

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

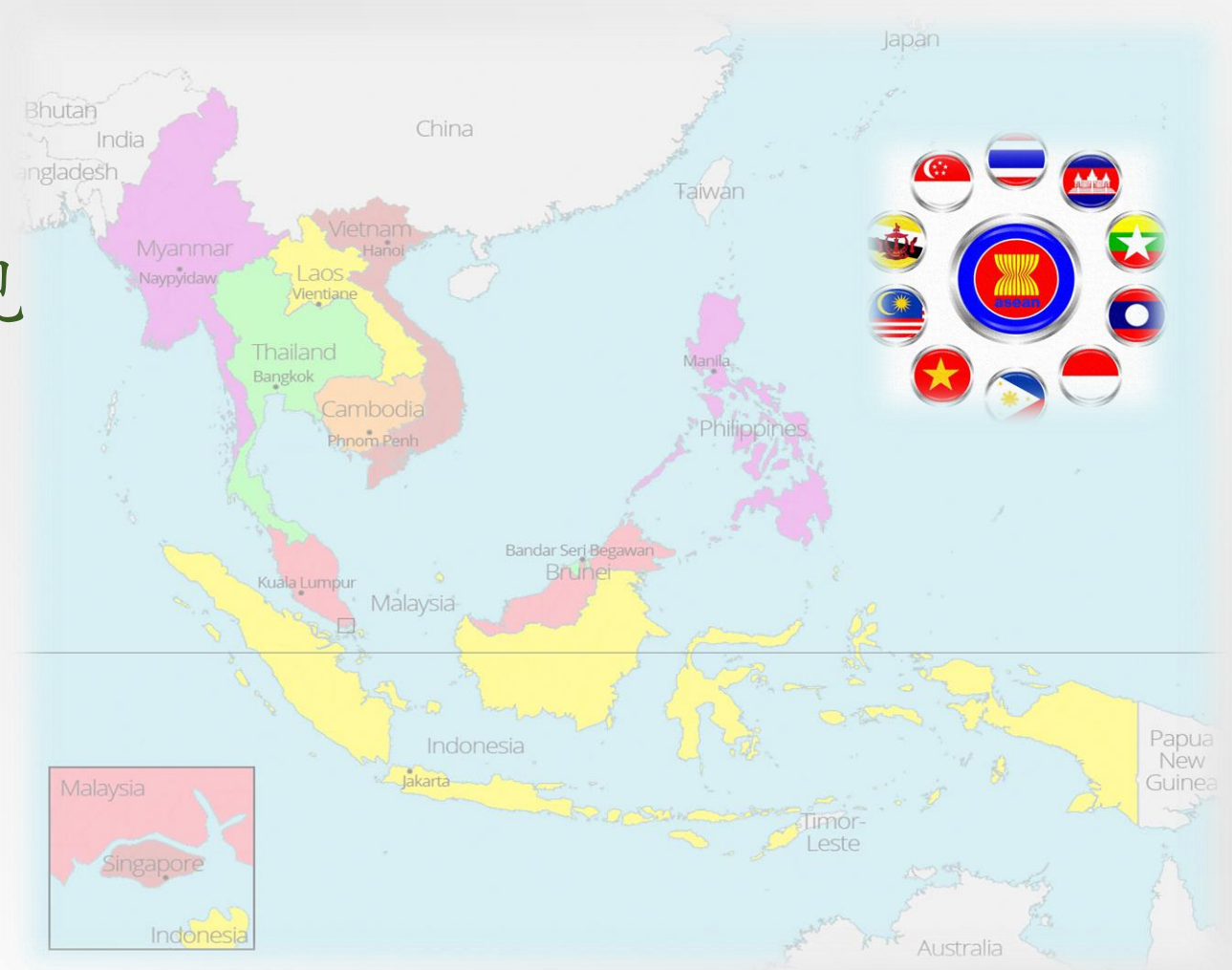


王文秀
東協保健品協會聯盟
8 September 2020



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



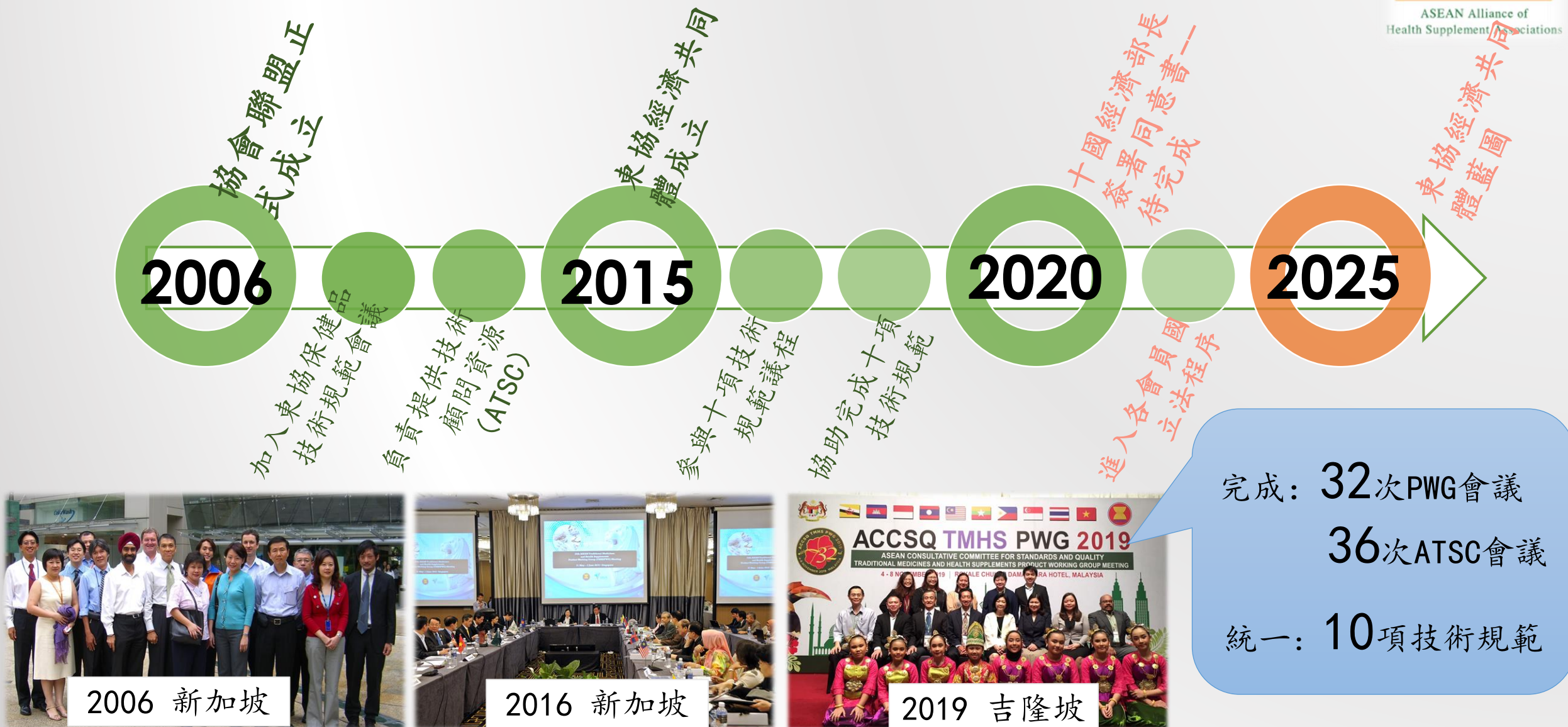
1. 東協保健品協會聯盟簡介

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



1. 東協保健品協會聯盟簡介

七個協會會員

- ❖ 汶來保健化妝品協會
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



隨著人們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的保健益處，其**複合年增長率(CAGR)**估計可高達**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

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

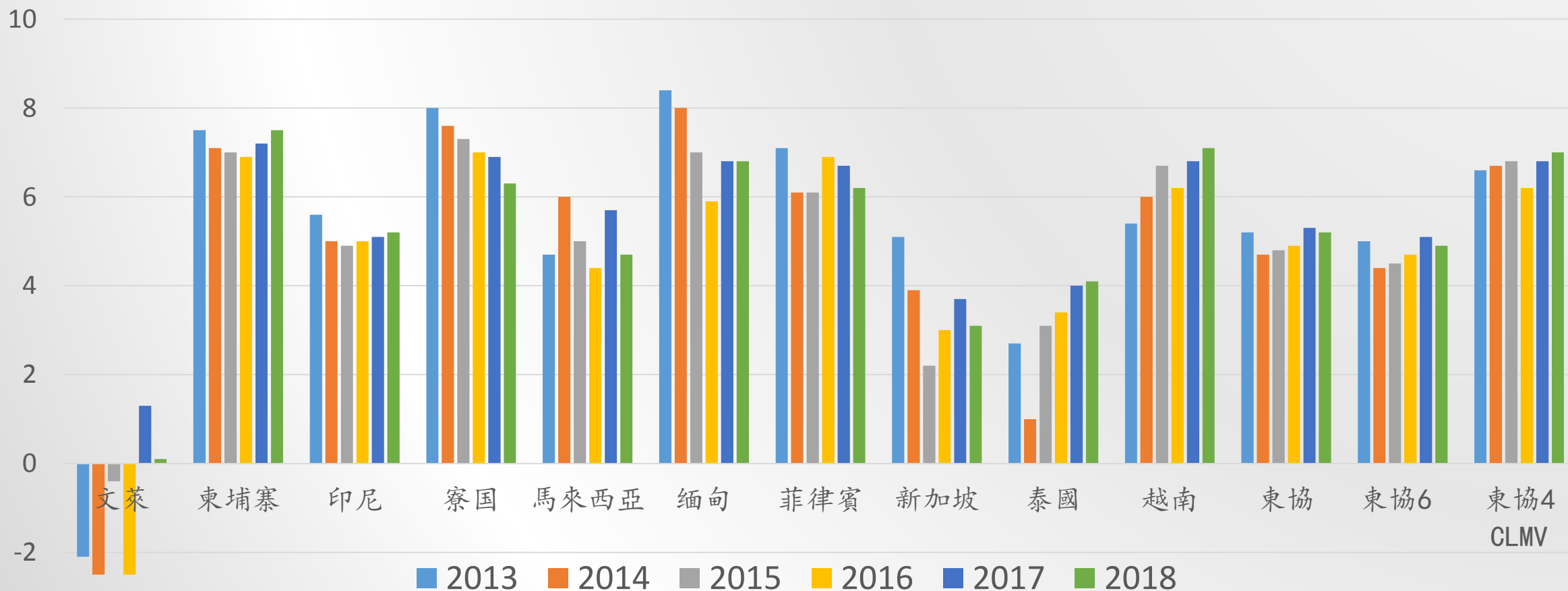


1. 東協保健品協會聯盟簡介

東協經濟增長



GDP Growth 東協國內生產總值同比增長



-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



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 Analysis | Fortune Business Insights™

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

As per the new Fortune Business Insights™ report, titled **"ASEAN 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"**, the market value stood at USD 6.92 billion in 2018. The **ASEAN Dietary Supplements Market Size** is set to reach USD 10.60 billion by 2026, exhibiting a CAGR of 5.60% during the forecast period. Increasing prevalence of lifestyle-induced disorders, or Non-Communicable Diseases, and cancer, will be a key factor driving the food supplements market growth. Estimates computed by the World Health 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.

東協保健品2018年市值調查：
69.2億美元！



HOME



INDUSTRIES



SERVICES



INSIGHTS



ABOUT



Food & Beverages / Southeast Asia Dietary Supplements Market

"Market Intelligence"
Your Success

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

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Summary

Table of Content

Market Segmentation

Methodology

Infographics

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KEY MARKET INSIGHTS



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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>

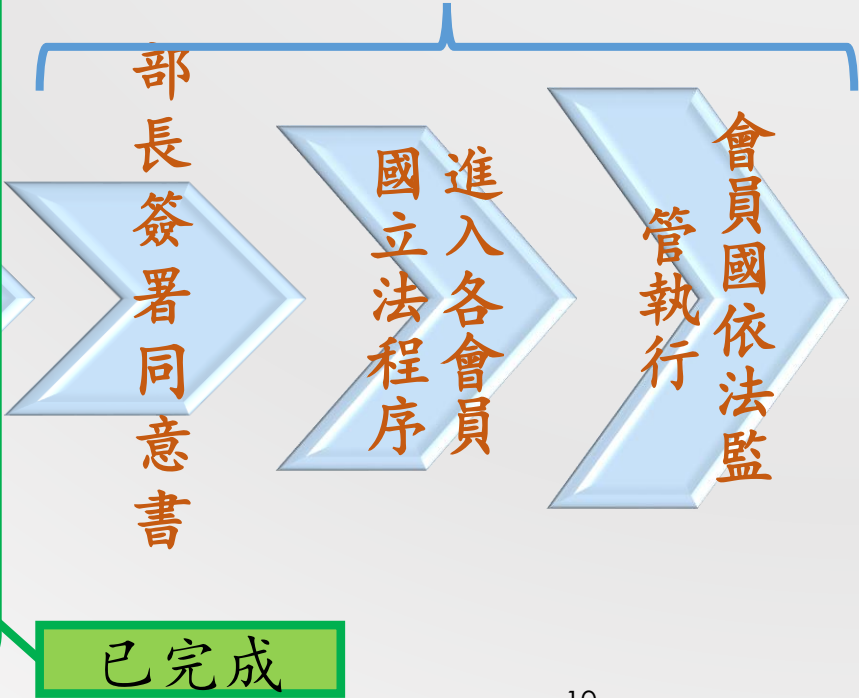
1. 東協保健品協會聯盟簡介



東協2025經濟共同體藍圖



預估在2025年前完成



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	汶來	馬來西亞	印尼	越南	菲律賓	泰國	寮國	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 部門	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 SAFET Y 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 鏈接	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.fda.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) [汶來保健品上市相關法規](#)
<http://www.moh.gov.bn/Shared%20Documents/Traditional%20Medicines/1.1%20Guideline%20for%20Importation%20and%20sale%20of%20TMHS.pdf>
- 8) [寮國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](#) https://www.ddfcambodia.com/food_safety.html
- 10) [緬甸保健品上市申請相關法規](#) <https://www.fda.gov.mm/?cat=15>

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	<p>(一) 產品宣告 (product declaration) (請參考第15/2018/ND-CP號議定第7條) :</p> <ol style="list-style-type: none">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。 <p>(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) :</p> <ol style="list-style-type: none">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 <p>(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) :</p> <ol style="list-style-type: none">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	<p>(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</p> <p>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：</p> <p>(一) 申請進口食品進入泰國許可證</p> <p>(二) 申請人的身分證影本</p> <p>(三) 公司營業登記</p> <p>(四) 公司營業執照</p> <p>(五) 進口場地的照片(彩色)</p> <p>(六) 戶籍謄本影本</p> <p>(七) 進口倉儲場地的格局</p> <p>(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</p> <p>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。</p> <p>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</p> <p>E-submission:</p> <p>(1) 配方及成份</p> <p>(2) 台灣FDA許可證</p> <p>(3) 工廠生產著證明</p> <p>(4) 有效原料成分規格</p> <p>(5) 額外文件，依情況所需</p>

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	<ol style="list-style-type: none">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	<ol style="list-style-type: none">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可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 <ol style="list-style-type: none">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。 <ol style="list-style-type: none">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	<p>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。</p> <p>(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。)</p>
二、法源依據	
三、進口程序	<p>(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。</p> <p>(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。</p> <p>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</p>

2. 縱觀現行東協國家保健品法規-菲律賓



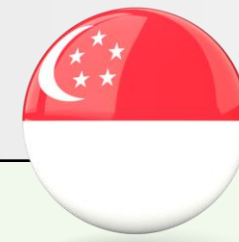
一、主管機關	菲律賓衛生部食品藥物管理署
二、法源依據	(一) 由於東協傳統藥物及保健品法案尚未通過，菲國未列有獨立之「保健食品」分類，故此保健食品目前適用菲國食品相關法規。
三、進口程序	<p>(一) 菲國上市及進出口之保健食品均須至菲國衛生部 FDA 之電子註冊系統 (Electronic Registration) 登記，取得產品註冊證 Certificate of Product Registration。登記流程、電子許可步驟與產品註冊及經營許可證分別規範於菲國FDA第 2016 014號通告、第 2016 004號通告及 2014 0029號行政命令。</p> <p>(二) 菲國FDA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」。</p> <p>三) 檢附上述相關法規如附件。</p> <p>附件：</p> <p>___ 「檔案下載」菲律賓保健食品市場法規及證照申請說明.pdf</p> <p>___ 「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</p> <p>___ 「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</p> <p>___ 「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</p> <p>___ 「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</p> <p>___ 「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</p>

2. 縱觀現行東協國家保健品法規-汶來



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	<p>每次輸入TMHS都必須通過文萊國家單一窗口（BDNSW）認可。 為了使進口程序通暢，鼓勵您在進口前將TMHS的進口和/或銷售申請提交給TMHS部門。</p> <p>http://www.moh.gov.bn/Shared%20Documents/Traditional%20Medicines/1.1%20Guideline%20for%20Importation%20and%20sale%20of%20TMHS.pdf</p>

2. 縱觀現行東協國家保健品法規- 新加坡



一、主管機關	Health Sciences Authority
二、法源依據	
三、進口程序	<p>Health supplements are not subject to approvals and licensing by HSA for their importation, manufacture and sales. HSA prohibits the addition of medicinal ingredients such as steroids in health supplements. HSA also sets strict limits on toxic heavy metals in these products. Dealers (importers, manufacturers, wholesale dealers and sellers) have the obligation to ensure that their products are not harmful or unsafe, and that they conform with the following guidelines before supplying health supplements into Singapore.</p>

2. 縱觀現行東協國家保健品法規

保健品上市/注册所需文件

Overview of Document Requirements for New Product Registration Submission / Importation Application in Asia

Type of documents	Myanmar	Laos	Cambodia	Vietnam	Brunei	Philippines	Indonesia	Thailand		Malaysia
	Food	Food/Food Supplement	Food/Food Supplement	Health Supplement	Food	Food Supplement	Food Supplement	Dietary Supplement SB3	Dietary Supplement SB5	Dietary Supplement
Application/ Assessment Form			1			1				
Company Licence (eg. Business license, wholesale license, distributor license)			1			1				
Letter of Attorney/ Authorization/ Appointment		1			1	1	1			1
Supporting document of the use of product name										1
Product Formula	1	1		1		1	1	1	1	1
Batch Manufacturing Formula							1			1
Cert. of Additives					1					
Flavor Safety cert from supplier						1				
Manufacturing Process/Flowchart				1		1	1	1		1
Finished Product Spec	1					1	1	1		1
Cert of Analysis (COA)	1	1	1	1	1		1			1
Analysis report - Microbiological				1		1	1	1		1
Analysis report - Heavy Metals				1		1	1	1		1

2. 縱觀現行東協國家保健品法規

保健品上市/注册所需文件



Overview of Document Requirements for New Product Registration Submission / Importation Application in Asia

Type of documents	Myanmar	Laos	Cambodia	Vietnam	Brunei	Philippines	Indonesia	Thailand		Malaysia
	Food	Food/Food Supplement	Food/Food Supplement	Health Supplement	Food	Food Supplement	Food Supplement	Dietary Supplement SB3	Dietary Supplement SB5	Dietary Supplement
Analysis report - Nutrients				1			1	1		1
Analysis report - Active Components				1			1	1		1
Analysis report - Containments				1				1		
Analysis report - alcohol content for liquid product							1			
Analysis report - Cyprohepdatine for children range							1			
Analysis report - Chloramphenicol for honey products							1			
Safety Assessment/ Toxicity Study Report								1		1
Efficacy Study Report/Justification on product claims						1	1			1
Stability data/ Product Shelf life report						1	1			1
Production Information (Country specific requirements)							1	1	1	1
Raw Materials Spec / COA / others (country specific)							1	1	1	
Packaging Material Specification							1			
Product Research and development (eg. Formula rational, claims determination)							1			
Manufacturing plant facilities and practices							1			
Product Coding System							1			
Factory Cleaning Process							1			
Glass Jar and Cap Cleaning Process							1			

2. 縱觀現行東協國家保健品法規

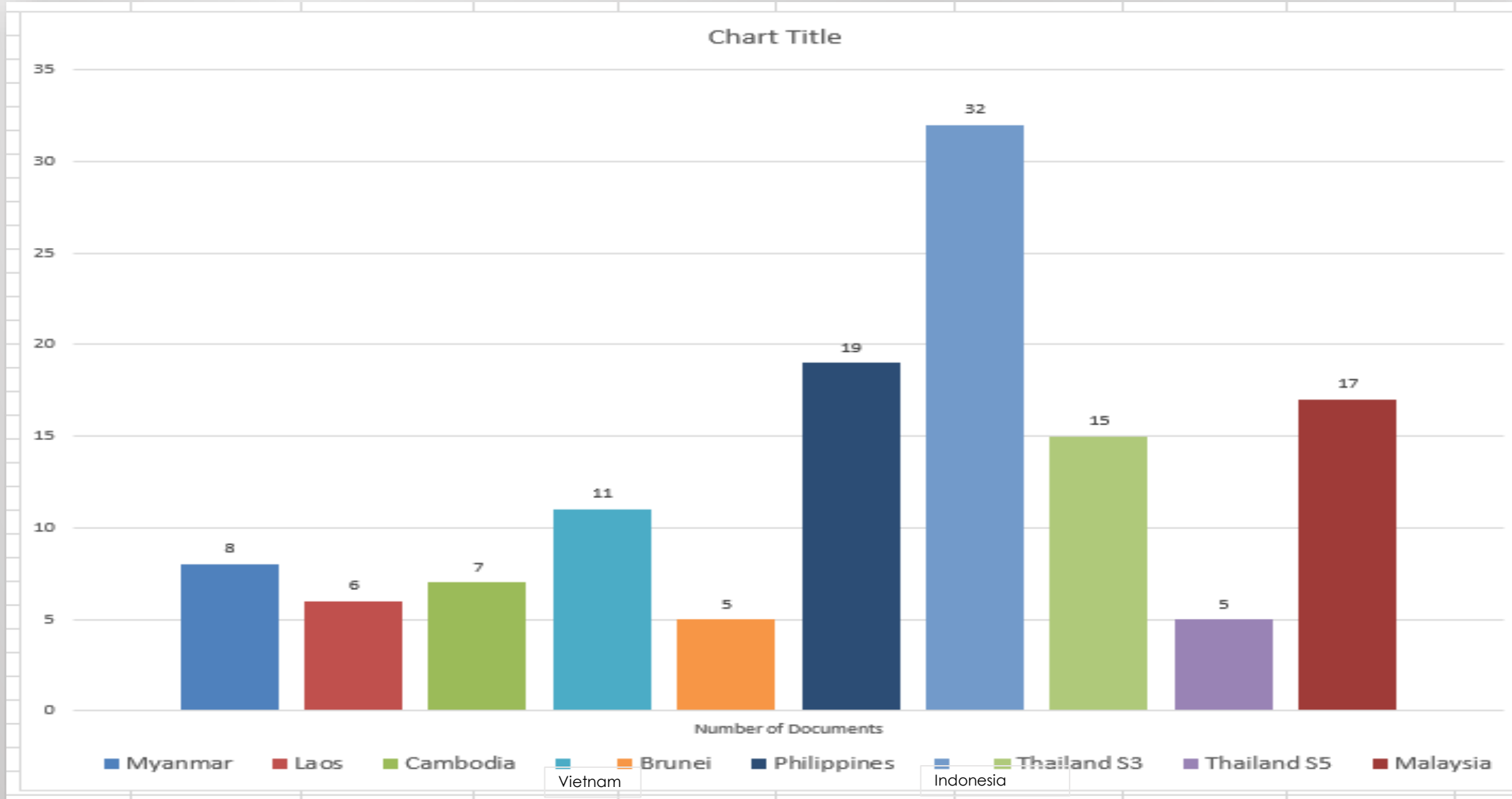
保健品上市/注册所需文件

Overview of Document Requirements for New Product Registration Submission / Importation Application in Asia

Type of documents	Myanmar	Laos	Cambodia	Vietnam	Brunei	Philippines	Indonesia	Thailand		Malaysia
	Food	Food/Food Supplement	Food/Food Supplement	Health Supplement	Food	Food Supplement	Food Supplement	Dietary Supplement SB3	Dietary Supplement SB5	Dietary Supplement
Official evidence of registration approval, Ref standard of product standards for country of origin or international organisation								1		
Tax Cert			1							
Free Sales Cert. (FSC)	1	1	1	1		1	1	1		1
Manufacturing Licence, GMP, ISO, HACCP etc	1	1	1	1	1	1	1	1	1	1
Registered product license (for renewal)	1					1	1			
Sample	1	1	1		1	1	1		1	
Product Label	1			1		1	1	1		
Original Label						1	1			
Proforma/ Sales invoice						1				
Packaging Material Cert. of suitability for food						1				
Batch Manufacturing Record (real)							1			
Site Master File (if Pharma GMP is unavailable)							1			
Stability Study Protocol			7				1			
	8	6	7	11	5	19	32	15	5	17

2. 縱觀現行東協國家保健品法規

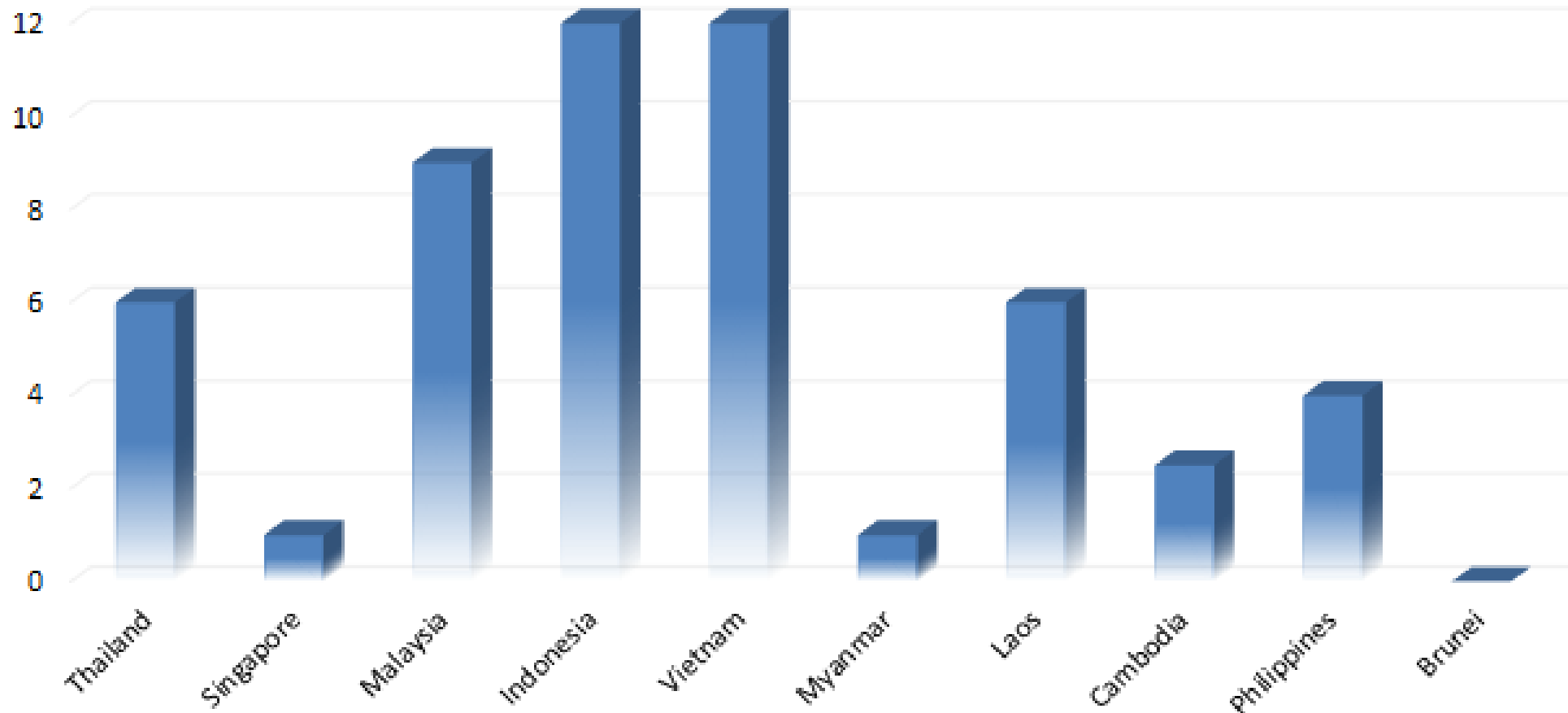
保健品上市/注册所需文件



2. 縱觀現行東協國家保健品法規

保健品上市/注册所需时间

MIN REGISTRATION LEADTIME (MONTHS)





ASSOCIATION
OF SOUTHEAST
ASIAN NATIONS



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

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）。

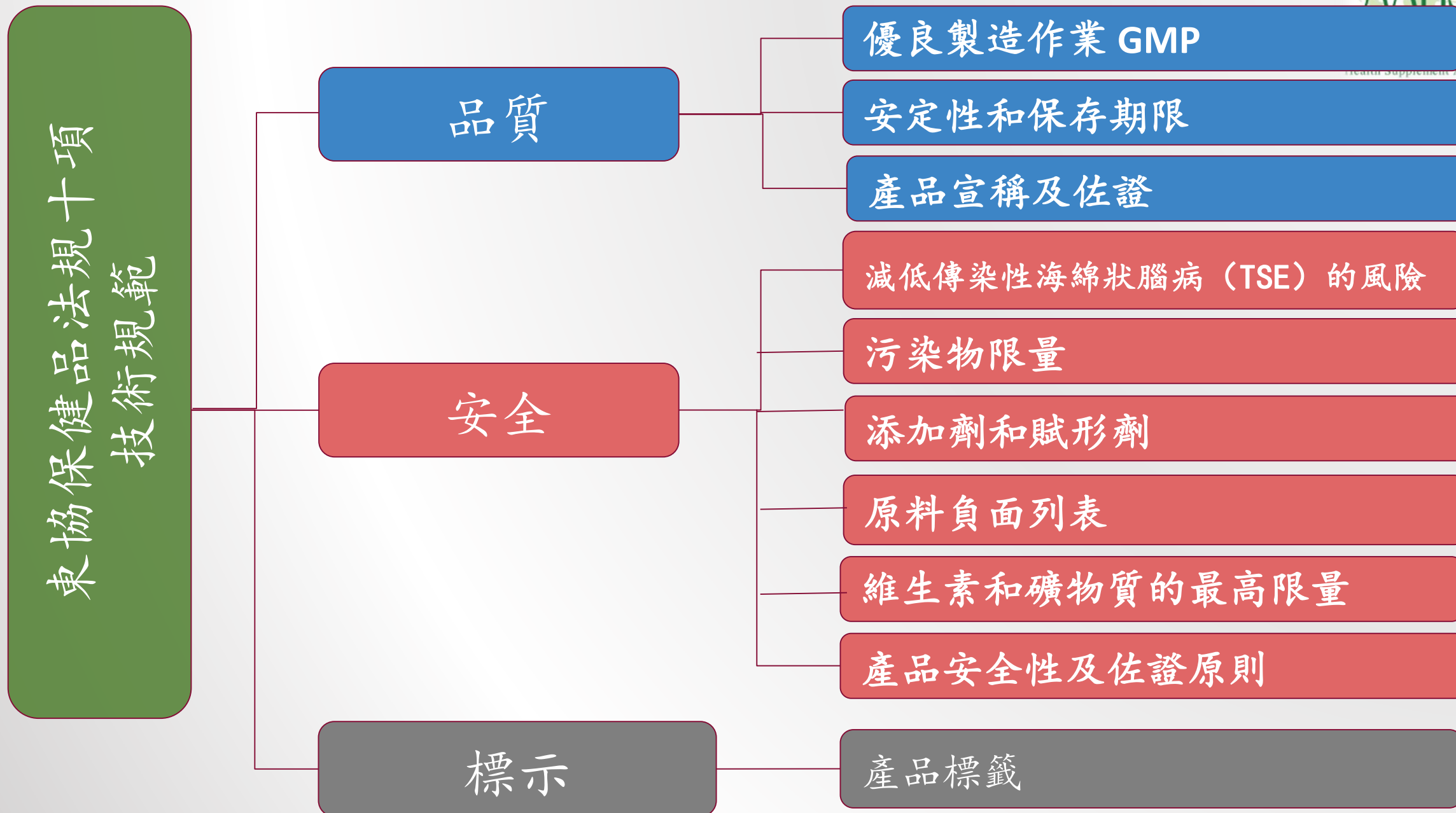
Purpose	any product that is used to supplement a diet and to maintain, enhance and improve the healthy function of human body
Composition/ Ingredient	contains one or more, or a combination of: i. Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and other bioactive substances ii. Substances 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	有無對應的台灣法規？	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	減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	維生素和礦物質最高限量 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

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！**



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.

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

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
<i>Abrus precatorius</i> L.	Indian Licorice, Precatory bean, Jequerity, Mutual love Bean (China), Kudri Mani (Tamil), Guru Ginja (Telugu)	Seed	Abrin, which consists of abrus agglutinin, and toxic lectins abrisins	Banned
<i>Aconitum</i> spp. containing aconite alkaloids	Monkshood, Aconite	Whole plant	Aconite alkaloids	Banned
<i>Adonis vernalis</i> 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

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，藥用賦形劑手冊，藥典
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！



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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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

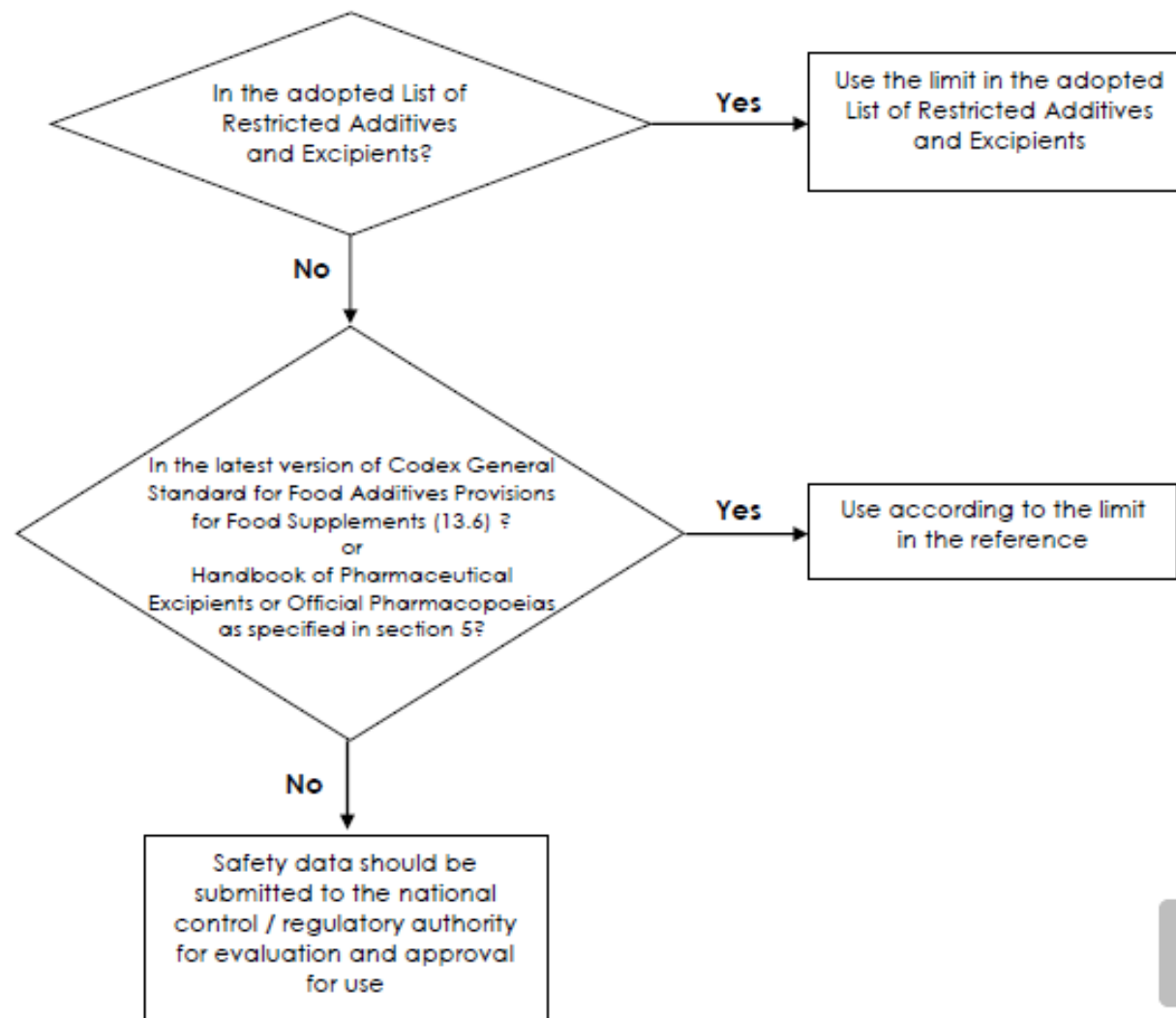
確定在保健品中使用添加劑和賦形劑的程序：

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

Diagram 1: Procedures for Determination of the Use of Additives and Excipients in Health Supplements



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

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
2	Brilliant Blue FCF	133
3	Caramel III – Ammonia process	150c
4	Caramel IV - Sulphite Ammonia Process	150d
5	Carmines	120

FAO/WHO Food Standards
CODEX alimentarius

ENGLISH | FRANÇAIS | ESPAÑOL

GSFA Online
Updated up to the 42nd Session of the Codex Alimentarius Commission
FOOD ADDITIVE INDEX

This page contains an index of individual food additives. Clicking on an individual food additive or food additive group will display food additive information. Clicking on "Show synonyms" will display food additive synonyms.

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 2017
A British Pharmacopoeia

Incorporating International Nonproprietary Names

A dictionary of drugs for regulatory use

PP
Pharmaceutical Press

APRA

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

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Shalini Amnee Neeliah
Sustainable Agri-Food Systems, Quatre-Bornes, Mauritius

Food additive control
353
Received 17 May 2012
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 (Ibback 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.

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DOI: 10.1108/BFJ-05-2012-0125

Emerald

3. 未來東協保健品法規十項技術規範-

附件3 污染物限量

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



Association of South East Asian Nations (ASEAN)

ANNEX III

ASEAN GUIDELINES ON LIMITS OF CONTAMINANTS FOR HEALTH SUPPLEMENTS

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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	<ul style="list-style-type: none"> - NMT 10^3 CFU of <i>Escherichia coli</i> in 1g or 1mL - Absence of <i>Salmonella</i> 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	<ul style="list-style-type: none"> - NMT 10^2 CFU of bile-tolerant gram-negative bacteria in 1g or 1mL - Absence of <i>Escherichia coli</i> in 1g or 1mL
category			<ul style="list-style-type: none"> - Absence of <i>Salmonella</i> 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

<p>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</p>	<p>NMT 5 x 10⁵</p>	<p>NMT 5 x 10⁴</p>	<p>- NMT 10⁴ CFU of bile-tolerant gram-negative bacteria in 1g or 1mL</p> <p>- Absence of <i>Escherichia coli</i> in 1g or 1mL</p> <p>- Absence of <i>Salmonella</i> in 25g or 25mL</p>
<p>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 10³ CFU/gram or CFU/mL</p>	<p>NMT 2 x 10⁴</p>	<p>NMT 2 x 10³</p>	<p>- NMT 10³ CFU of bile-tolerant gram-negative bacteria in 1g or 1mL</p> <p>- Absence of <i>Salmonella</i> in 10g or 10mL</p> <p>- Absence of <i>Escherichia coli</i> in 1g or 1mL</p> <p>- Absence of <i>Staphylococcus aureus</i> in 1g or 1mL</p>

2. 微生物限量:

<p>E. Aqueous preparations which does not fall under category A, B, C or D</p>	<p>NMT 2 x 10³</p>	<p>NMT 2 x 10</p>	<p>- Absence of <i>Escherichia coli</i> in 1g or 1mL</p>
<p>F. Non-aqueous preparations which does not fall under category A, B, C or D</p>	<p>NMT 2 x 10³</p>	<p>NMT 2 x 10³</p>	<p>- Absence of <i>Escherichia coli</i> in 1g or 1mL</p>

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:

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

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. 原料廠商提供來源聲明書
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

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 Risk of Transmission of Transmissible Spongiform Encephalopathies in Health Supplements. I hold evidence to demonstrate that the product is prepared

- from ruminant-derived materials without any risk of TSE transmission and the regulatory authority in the country of origin has endorsed that the materials are free from TSE agents

- 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
來源聲明書

APPENDIX 4 SAMPLE OF CHECKLIST FOR SELF-ASSESSMENT

Check if available	Document	Enclosure number
1. Source of Animal		
<input type="checkbox"/>	Updated notification of BSE cases in country where each animal material is sourced, where applicable	
<input type="checkbox"/>	Justification for using animal materials from BSE (if applicable)	
<input type="checkbox"/>	Documentary proof issued by health authorities to show that the raw materials used are sourced from healthy animals	
2. Nature of animal tissue used in manufacturing		
<input type="checkbox"/>	Detailed information on the nature and quantity of each animal-derived material: <ul style="list-style-type: none"> Used in the manufacturing process (whether or not this is present in the final products) Present in the final product formulation 	
<input type="checkbox"/>	Letter of confirmation or assurance from the raw materials supplier and/or manufacturer that: <ul style="list-style-type: none"> Considerations to reduce cross contamination between different tissues have been taken when obtaining the raw materials 	
3. Manufacturing process(es)		
<input type="checkbox"/>	Letter of confirmation or assurance from the manufacturer that: <ul style="list-style-type: none"> 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

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

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Version 2.0

重點提示：

產品宣稱	佐证程度	数据资料标准	资料
一般產品 宣稱或營 養宣稱	一般	e.g. 15% Codex NRV	參考文獻 書 籍
功能宣稱	中	國際或先進國 家認可的營養 或身體功能宣 稱	1 + 1
降低疾病 風險宣稱	高	功能機制有持 續的證據支持	人體試驗 + 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

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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	<u>ASEAN GMP</u>	<u>營養保健食品業者優良製造作業指引</u>	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

重點提示：

- (a) 產品名
- (b) 劑型
- (c) 主成分及劑量
- (d) 批號
- (e) 生產日期及保存期限，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) 製造商名稱及地址
- (k) 授權商名稱及地址
- (l) 警語
- (m) 包裝數量
- (n) 其他說明
- (o) 國家語文或英語



Association of South East Asian Nations (ASEAN)

ANNEX IX

ASEAN GUIDELINES ON LABELLING REQUIREMENTS FOR HEALTH SUPPLEMENTS

Disclaimer:

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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

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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	泰國*	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	泰國*	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	泰國*	印尼*	馬來西亞*	備註
21	Iodine	0.15 mg			0.3 mg	<p>*依照国家特殊要求</p> <p>**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.</p>
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				



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