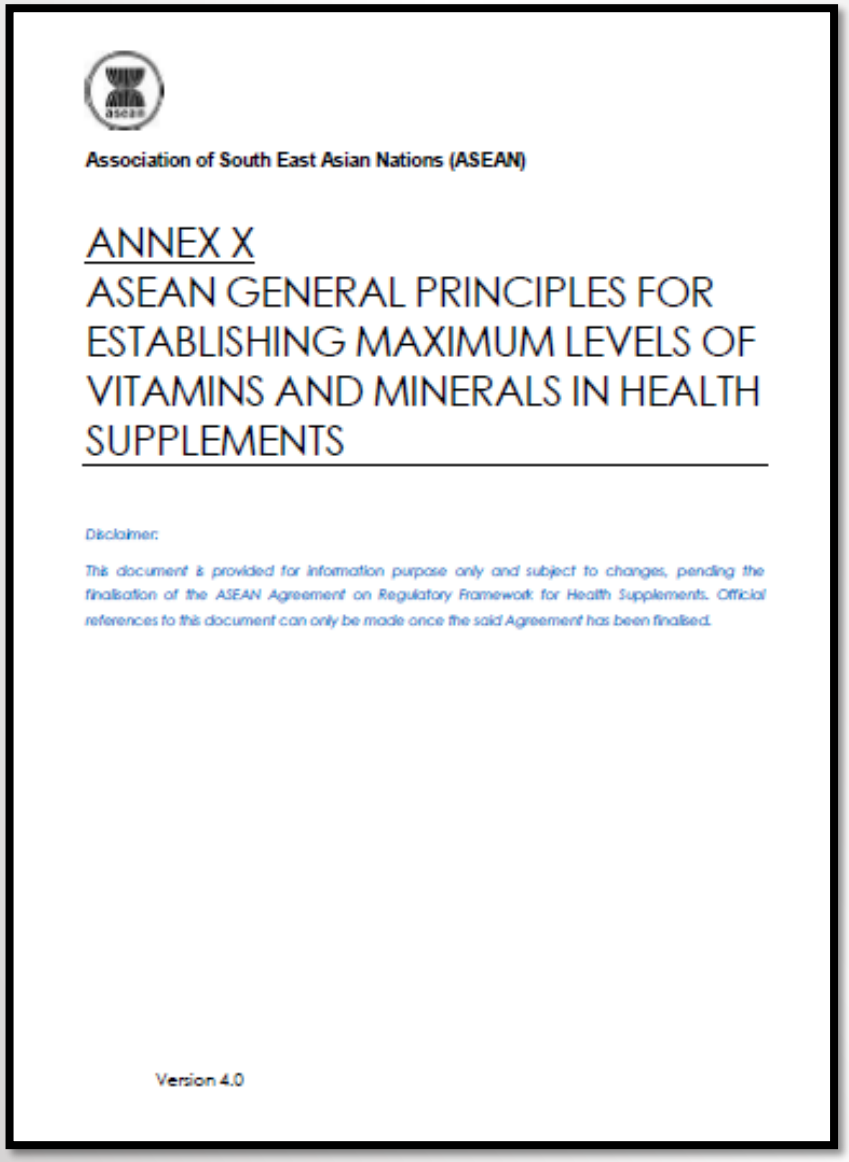
Version 1.0

重點提示：

(a) 产品名
(b) 剂型
(c) 主成分及剂量
(d) 批号
(e) 生产日期及保存期限，或只有保存期限
(f) 服用方法
(g) 用途
(h) 保存方式
(i) 产品注册号码
(j) 制造商名称及地址
(k) 授权商名称及地址
(l) 警语
(m) 包装数量
(n) 其他说明
(o) 国家语文或英语

3. 未來東協保健品法規十項技術規範–
附件10 維生素和礦物質的最高限量



Association of South East Asian Nations (ASEAN)

ANNEX X

ASEAN GENERAL PRINCIPLES FOR ESTABLISHING MAXIMUM LEVELS OF VITAMINS AND MINERALS IN HEALTH SUPPLEMENTS

Disclaimer:

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Version 4.0

3. 未來東協保健品法規十項技術規範–

附件10 維生素和礦物質的最高限量

	Maximum Levels of Vits & Mins	限量/每日	泰国*	印尼*	馬來西亞*	備註
1	Vitamin A (Retinol)	1.5 mg (5000 IU)	0.8 mg			*依照国家特殊要求
2	Vitamin D	0.025 mg (1000 IU)	0.005 mg	0.005 mg		
3	Vitamin E	536 mg (800 IU)	10 mg	10 mg		
4	Vitamin K	0.12 mg	0.08 mg			
5	Vitamin C	C 1000 mg				
6	Vitamin B1	100 mg				
7	Vitamin B2	40 mg	2 mg			
8	Vitamin B6	100 mg				
9	Folic Acid	0.9 mg	0.2 mg			
10	Vitamin B12	0.6 mg				

3. 未來東協保健品法規十項技術規範–

附件10 維生素和礦物質的最高限量

	Maximum Levels of Vits & Mins	限量/每日	泰国*	印尼*	馬來西亞*	備註
11	Biotin	0.9 mg				*依照国家特殊要求
12	Nicotinic acid	15 mg				
13	Nicotinamide	450 mg	20 mg			
14	Pantothenic acid	200 mg				
15	Calcium	1200 mg	800 mg			
16	Phosphorous	800 mg				
17	Magnesium	350 mg				
18	Boron	6.4 mg	NA			
19	Chromium	0.5 mg				
20	Copper	2 mg				

3. 未來東協保健品法規十項技術規範–
附件10 維生素和礦物質的最高限量

	Maximum Levels of Vits & Mins	限量/每日	泰国*	印尼*	馬來西亞*	備註
21	Iodine	0.15 mg			0.3 mg	*依照国家特殊要求 **For pre and antenatal use, as part of a multivitamin and mineral preparation, levels higher than the 20 mg limit established for adults may be permitted at the discretion of the DCA.*
22	Iron	15 mg		20 mg**	20 mg**	
23	Manganese	3.5 mg				
24	Molybdenum	0.36 mg	0.16 mg			
25	Selenium	0.2 mg	0.07 mg			
26	Zinc	15 mg				

東協保健品法規技術統一規範之現況–B

Health Supplement Regulatory Harmonization in ASEAN – Part B

王文秀
東協保健品協會聯盟
8 September 2020

內容大綱

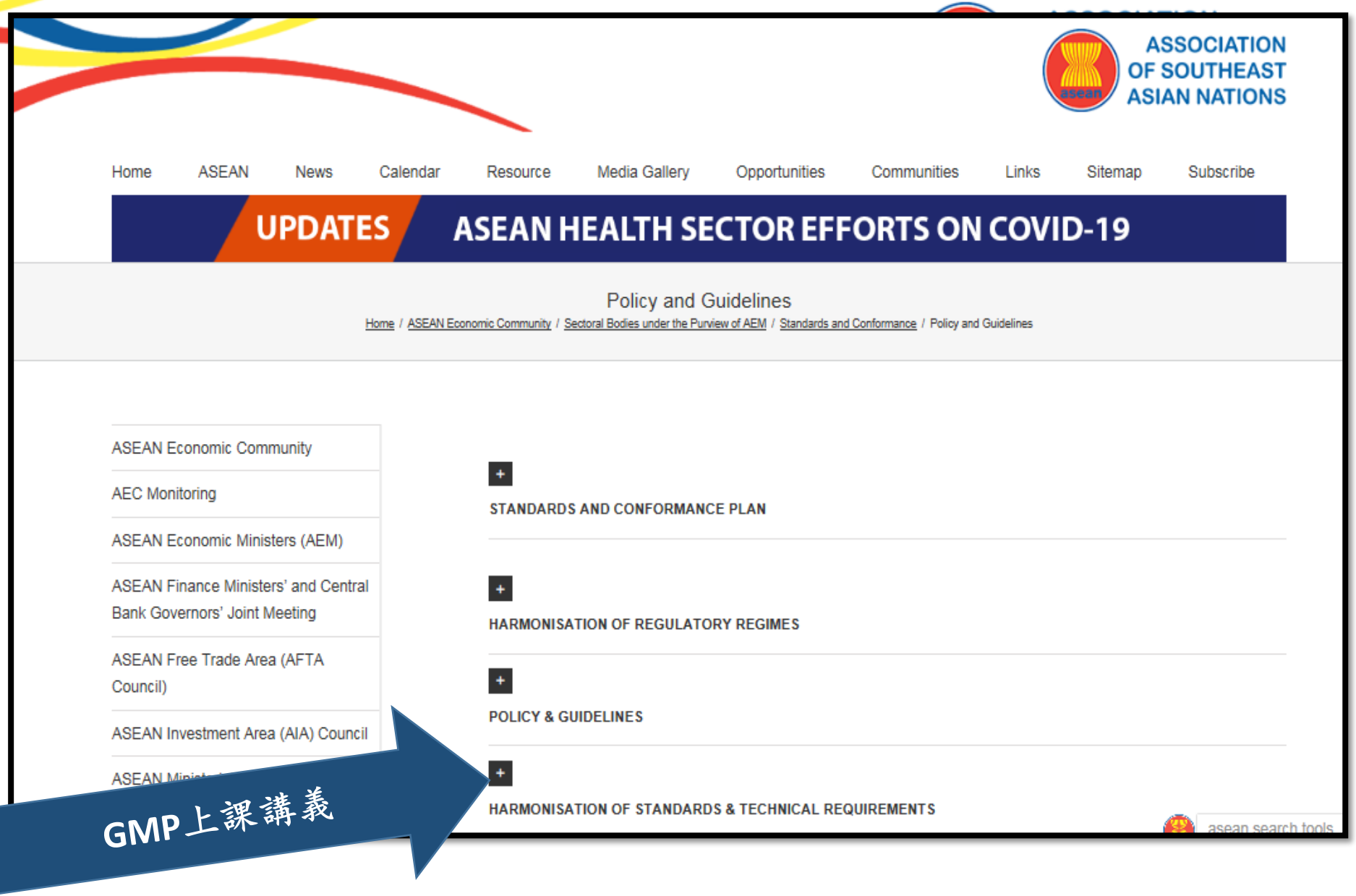
東協保健品法規技術規範工作坊

練習題 1 – 成分配方及標籤技術規範評估

練習題 2 – 安定性和保存期限技術規範評估

https://asean.org/asean-economic-community/sectoral-bodies-under-the-purview-of-aem/standards-and-conformance/policy-and-guidelines/

https://asean.org/asean-econon
aem/standards-and-conformance/policy-and-guidelines/



GMP上課講義

https://asean.org/asean-economic-community/sectoral-bodies-under-the-purview-of-aem/standards-and-conformance/policy-and-guidelines/

11. Traditional Medicines and Health Supplement Product Working Group (TMHSPWG)

- ASEAN TMHS GMP Training
  - ASEAN TMHS GMP Training – Chapter 1 Quality Management
  - ASEAN TMHS GMP Training – Chapter 2 Personnel FD
    - Chapter 2 Annex 1 – Example of Job Description
  - ASEAN TMHS GMP Training – Chapter 3 Premises and Equipment FD
  - ASEAN TMHS GMP Training – Chapter 4 Sanitation and Hygiene FD
    - Chapter 4 Annex 1 – SOP on Personal Hygiene
    - Chapter 4 Annex 2 – Record Daily Inspection on Personal Hygiene
    - Chapter 4 Annex 3 – Sample SOP General Health Examination
    - Chapter 4 Annex 4 – Employee Illness Report Form
    - Chapter 4 Annex 5 – Sample Pest Control Inspection Record
    - Chapter 4 Annex 6 – Sample of Pest Control Monitoring Record
    - Chapter 4 Annex 7 – Sample SOP on Pest Control
    - Chapter 4 Annex 8 – SOP on Cleaning of Equipment and Accessories
    - Chapter 4 Annex 9 – Cleaning Schedule Form
    - Chapter 4 Annex 10 – Cleaning Record Form
    - Chapter 4 Annex 11– Cleaning Inspection Form
  - ASEAN TMHS GMP Training – Chapter 5 Documentation FD
    - Chapter 5 Annex 1 – Specification on Raw Herb Examples Foeniculi Vulgare's
    - Chapter 5 Annex 2 – Text Method for Foeniculi Vulgare
    - Chapter 5 Annex 3 – Ascorbic Acid Specification
    - Chapter 5 Annex 4 – Ascorbic Acid Test Method
    - Chapter 5 Annex 5 – Sample Batch Manufacturing Record
  - ASEAN TMHS GMP Training – Chapter 6 Production FD
  - ASEAN TMHS GMP Training – Chapter 7 Quality Control FD
    - Chapter 7 Annex 1 – Testing Parameters Stability Study
  - ASEAN TMHS GMP Training – Chapter 8 Contract Manufacturing and Analysis
  - ASEAN TMHS GMP Training – Chapter 9 Complaints and Recalls FD
    - Chapter 9 Annex 1 – Sample SOP on Handling of Complaints
    - Chapter 9 Annex 2 – Sample Complaint Register
    - Chapter 9 Annex 3 – Sample Complaint Record Form
    - Chapter 9 Annex 4 – Sample SOP on Product Recalls
    - Chapter 9 Annex 5 – Sample Product Recalls Form
  - ASEAN TMHS GMP Training – Chapter 10 Self Inspection FD
    - Chapter 10 Annex 1 – Sample SOP on Self Inspection
    - Chapter 10 Annex 2 – Sample Record on Self Inspection
  - ASEAN TMHS GMP Training – Appendix 2 Verification FD
  - ASEAN TMHS GMP Training – GMP Inspection
    - Preparation for GMP Inspection
    - Conducting GMP Inspection
    - Classification of GMP Non-Conformance
    - Preparation of GMP Report
    - Evaluation of Corrective Actions and Preventive Actions (CAPA)
    - Case Study & Discussion

ASSOCIATION OF SOUTHEAST ASIAN NATIONS

GMP上課講義

https://asean.org/asean-economic-community/sectoral-bodies-aem/standards-and-conformance/policy-and-guidelines/

練習題 1 – 成分、配方及標籤技術規範

ABC PTE LTD

產品配方

產品名：CAL-M Curcumin Tablet 鈣鎂薑黃素錠				Version：1.0
成分	**重量（毫克/錠）**	**有效成分（毫克/錠）**	**有效成分（毫克/日/2 錠）**	**備註**
碳酸鈣 (40% 鈣) Calcium carbonate (40% calcium)	625	250	500	
氧化鎂 (60% 鎂) Magnesium Oxide (60% Magnesium)	100	60	120	
薑黃素 (70% 薑黃素) Curcumin *Turmeric (Curcumin longa)* (70% curcuminoids)	30	21	42	
維生素 D3 Vitamin D3	0.005	200 IU	400 IU	
微结晶纖維素 Micro-Crystalline Cellulose	30	-	-	
硬脂酸鎂 Magnesium Stearate	5	-	-	
聚乙烯聚吡咯烷酮 Crospovidone	5	-	-	
羥丙基甲基纖維素 Hydroxypropyl Methylcellulose	4.5	-	-	
Total	800			

ABC公司想要進軍泰国及新加坡！

技術規範自我評估

1) 製造廠：XYZ 保健食品公司，台灣
地址：YL 縣TC鎮 中山路15 號
2) 每日建議量：2 錠
3) 使用方式：餐後與開水一起服用
4) 保存期限：2 年
5) 保存方式：25°C 以下，陰涼乾燥處，避免光線直射
6) 包裝：每瓶120 錠，HDPE瓶

練習題 1 – 成分配方及標籤技術規範評估

附件	東協保健品技術規範	泰国	新加坡
1	原料負面列表 Negative List of Substances	✓ 不含負面列表原料	✓
2	添加劑和賦形劑 Additives and Excipients		
3	污染物限量 Limits of Contaminants		
4	减低傳染性海綿狀腦病（TSE）的風險 Minimising the Risk of Transmissible Spongiform	✓ 不含具此風險之原料	✓
5	安定性和保存期限 Stability and Shelf-Life		
6	產品安全及佐證原則 Safety and Substantia	✓ 不含新穎原料	✓
7	產品宣稱及佐證 Claims and Claims Substantiation		
8	優良製造作業 GMP	✓	✓
9	產品標籤 Labeling Requirements		
10	维生素和矿物质最高限量 Maximum Levels of Vits & Mins		

檢查原料成分

檢查原料成分配方

檢查原料成分

檢查原料成分配方

假設已獲得台灣FDA證書

練習題 1 – 成分、配方及標籤技術規範

ABC公司想要进军泰国及新加坡！

ABC PTE LTD

產品配方

產品名：CAL-M Curcumin Tablet 鈣鎂薑黃素錠	Version：1.0

成分	重量（毫克/錠）	有效成分（毫克/錠）	有效成分（毫克/日/2 錠）	備註
碳酸鈣 (40% 鈣) Calcium carbonate (40% calcium)	625	250	500	
氧化鎂 (60% 鎂) Magnesium Oxide (60% Magnesium)	100	60	120	
薑黃素 (70% 薑黃素) Curcumin *Turmeric (Curcumin longa)* (70% curcuminoids)	30	21	42	
维生素 D3 Vitamin D3	0.005	200 IU	400 IU	
微結晶纖維素 Micro-Crystalline Cellulose	30	-	-	
硬脂酸鎂 Magnesium Stearate	5	-	-	
聚乙烯聚吡咯烷酮 Crospovidone	5	-	-	
羥丙基甲基纖維素 Hydroxypropyl Methylcellulose	4.5	-	-	
Total	800			

主成分

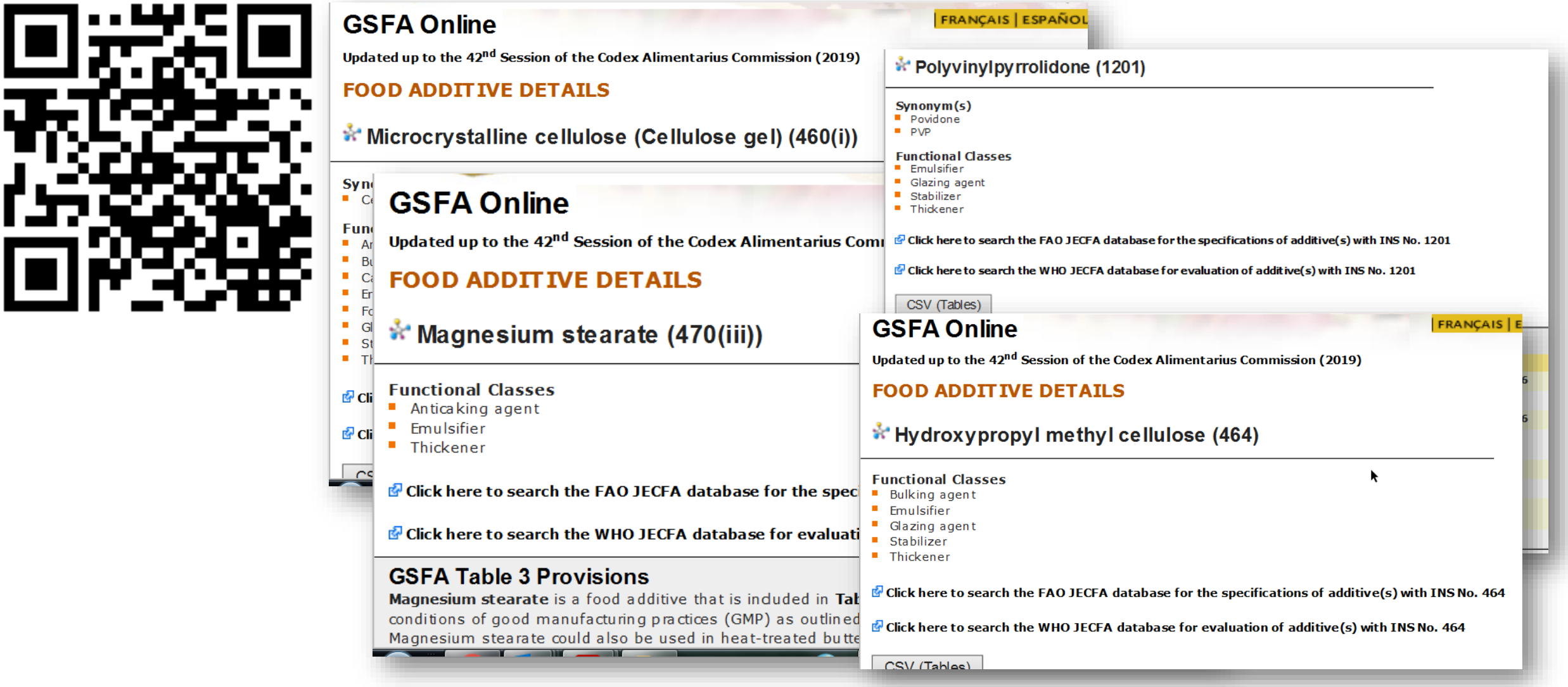
添加劑
賦形劑
➡CODEX

1) 製造廠：XYZ 保健食品公司，台灣
地址：YL 縣TC鎮 中山路15 號
2) 每日建議量：2 錠
3) 使用方式：餐後與開水一起服用
4) 保存期限：2 年
5) 保存方式：25°C 以下，陰涼乾燥處，避免光線直射
6) 包裝：每瓶120 錠，HDPE瓶

練習題 1 – 成分配方及標籤技術規範

http://www.fao.org/gsfaonline/additives/index.html

CODEX GSFA 13.6 Food Supplements



練習題 1 – 成分配方及標籤技術規範

ABC PTE LTD

產品配方

產品名：CAL-M Curcumin Tablet 鈣鎂薑黃素錠				Version

成分	重量 (毫克/錠)	有效成分 (毫克/錠)	有效成分 (毫克/日/2 錠)	備
碳酸鈣 (40% 鈣) Calcium carbonate (40% calcium)	625	250	500	
氧化鎂 (60% 鎂) Magnesium Oxide (60% Magnesium)	100	60	120	
薑黃素 (70% 薑黃素) Curcumin *Turmeric (Curcumin longa)* (70% curcuminoids)	30	21	42	
維生素 D3 Vitamin D3	0.005	200 IU	400 IU	
微結晶纖維素 Micro-Crystalline Cellulose	30	-	-	
硬脂酸鎂 Magnesium Stearate	5	-	-	
聚乙烯聚吡咯烷酮 Crospovidone	5	-	-	
羥丙基甲基纖維素 Hydroxypropyl Methylcellulose	4.5	-	-	
Total	800			

3. 未來東協保健品法規十項技術規範–

附件10 維生素和礦物質的最高限量

	Maximum Levels of Vits & Mins	限量/每日	泰国*	印尼*	馬來西亞*	備
11	Biotin	0.9 mg				*
12	Nicotinic acid	15 mg				
13	Nicotinamide	450 mg	20 mg			
14	Pantothenic acid	200 mg				
15	Calcium	1200 mg	800 mg			
16	Phosphorous	800 mg				
17	Magnesium	350 mg				
18	Boron	6.4 mg	NA			
19	Chromium	0.5 mg				
20	Copper	2 mg				

練習題 1 – 成分配方及標籤技術規範

ASEAN Alliance of Health Supplement Associations

ABC PTE LTD

產品配方

產品名：CAL-M Curcumin Tablet 鈣鎂薑黃素錠	Version：1.0

成分	重量 (毫克/錠)	有效成分 (毫克/錠)	有效成分 (毫克/日/2 錠)	備註
碳酸鈣 (40% 鈣) Calcium carbonate (40% calcium)	625	250	500	
氧化鎂 (60% 鎂) Magnesium Oxide (60% Magnesium)	100	60	120	
薑黃素 (70% 薑黃素) Curcumin *Turmeric (Curcumin longa)* (70% curcuminoids)	30	21	42	
維生素 D3 Vitamin D3	0.005	200 IU	400 IU	
微結晶纖維素 Micro-Crystalline Cellulose	30	-	-	
硬脂酸鎂 Magnesium Stearate	5	-	-	
聚乙烯聚吡咯烷酮 Crospovidone	5	-	-	
羥丙基甲基纖維素 Hydroxypropyl Methylcellulose	4.5	-	-	
Total	800			

3. 未來東協保健品法規十項技術規範–

附件10 維生素和礦物質的最高限量

	Maximum Levels of Vits & Mins	限量/每日	泰国*	印尼*	馬來西亞*
1	Vitamin A (Retinol)	1.5 mg (5000 IU)	0.8 mg		
2	Vitamin D	0.025 mg (1000 IU)	0.005 mg (200 IU)	0.005 mg (200 IU)	
3	Vitamin E	536 mg (800 IU)	10 mg	10 mg	
4	Vitamin K	0.12 mg	0.08 mg		
5	Vitamin C	C 1000 mg			

練習題 1 – 成分配方及標籤技術規範

化學性質

鈣 Calcium	≥ 250 毫克	FIRDI / HPLC
鎂 Magnesium	≥ 60 毫克	
薑黃素 Curcuminoids	≥ 21 毫克	
維生素 D3 Vitamin D3	≥ 200 IU	

微生物

Total Aerobic Microbial count	NMT 1 x 10^5 cfu/g
E.coli	Absent in 1 g
Staphylococcus aureus	Absent in 1 g
Yeast & Mould	NMT 5 x 10^2 cfu/g
Salmonella p.p	Absent in 1 g

1

重金屬

砷 Arsenic	≤ 5 ppm	SGS Taiwan/ ICP/MS
鉛 Lead	≤ 20 ppm	SGS Taiwan/ ICP/MS
汞 Mercury	≤ 0.5 ppm	SGS Taiwan/ ICP/MS
鎘 Cadmium	≤ 1 ppm	SGS Taiwan/ ICP/MS

重金屬	鉛 Lead	砷 Arsenic	汞 Mercury	鎘 Cadmium
限量	NMT 10.0 mg/kg or 10.0 mg/L (10.0ppm)	NMT 5.0 mg/kg or 5.0 mg/L (5.0ppm)*	NMT 0.5 mg/kg or 0.5 mg/L (0.5ppm)	NMT 0.3 mg/kg or 0.3 mg/L (0.3ppm)
		*菲律賓：0.3 mg/kg or 0.3 mg/L (0.3 ppm)		
台灣健康食品限量	≤ 20ppm	≤ 2ppm	無規定	無規定

練習題 1 - 成分配方及標籤技術規範

化學性質

鈣 Calcium	≥ 250 毫克	FIRDI / HPLC
鎂 Magnesium	≥ 60 毫克	FIRDI / HPLC
薑黃素 Curcuminoids	≥ 21 毫克	FIRDI / HPLC
維生素 D3 Vitamin D3	≥ 200 IU	FIRDI / HPLC

2

微生物

Total Aerobic Microbial count	NMT 1 x 10^5 cfu/g	FIRDI/ CNS 12542
E.coli	Absent in 1 g	FIRDI/ CNS12542
Staphylococcus aureus	Absent in 1 g	FIRDI/ CNS12542
Yeast & Mould	NMT 5 x 10^2 cfu/g	FIRDI/ CNS12542
Salmonella p.p	Absent in 1 g	FIRDI/ CNS10952

重金屬

砷 Arsenic	≤ 5 ppm	SGS Taiwan/ ICP/MS
鉛 Lead	≤ 20 ppm	SGS Taiwan/ ICP/MS
汞 Mercury	≤ 0.5 ppm	SGS Taiwan/ ICP/MS
鎘 Cadmium	≤ 1 ppm	SGS Taiwan/ ICP/MS

須先確定原料的微生物負荷量和產品製程的控制方法，才能決定微生物標準的類別。

3

3. 農藥殘留管理原則：
   - ✓ 廠商自主管理
   - ✓ 原料源頭管控(GAP)
   - ✓ GMP廠家嚴格把關 農殘超標原料

3. 未來東協保健品法規十項技術規範–

附件3 污染物限量

2. 微生物限量:

✓ 根據英國藥典2013版, 得以逐年更新或增加。

✓ 依劑型，原料及製程不同而分為6類產品。

Route of Administration	Acceptable criteria for microbiological quality		
	TAMC (CFU/g or CFU/mL)	TYMC (CFU/g or CFU/mL)	Specified Microorganisms
For Oral Use			
A. Health supplement products containing material of plant origin, with or without excipients, intended for the preparation of infusions and decoctions using boiling water (for example herbal teas, with or without added flavourings)	NMT 5×10^7	NMT 5×10^5	- NMT 10^3 CFU of *Escherichia coli* in 1g or 1mL - Absence of *Salmonella* in 25g or 25mL
B. Health supplement products containing materials of plant origin, with or without excipients, where the method of processing (for example, extraction) or pre-treatment reduces the levels of organisms to below those stated for this	NMT 5×10^4	NMT 5×10^2	- NMT 10^2 CFU of bile-tolerant gram-negative bacteria in 1g or 1mL - Absence of *Escherichia coli* in 1g or 1mL
			- Absence of *Salmonella* in 25g or 25mL

茶包之類產品

製程有預先處理, 例如萃取

3. 未來東協保健品法規十項技術規範–

附件3 污染物限量

C. Health supplement products containing materials of plant origin, with or without excipients where it can be demonstrated that the method of processing (fo example, extraction with low strength ethanol or water that is not boiling or low temperature concentration) or, of pre-treatment, would not reduce the level of organisms sufficiently to reach the criteria required under B	NMT 5×10^5	NMT 5×10^4	- NMT 10^4 CFU of bile-olerant gram-negative bacteria in g or 1mL - Absence of *Escherichia coli* in 1g or 1mL - Absence of *Salmonella* in 25g or 25mL
D. Health supplement products containing materials of natural (animal, plant or mineral) origin for which antimicrobial pre-treatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 10^3 CFU/gram or CFU/mL	NMT 2×10^4	NMT 2×10^3	- NMT 10^2 CFU of bile-tolerant gram-negative bacteria in 1g or 1mL - Absence of *Salmonella* in 10g or 10mL - Absence of *Escherichia coli* in 1g or 1mL - Absence of *Staphylococcus aureus* in 1g or 1mL

製程用低濃度乙醇或非沸騰或低溫濃縮水萃取，預處理的方式，但不足以達到B要求的微生物標準。

微生物預處理不可行，政府法規可接受其原料的TAMC超過10^3 CFU／克或CFU ／ mL

2. 微生物限量：

以上４類之外的液態製劑

E. Aqueous preparations which does not fall under category A, B, C or D	NMT 2×10^3	NMT 2×10	- Absence of *Escherichia coli* in 1g or 1mL

以上４類之外的固態製劑

F. Non-aqueous preparations which does not fall under category A, B, C or D	NMT 2×10^3	NMT 2×10^2	- Absence of *Escherichia coli* in 1g or 1mL

練習題 1 – 成分配方及標籤技術規範

產品標籤技術規範–

(a) 产品名
(b) 剂型
(c) 主成分及剂量
(d) 批号
(e) 生产日期及保存期限，或只有保存期限
(f) 服用方法
(g) 用途
(h) 保存方式
(i) 產品註冊號碼
(j) 制造商名称及地址
(k) 授权商名称及地址
(l) 警语
(m) 包装数量
(n) 其他说明
(o) 国家语文或英语

ABC PTE LTD

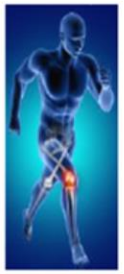
產品標籤及包裝

進口商:ABC Pte Ltd Thailand
地址:ZZZZZBangkok, Thailand
製造廠：XYZ 保健食品公司
地址：YL 縣 TC 鎮中山路 15 號, 台灣
FDA 註冊號碼:
批号：080915BCA
生产日期：08092015
保存期限：08092017

ABC™

鈣鎂薑黃素錠

CAL-M Curcumin Tablet



- ✓ 全方位活動力配方
- ✓ 鈣鎂協調筋骨肌肉
- ✓ 有助預防骨質酥鬆
- ✓ 薑黃素強力抗氧化
- ✓ 有助減少發炎反應

120 錠

主成分及剂量（每錠含）：
鈣 Calcium 250 毫克
鎂 Magnesium 60 毫克
薑黃素 Curcuminoids 21 毫克
维生素 D3 Vitamin D3 200 IU
每日建議量：2 錠
使用方式：餐後與開水一起服用
保存方式：25℃ 以下陰涼乾燥處，避免光線直射。

練習題 2 – 安定性和保存期限技術規範評估

Product Stability Study Report

Product Name: CAL-M Curcumin Tablet 鈣鎂薑黃素錠 120 Tablets

Production Date: 08/11/2015 **Batch No.: 080915BCA**

Real Time Condition (30±2°C)							
Testing Period	Specification	3M	6M	9M	12M	18M	24M
Date of Analysis		08/02/16	08/05/16	08/08/16	08/11/16	08/05/17	08/11/17
Physical							
Appearance	米色长椭圆形锭	OK	OK	OK	OK	OK	OK
Moisture Content (%)	< 5% w/w	1.15			1.35		1.60
Disintegration Time (min)	< 30 分	10.5			11.00		12.32
Tablet Thickness	4.65-4.95mm	4.89			4.89		4.89
Tablet Hardness	12-20 kgf	17.80			17.80		17.20
Friability	< 1%	0			0		0
Microbial							
E. Coli	Absent in 1 g				0		0
Coliform	Negative				0		0
Total Plate Count	NMT 1 x 10^3 cfu/g				20		40
Yeast & Mold	NMT 5 x 10^2 cfu/g				2		5
Chemical Assay							
	Label (mg/tablet)	mg/100g	mg/100g	mg/100g	mg/100g	mg/100g	mg/100g
Calcium	≥250	≥31250	31300				31280
Magnesium	≥60	≥7500	7620				7580
Vtiamin D3 (IU)	≥200 IU	≥25000	24900				23800
Curcuminoids	≥21	≥2625	2708				2200

Real Time Condition (40±2°C)							
Testing Period	Specification	1M	2M	4M	6M		
Date of Analysis		08/12/15	08/01/16	08/03/16	08/05/16		
Appearance	米色长椭圆形锭	OK	OK	OK	OK		
Disintegration Time (min)	< 30 分	15.00	16.30	17.05	17.30		
Friability	< 1%	0	0	0	0		

1. 此產品之安定報告是否符合東協保健品安定性和保存期限的技術規範?

2. 請列出需要改善之處?

練習題 2 – 安定性和保存期限技術規範評估

安定性試驗設計須考慮以下因素：

原則	規範	缺失	改善
1) 試驗設計	產品特性		
2) 批次選擇	至少2批		
3) 規格/測試參數	a) 物理 b) 化學 c) 微生物		
4) 測試頻率	a) 加速試驗 b) 實時試驗		
5) 儲存條件	a) 溫度 b) 濕度		
6) 容器封閉系統	材質，透水性，透氣性		
7) 評估	全方位系統性評估表		
8) 標籤	a) 儲存條件 b) 保存期限		

練習題１－ 成分配方及標籤技術規範評估

附件	東協保健品技術規範	泰国	新加坡
1	原料負面列表 Negative List of Substances		
2	添加劑和賦形劑 Additives and Excipients		
3	污染物限量 Limits of Contaminants		
4	减低傳染性海綿狀腦病（TSE）的風險 Minimising the Risk of Transmissible Spongiform Encephalopathies (TSE)		
5	安定性和保存期限 Stability and Shelf-Life		
6	產品安全及佐證原則 Safety and Substantiation		
7	產品宣稱及佐證 Claims and Claims Substantiation		
8	優良製造作業 GMP 假設已獲得台灣FDA證書		
9	產品標籤 Labeling Requirements		
10	维生素和矿物质最高限量 Maximum Levels of Vits & Mins		

AAHSA
ASEAN Alliance of Health Supplement Associations

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ASEAN Alliance of Health Supplement Associations
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Association of South East Asian Nations (ASEAN)

ANNEX V
ASEAN GUIDELINES ON STABILITY STUDY AND SHELF-LIFE OF HEALTH SUPPLEMENTS

Disclaimer:

This document is provided for information purpose only and subject to changes, pending the finalisation of the ASEAN Agreement on Regulatory Framework for Health Supplements. Official references to this document can only be made once the said Agreement has been finalised.

Version 1.0

DOCUMENT INFORMATION

This version was adopted at the 20th ASEAN TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS SCIENTIFIC COMMITTEE MEETING (ATSC) 26-29 August 2013, Bangkok and endorsed at the 20th ACCSQ TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS PRODUCT WORKING GROUP (TMHSPWG) MEETING 15-16 November 2013, Yogyakarta, Indonesia.

CONTENTS

INTRODUCTION

Stability is an essential factor of quality in health supplements (HS). It is determined by a series of tests conducted, namely to ensure maintenance of the specifications of the finished product when packed in its specified packaging material and stored in the established storage condition within the determined shelf-life.

The aim of conducting a stability study on HS is to determine its shelf-life as a finished product in its container closure system under the recommended storage condition, within which the finished product still meets its established physical, microbiological and/or chemical specifications.

OBJECTIVE

This guideline is intended to provide recommendations on the core stability study required for products; nevertheless it leaves sufficient flexibility to encompass the variety of different practical situations that may be encountered due to specific scientific considerations and characteristics of the products being evaluated.

DESIGN

1. GENERAL

The design of a stability study for the product should be based on the nature of the product. It should take into account of the following:

- Selection of batches;
- Specifications/Testing parameters;
- Testing frequency;
- Storage condition.
- Container closure system

2. SELECTION OF BATCHES

Stability data should be provided for batches of the same formulation and dosage form in the container closure system intended for marketing.

- Stability data from at least two batches would be required, derived either from pilot scale, primary scale, production scale or their combination.
- The manufacturing process of batches used in stability studies should simulate that of production batches and should be of the same quality as well as meet the same specification as those batches intended for marketing.
- Stability studies should be performed on individual strengths of the product and/or type of container closure system in which the finished product is packed unless bracketing/matrixing is applied as in Appendix 1.

3. Specification / Testing Parameters

A stability study should cover the testing of the physical, chemical, and microbiological properties of a finished product that are susceptible to change during storage and are likely to influence quality when changed.

The list of testing parameters is presented as a guide for the types of tests to be included in a stability study as in Appendix 2.

The list of tests for each product is not intended to be exhaustive, nor is it expected that every listed test to be included in the design of the stability study protocol for a particular finished product.

For a product containing ingredients without known marker(s), physical parameters may be used as surrogate indicators during storage, when the use of such parameters can be justified. The physical parameters of the finished product can be checked by at least one of the following test methods:

I. Gross organoleptic analysis; Examination by general impression
II. Other scientifically valid criteria.

For a combination product containing multiple active ingredients, although it may not be necessary to assay all the active ingredients, it may be appropriate to assay one, and in some cases, more than one active ingredient, or a surrogate marker that is known to be susceptible to change during storage and is likely to influence the quality of the combination product. A valid justification shall be submitted.

4. Testing Frequency

For accelerated and real time stability studies, frequency of testing should be sufficient to establish the stability profile of the finished product. At the accelerated storage condition,

a minimum of three time points, including the initial and final time points, for example, 0, 3, and 6 months for a 6-month study, is recommended.

The frequency of testing at real time storage conditions should normally be every 3 months over the first year, every 6 months over the second year and annually thereafter through the proposed shelf-life. A typical testing frequency is as shown in Table 1 below.

Table 1 A typical testing frequency

Storage Condition	Testing Frequency
Real Time	0, 3, 6, 9, 12, 18, 24 months and annually there after through the proposed shelf-life
Accelerated	0, 3 and 6 months

Reduced designs, i.e., matrixing or bracketing, where the testing frequency is reduced or certain factor combinations are not tested at all, can be applied, if justified, as in Appendix 1.

Where an expectation (based on development experience) exists that outcomes from accelerated studies are likely to approach significant change criteria, i.e. parameters tested are out of the specifications set, it is advised an increased testing should be conducted either by adding samples at the final time point or by including a fourth time point in the study design.

If the "significant change" occurs within the first 3 months' testing at the accelerated storage condition, a justification should be provided to address the effect of short term excursions outside the label storage condition, e.g., during shipping or handling. This justification can be supported, if appropriate, by further testing on a single batch of the product for a period shorter than 3 months but with more frequent testing than usual. It is considered unnecessary to continue to test a product through the remaining months when a "significant change" has occurred within the first 3 months, and as such the shelf-life shall be based on real time data.

If "significant change" occurs between 3 and 6 months' testing at the accelerated storage condition, shelf-life shall be based on real time data.

5. STORAGE CONDITION

In general, HS as a finished product should be evaluated under its storage conditions (with appropriate tolerances) that test its thermal stability under recommended storage conditions and, if applicable, its sensitivity to moisture or potential for solvent loss. The storage conditions and the lengths of studies chosen should be sufficient to cover storage, shipment, and subsequent use, for example, after reconstitution or dilution as recommended in the labeling.

Specific recommended temperature and relative humidity conditions for storage applied to stability studies and types of container closure system are based on the nature of the products and the type of primary container used, in accordance with recommended storage condition on product label. Common storage conditions are shown in Table 2 below.

Table 2 Common storage conditions

TYPE OF CONTAINER CLOSURE SYSTEM / STUDY	STORAGE CONDITION
Products in primary containers permeable to water vapour	30°C ± 2°C/75% RH ± 5% RH
Products in primary containers impermeable to water vapour	30°C ± 2°C
Accelerated studies	40°C ± 2°C/75% RH ± 5% RH

If submitted data is based on conditions that are less stressful (e.g. 30°C/65% RH) than those required, the data should be accompanied by appropriate complementary data which will permit to conduct a proper scientific evaluation. Factors to be taken into consideration will include:

- Whether any instability is seen;
- Whether data have also been provided under accelerated conditions;
- The type of container closure system

Other storage conditions are allowable, if justified. Examples would include:

- Heat sensitive products which should be stored under lower temperature condition which will eventually become the designated long term storage temperature.

- Products containing less stable active ingredients and formulations not suitable for storage at elevated temperature will need real time stability studies.
- Where a lower temperature condition is used, the 6 month accelerated testing should be carried out at a temperature at least 15°C above the expected actual storage temperature (together with appropriate relative humidity conditions for that temperature). For example, for a product to be stored long term under refrigerated conditions, accelerated testing should be conducted at 25°C ± 2°C, 60% RH ± 5% RH. The designated real time testing conditions will be reflected in the labelling and shelf-life (expiration date). Typical storage conditions recommended for stability studies on products intended for storage in a refrigerator as shown in Table 3 below

Table 3 Typical storage conditions recommended for products intended in a refrigerator

STUDY	STORAGE CONDITION
Real Time	5°C ± 3°C
Accelerated	25°C ± 2°C/60% RH ± 5% RH

- Products which change physically or even chemically at lower storage temperature conditions e.g., suspensions or emulsions.

Data from the accelerated stability studies can be used to evaluate the effect of short-term excursions outside the label storage conditions such as during shipping. The data from accelerated study and ongoing real time stability study can be used to justify an interim extrapolated shelf-life. However, the actual shelf-life should be based ultimately on the real time stability data at the recommended storage conditions.

6. Container Closure System

Stability testing should be conducted on the product packaged in the primary container closure system proposed for marketing including, as appropriate, any secondary packaging.

Finished products packed in moisture-impermeable primary containers are not required to be tested under high humidity conditions. Generally considered moisture- impermeable containers include aluminum/aluminum blisters, High Density Polyethylene (HDPE) or glass bottles fitted with metal or HDPE closures .

When using moisture-permeable containers for packaging, due consideration should be given to the stability of the contents under high humidity conditions. Moisture may have an undesirable effect on chemical and physical stability of a finished product.

The issue of the different permeability of various packaging materials should be addressed e.g. the effect of high humidity on solid dosage forms packaged in containers permeable to moisture should be supported by data and an indication, like "keep in a dry place or protect from moisture" should be added to the label. Examples of moisture permeable containers include polyvinyl chloride (PVC) blisters, low density polyethylene (LDPE) bottles, glass or HDPE bottles when fitted with polypropylene closures.

7. EVALUATION

A systematic approach should be adopted in the presentation and evaluation of the stability information, which should include, as appropriate, results from the physical, chemical and microbiological tests. Any evaluation should consider not only the assay, but also other appropriate test attributes. A recommended presentation of the summary table of stability results appears as in Appendix 3.

8. LABELLING

The storage conditions that include temperature, light and humidity indicated on the label should be based on the stability evaluation of the product. General precautionary statements, such as "Protect from light" and/or "Store in a dry place", may be included, but should not be used to conceal stability problems of the finished product. Specific instruction on storage condition should be provided. Terms such as `ambient conditions' or 'room temperature' should be avoided.

GLOSSARY

Assay

A test procedure for measuring or determining the quantity of active ingredient or marker in a finished product.

Batch

A quantity of the finished product produced during a given cycle of manufacture and from a specific formulation order, that is uniform in character and quality [the essence of a manufacturing batch is its homogeneity]

Pilot Scale Batch

A batch of substances or product manufactured by procedure fully representative of and simulating that to be applied to a full production scale batch. A pilot scale is generally, at minimum, one tenth that of a full production scale.

Primary Scale Batch

A batch of product manufactured by a procedure fully representative of and simulating that to be applied to a full production scale batch. A primary scale may comprise ten to one hundred percent of a full production scale.

Production Scale Batch

A batch of product manufactured at production scale by using production equipment in a production facility as specified in the application.

Container Closure System

The sum of packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if latter are intended to provide additional protection to the finished product. A packaging system is equivalent to a container closure system.

Disintegration

The rate that tablets or capsules disintegrate within the prescribed time when placed in a liquid medium and under the experimental conditions as prescribed in references such as official pharmacopoeia.

Dissolution

The quantity of active substance dissolved in a specified time, expressed as a percentage of the content stated on the product label.

Expiry Date

The date placed on the container label of a finished product designating the time prior to which a batch of the product is expected to remain within the approved shelf-life specification if stored under defined conditions.

Hardness/friability

Is the resistance to crushing of tablets, measured by the force needed to disrupt it by crushing.

Impermeable Containers

Containers that provide a permanent barrier to the passage of gases or solvents, e.g., sealed aluminum tubes, sealed glass ampoules for solutions.

Water content

A measure of free water content of product when surrounded by air at a specified relative humidity and temperature.

Microbial content

Is the amount of microorganisms including bacteria, yeast and mold present in the product.

pH

The pH value of an aqueous solution is a number describing its acidity or alkalinity. A pH is the negative logarithm (base 10) of the concentration of hydrogen ions (equivalent per liter). The pH value of a neutral solution is 7. An acidic solution has a pH less than 7, while a basic solution has a pH greater than 7, up to 14.

Shelf-life (also referred to as expiration date period)

The time period during which a product is expected to remain within the approved specification provided it is stored under the condition defined on the container label.

Specification

A list of tests, references to analytical procedures, and appropriate acceptance criteria which are numerical limits, ranges, or other criteria for the tests described. (It establishes the set of criteria to which a substance, product or material at other stages of its manufacture should conform to be considered acceptable for its intended use.

"Conformance to specification" means that the substance and product, when tested according to the listed analytical procedures, will meet the acceptance criteria. Specifications are critical quality standards that are proposed and justified by the manufacturer and approved by regulatory authorities as conditions of approval).

Stability Study Protocol

A document describing rationale, goals, methodology, and statistical methods of the stability study which specifies the terms and conditions under which the stability study must be conducted and managed.

Stability Studies

Real time and accelerated studies/testing undertaken on primary batches according to a prescribed stability protocol to establish or confirm the re-test period of a substance or shelf-life of a finished product.

- Accelerated Stability Studies

Studies designed to increase the rate of chemical degradation or physical change of a finished product by using exaggerated storage conditions as part of the formal stability studies. (Data from these studies, in addition to long term stability studies, can be used to assess longer term chemical effects at non-accelerated condition and to evaluate the effect of short term excursions outside the label storage conditions such as might occur during shipping. Results from accelerated testing studies are not always predictive of physical changes; see also Stability and related terms).

- Real Time Stability Studies

Stability studies under the recommended storage condition for the re-test period or shelf-life proposed (or approved) for labelling.

Storage Condition

Condition for intended storage of a finished product defined on the container label based on the stability study.

Supporting Data

Data, other than those from formal stability studies that support the analytical procedures, the proposed re-test period or shelf-life, and the label storage statements.

Viscosity

The tendency of a fluid to resist flowing because of molecular attraction (cohesion). Is a property of liquid that is closely related to its resistance to flow.

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APPENDICES

APPENDIX 1 REDUCED DESIGN (BRACKETING AND MATRIXING)

A full study design is one in which samples for every combination of all design factors are tested at all time points whereas a reduced design is one in which samples for every factor combination are not all tested at all time points. A reduced design can be a suitable alternative to a full design when multiple design factors are involved.

Any reduced design should have the ability to adequately predict the shelf-life. Before a reduced design is considered, certain assumptions should be assessed and justified. The potential risk when establishing a shorter shelf-life using a reduced design should be considered due to the reduced amount of data collected compared to data derived from a full design.

During the course of a reduced design study, a change to full testing or to a less reduced design can be considered if justification is provided and the principles of full designs and reduced design studies are followed. However, proper adjustments should be made to the statistical analysis, where applicable, to account for the increase in sample size as a result of the change. Once the design is changed, full testing or less reduced testing should be carried out through the remaining time points of the stability study.

Bracketing

Bracketing is the design of a stability schedule such that only samples on the extremes of certain design factors, for example, strength, container size and/or fill, are tested at all time points as in a full design. The design assumes that the stability of any intermediate levels is represented by the stability of the extremes tested.

Design Example

An example of a bracketing design is given in Appendix Table 1 below. This example is based on a product available in three strengths and three container sizes. In this example, it demonstrated that the 15 ml and 500 ml high-density polyethylene container sizes truly

represent the extremes. The batches for each selected combination should be tested at each time point as in a full design.

Appendix Table 1: Example of a Bracketing Design

Strength		50 mg			75 mg			100 mg		
Batch		1	2	3	1	2	3	1	2	3
Container Size	15 ml	T	T	T				T	T	T
	100 ml									
	500 ml	T	T	T				T	T	T

Key: T = Sample tested

Matrixing

Matrixing is the design of a stability schedule such that a selected subset of the total number of possible samples for all factor combinations would be tested at a specified time point. At a subsequent time point, another subset of samples for all factor combinations would be tested. The design assumes that the stability of each subset of samples tested represents the stability of all samples at a given time point. The differences in the samples for the same finished product should be identified as, for example, covering different batches, different strengths, different sizes of the same container closure system, and possibly, in some cases, different container closure systems.

When a secondary packaging system contributes to the stability of the finished product, matrixing can be performed across the packaging systems. Each storage condition should be treated separately under its own matrixing design. Matrixing should not be performed across test attributes. However, alternative matrixing designs for different test attributes can be applied if justified.

Design Examples

Examples of matrixing designs on time points for a product in two strengths (S1 and S2) are shown in Appendix Table 2 below. The terms "one-half reduction" and "one-third reduction" refer to the reduction strategy initially applied to the full study design. For example, a "one-half reduction" initially eliminates one in every two time points from the full study design

and a "one-third reduction" initially removes one in every three. In the examples shown in Appendix Table 2, the reductions are less than one-third due to the inclusion of full testing of all factor combinations at some time points. These examples include full testing at the initial, final, and 12- month time points as shown in Appendix Table 2.

Appendix Table 2: Example of Matrixing Design on Time Points for a Product with Strengths "One-Half Reduction"

Time point (months)			0	3	6	9	12	18	24	36
Strength	S1S1	Batch1	T	T		T	T		T	T
		Batch2	T		T		T	T		T
	S2S2	Batch1	T		T		T		T	T
		Batch2	T	T		T	T	T		T
				At least 6 out of 12 time points				At least 4 out of 8 time points		

Examples of Matrixing Designs on Time Points for a Product with Strengths "One-Third Reduction"

Time point (months)			0	3	6	9	12	18	24	36
Strength	S1S1	Batch1	T	T		T	T	T	T	T
		Batch2	T	T	T		T	T		T
	S2S2	Batch1	T		T	T	T	T	T	T
		Batch2	T	T		T	T		T	T
				At least 8 out of 12 time points				At least 6 out of 8 time points		

Time point (months)			0	3	6	9	12	18	24	36
Strength	S1S1	Batch1	T	T		T	T	T	T	T
		Batch2	T	T	T		T	T		T
	S2S2	Batch1	T		T	T	T	T		T
		Batch2	T	T		T	T		T	T
	S3S3	Batch1	T		T	T	T	T	T	T
		Batch2	T	T		T	T		T	T
				At least 12 out of 18 time points				At least 8 out of 12 time points		

Key: T = Sample tested

APPENDIX 2 TABULATED LIST OF STABILITY INDICATING PARAMETERS FOR HEALTH SUPPLEMENT

The tabulated list of parameters for each dosage form is presented as a guide for the following types of tests to be included in a stability study.

HS Dosage Form

Testing Parameters / HS Dosage Form	Organoleptic characteristics	Assay	Hardness/ friability	Dissolution /Disintegration	Water content	Viscosity	pH	Microbial content	Granules/Particle Size	Resuspendability
Oral powder	√	√			√			√		
Hard capsule	√	√		√	√			√		
Soft capsule	√	√		√				√		
Coated and Uncoated Tablet	√	√	√	√	√			√		
Coated and Uncoated Pill/Pellet	√	√		√	√			√		
Suspension	√	√				√	√	√	√	√
Solution	√	√				√	√	√		
Emulsion	√	√				√	√	√		
Granules	√	√			√			√	√	

APPENDIX 3 RECOMMENDED PRESENTATION OF THE SUMMARY TABLE OF STABILITY RESULTS

Product Name	:	Storage Conditions	: .....
Dosage Form	:	Batch No.	: .....
Strength	:	Manufacturing Date	: .....
Container	:	Date of Report	: .....
Pack Size	:	Period of the study	: .....

Testing Parameters (as applicable)	Permissible Level /Acceptance Criteria	Testing Frequency (Months)							
		0	3	6	9	12	18	24	
Organoleptic characteristics									
Assay									
Hardness/Friability									
Dissolution/Disintegration									
Water content									
Viscosity									
pH									
Microbial content									
Granules/Particle size variation									
Resuspendability									

Conclusion:

Prepared by Checked by Approved by