

健康食品查驗登記申請書表 (規格標準)-初審

APPLICATION FORM FOR REGISTRATION OF HEALTH FOOD (Specification Standards)-Preliminary Review

品 名 :

Product Name

申請廠商 :

Applicant

聯絡人 :

Contact Person

聯絡人電話 :

Telephone No.

聯絡人電子郵件 :

Contact E-mail

本申請案均已審慎確認文件資料正確性。

The accuracy of the documents and information
for this application has been duly affirmed.



填 表 須 知

Instructions

一、一般注意事項 General Notifications

1. 健康食品查驗登記申請書表請由網際網路下載使用，下載之申請書表如不敷使用，請依本部所訂格式自行複製，自行複製之書表應於標題後面加註編號，例如：產品包裝標籤及說明書(一)、(二)、(三)。

Please download the Application Form for Health Food Registration from the internet. If there isn't enough space on the downloaded application form, please make copies of the forms and each with the same format. Each copy shall have a number after the title, for example: Product Packaging Label and Instruction Manual (1), (2), (3).

2. 申請書表應以電腦鍵入相關資料列印之（軟體：Microsoft Word；字體標楷體，字體大小可視實際需要加以調整），並以活頁方式裝訂成冊。送審時應檢附儲存有前述檔案之光碟片，以利審查作業之進行。

The application form shall be typewritten using a computer and printed out (Software: Microsoft Word; Font: DFKai-SB; Size: subject to adjustment as needed), and bound with loose-leaf binders. A disc containing the foregoing file shall be included in the submittal to facilitate the review procedure.

3. 檢送之書件、資料、文獻，應以 A4 紙張（210mm×297mm）製作；如大於 A4，請摺疊成 A4 大小，並請依序排列，檢附於附件處，且編訂頁碼，以利審查。

The documents, information, and literature shall be printed on A4-size (210mm × 297mm) papers; if the papers are larger than A4 size, please fold them into the size of A4, place them in order as attachments, and insert the page number to facilitate the review procedure.

4. 書件、資料、文獻之摘要表、一覽表內記載之資料編號順序，應與所檢附附件（書件、資料、文獻）之序號相同。

The numbering sequence of documents, information, literature summary table, and overall list shall correspond to that of the annexed attachments (documents, information, literature).

5. 檢送之書件、資料、文獻，如以非英文之外文撰寫者，應另檢附一份經政府立案翻譯社翻譯之中譯本。簡體中文者，應另檢附一份繁體中文本，得自行翻譯。

If the submitted documents, information, literature are not in English, please submit a Chinese version translated by a government-accredited translation service company. Those in simplified Chinese shall be submitted with a traditional Chinese version which can be translated by applicant.

二、填表說明 Instructions for Completing the Form

1. 申請廠商基本資料

Basic Information of the Applicant :

- (1) 申辦「輸入」健康食品查驗登記者，製造廠欄位之負責人、工廠登記證編號、統一編號等免填。
An applicant applying for registration of “imported” health food is not required to fill out the fields of the responsible person of the manufacturer, factory registration number, and unified business number.

- (2) 產品如係「委託製造」，應填明「委託製造者」欄位之相關資料，並檢附經委託者及受委託者雙方簽署之委託製造合約書正本乙份。

Where products are manufactured by a contract manufacturer, please fill out the “Contract Manufacturer” field and attach an original copy of the contract manufacturing agreement signed by the contracting parties.

健康食品查驗登記資料

Health Food Registration Information :

- (1) 品名不得有仿冒或影射他人已註冊商標之情事。

The product name shall not counterfeit or allude to the registered trademarks of others.

- (2) 原料成分之含量應包括所有原料及食品添加物之詳細名稱（中英文並列）及含量；依其含量多寡由高往低列出，含量單位以重量百分比表示。原料之名稱應使用一般通用名稱，不得使用商品名；食品添加物應使用衛生福利部公告「食品添加物使用範圍及限量暨規格標準」規定之品名。

The ingredient content information shall include the names of all ingredients and food additives (in both Chinese and English) and the content shall be listed in order from the highest percentage by weight to the lowest percent by weight. The names of the ingredients shall be the generic names instead of trade names; the names of the food additives shall be in compliance with the “Standards for Specification, Scope, Application and Limitation of Food Additives” as announced by the Ministry of Health and Welfare.

- (3) 保健功效敘述及其原料成分欄，應列出保健功效內容，並於該內容之後，依保健功效作用之大小為序，標明「保健功效成分（原料）」；若同時申請一種以上之保健功效，則應逐一列出。

In the field of “health care effect and the ingredient content”, descriptions of the health health care effect shall be provided and after which, the “content (ingredient) with health health care effect” shall be specified in order of degree of efficacy of the health health care effect t. If more than one type of health health care effect is being applied, each type of health health care effect shall be listed.

- (4) 填寫之食用方法（攝取量、注意事項、警語）、保存方式（保存方法、條件、期間）、保健功效敘述等項應與評估、試驗報告結果相符。

The usage instructions (amount of intake, precaution and warning),

preservation method (storage method, storage condition and shelf life), health health care effect descriptions shall match those of the assessment and testing reports.

- (5) 食品外觀形態，應載明如液狀、粉狀、錠狀或膠囊狀……等。

The appearance of the food shall be clearly stated as liquid, powder, tablet, capsule, etc

- (6) 包裝（材質、重量容量）欄位，應載明所有包裝種類；材質應載明內、外包裝材料。材質與重量容量之編號應相互對應。

In the field of packaging (material, weight capacity), all types of packaging shall be clearly stated; materials shall be marked as for inside and outer packaging. The numbering of material shall correspond to that of weight capacity.

- (7) 申請查驗登記之緣由欄位，應具體填明產品具有保健功效之理由。

The field of “application reason(s)” shall clearly state the reason(s) why the product has health benefits.

2. 產品原料成分規格含量表

Specifications of the Raw Materials and Quantity of Ingredients of the Product :

- (1) 原料成分之含量應包括所有原料及食品添加物之詳細名稱（中英文並列）及含量；依其含量多寡由高往低列出，含量單位以重量百分比表示。原料之名稱應使用一般通用名稱，不得使用商品名；食品添加物應使用衛生福利部公告「食品添加物使用範圍及限量暨規格標準」規定之品名。

The ingredient content information shall include the names of all ingredients and food additives (in both Chinese and English) and the content shall be listed in order from the highest percentage by weight to the lowest percent by weight. The names of the ingredients shall be the generic names instead of trade names; the names of the food additives shall be in compliance with the “Standards for Specification, Scope, Application and Limitation of Food Additives” as announced by the Ministry of Health and Welfare.

- (2) 將製造廠出具之產品原料及成分規格書內容，摘錄於本表，並將正本檢附於附件處。

The specifications of the raw materials and quantity of ingredients of the product issued by the manufacturer shall be summarized and included in the form and the original document shall be annexed as attachment.

3. 產品之成分規格檢驗報告摘要表

Summary Table of Ingredients Specification Test Report of a Product :

- (1) 成分規格檢驗報告應由製造廠或委託其他檢驗機構於一年內簽發者，摘錄於本表，並將原始報告檢附於附件處並應將檢驗方法（包括：定性、定量）列示或檢附於報告中。

The ingredient specifications test report shall be issued by the manufacturer or an inspection body within one year. The report shall be summarized and included in the form and the original one shall be annexed as attachment.

Moreover, the examination method, including qualitative analysis and quantitative analysis, shall be provided or attached to the report.

- (2) 應檢附三批。

Three batches shall be attached.

4.產品及其保健功效成分安定性試驗報告摘要表

Summary Table of Test Report on the Ingredient Stability of a Product and its Health Care Effect :

- (1) 將製造廠或委託其他檢驗機構提具之安定性試驗報告（包括試驗方法、數據、結果）內容，摘錄於本表，並將原始報告檢附於附件處。

The stability test report (including testing method, data and results) issued by the manufacturer or an inspection body shall be summarized and included in the form and the original report shall be annexed as attachment.

- (2) 應檢附三批。

Three batches shall be attached.

5.產品製程概要

Summary of Manufacturing Process :

- (1) 將製造廠提具之製造加工流程證明資料，摘錄於本表，並將原始證明檢附於附件處，並編訂頁碼。

The documents substantiating the manufacturing and processing process issued by the manufacturer shall be summarized and included in the form, and the original report shall be annexed as attachment and numbered.

- (2) 製造加工流程應以具體完整之流程圖表示（包括原料調理），並應加註明確之加工條件。

The manufacturing and processing process shall be completely illustrated in a flow chart (including ingredient preparation); moreover, the processing conditions shall be clearly indicated.

- (3) 經萃取者，應說明萃取方法及其溶劑；經濃縮者應說明濃縮之倍數。

Those being extracted shall explain the extraction method and the solvents used. Those being concentrated shall be provided with the concentration multiple.

6.良好作業規範之證明資料摘要表

Summary Table of Documentary Evidence Good Manufacturing Practices :

- (1) 申辦「國產」健康食品查驗登記者，應將製造廠依「健康食品工廠良好作業規範」規定製作之相關製程管制資料，摘錄於本表，並將原始相關文件資料檢附於附件處。

An applicant applying for “domestically produced” health food registration shall include in the form the summary of the relevant manufacturing process control information prepared by the manufacturer in accordance with the requirements of “Good Manufacturing Practices of Health Food Manufacturer” and annex the original documents and information as attachment.

- (2) 申辦「輸入」健康食品查驗登記者，應將原製造廠提具之良好作業規範之官方證明文件內容，摘錄於本表，並將原始證明文件、原產國良好作業規範之法規全文、品管計畫書檢附於附件處。

An applicant applying for “imported” health food registration shall include in the form the summary of the official document substantiating the good manufacturing practices presented by the original manufacturer and annex the original substantiating document, the full text of the Good Manufacturing Practices of the country of origin, quality management plan as attachment.

7.產品衛生檢驗規格及其檢驗報告摘要表

Summary Table of Sanitary Specifications and its Test Report :

- (1) 將製造廠提具之檢驗報告內容，摘錄於本表，並將原始報告檢附於附件處。如係委託其他檢驗機構代驗者，比照辦理。

The test report provided by the manufacturer shall be summarized and included in the form and the original report shall be annexed as attachment. The foregoing requirement shall apply if the test is conducted by another inspection body.

- (2) 應檢附三批。

Three batches shall be attached.

8.一般營養成分分析報告摘要表

Summary Table of General Nutrients Analysis Report :

- (1) 將製造廠提具之檢驗報告內容，摘錄於本表，並將原始報告檢附於附件處。如係委託其他檢驗機構代驗者，比照辦理。

The analysis report provided by the manufacturer shall be summarized and included in the form and the original report shall be annexed as attachment. The foregoing requirement shall apply if the analysis is conducted by another inspection body.

- (2) 應檢附三批。

Three batches shall be attached.

9.產品包裝標籤及說明書(一)、(二)、(三)

Package, Label and Product Instruction Sheet (1), (2), (3) :

- (1) 依健康食品管理法第十三條規定，將中 2) the content of the Chinese labels according to Article 13 of the Health Food C 文標示內容填入(一)、(二)。

Fill in (1) and (2) according to the Act.

- (2) 將包裝、標籤、說明書粘貼於(三)。標籤、說明書以粘貼全型實物為原則，包裝等如因實物過大或因包材之因素致不便於粘貼時，得以實物之彩色照片代替粘貼報核。

Paste the package, label, instruction sheet onto (3). In principle, the label and instruction sheet pasted shall be the real ones used by the company. Where pasting is not possible due to the oversize problem or packing material factor, the color photos of the actual packaging may be pasted onto the table as an

alternative.

10.公司登記或商業登記之證明文件影本粘貼表

Table for Pasting of the Copy of Certificate of the Applicant's Corporation or Business Registration :

公司證明文件影本請縮印粘貼於本表。

Paste the copy of business registration certificate or document in reduced format onto the form.

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附 件 Attachments :

1. 委託製造合約書正本 (非屬委託製造者, 本項應留空)

Original Copy of the Contract Manufacturing Agreement (Ignore if it's not an OEM contract) ()

2. 製造廠出具之產品原料及成分規格含量表正本

Original Copy of Specifications of the Raw Materials and Quantity of Ingredients of the Product ()

3. 成分規格檢驗報告正本

Original Copy of the Ingredients Specification Test Report of a Product ()

4. 保健功效安定性試驗報告正本

Original Copy of Test Report on the Ingredient Stability of a product and its health care effect ()

5. 製造廠出具之產品製程概要資料正本

Original Copy of Manufacturing Process ()

6. 良好作業規範之證明資料正本

Original Copy of Documentary Evidence of Good Manufacturing Practices ()

7. 產品衛生檢驗規格及其檢驗報告正本

Original Copy of Sanitary Specifications and Analysis Report ()

8. 一般營養成分分析報告正本

Original Copy of General Nutrients Analysis Report ()

製造（輸入）健康食品查驗登記規格標準初審申請書
Application Form of Preliminary Specification Standards for
Registration of Produced (Imported) Health Food

受文者：衛生福利部

Recipient: Ministry of Health and Welfare

主 旨：本公司擬☐製造☐輸入「中文品名：_____」食品乙種，
申請查驗登記。

Subject : The company intends to ☐produce ☐import _____ (Food Name),
and files an application for registration.

說 明：檢附之書件、資料如下：

Description: The attached documents and information include:

- 一、 申請廠商基本資料及健康食品查驗登記資料
Basic Information of the Applicant and Health Food Registration Information
- 二、 產品原料成分規格含量表
Specifications of the Raw Materials and Quantity of Ingredients of the Product
- 三、 產品之成分規格檢驗報告及其摘要表
Ingredients Specification Test Report of a Product and the Summary Table
- 四、 產品及其保健功效成分安定性試驗報告及其摘要表
Test Report on the Ingredient Stability of a Product, its Health Care Effect and the Summary Table
- 五、 產品製程概要
Summary of Manufacturing Process
- 六、 良好作業規範之證明資料及其摘要表
Documentary Evidence of Good Manufacturing Practices and the Summary Table
- 七、 產品衛生檢驗規格及其檢驗報告、摘要表
Sanitary Specifications, its Test Report and the Summary Table
- 八、 一般營養成分分析報告及其摘要表
General Nutrients Analysis Report and the Summary Table
- 九、 產品包裝標籤及說明書
Package, Label and Product Instruction Sheet
- 十、 申請者公司登記或商業登記之證明文件影本
Copy of Certificate of the Applicant's Corporation or Business Registration
- 十一、 完整樣品及審查費收據
Intact Sample and Review Fee Payment Receipt
- 十二、 光碟片 2 份
Two discs

申請廠商 Applicant :

(簽章 Seal)

負 責 人 Responsible Person :

(簽章 Seal)

地 址 Address :

聯 絡 人 Contact Person :

電 話 Telephone No :

電子郵件 Contact E-mail :

中 華 民 國 _____ 年 _____ 月 _____ 日
Date: _____

一、申請廠商基本資料

Basic Information of the Applicant

申請廠商 Applicant	名稱 Name	
	營業所在地 Address of Business	
	負責人 Responsible Person	
	食品業者登錄字號 Food Business Registration No.	
	電話 Telephone No.	()
	統一編號 Unified Business No.	
委託製造者 Contract Manufacturer	名 稱 Name	
	營業所在地 Address of Business	
	食品業者登錄字號 Food Business Registration No.	
	電話 Telephone No.	()
製造工廠 Manufacturer	廠名 Factory Name	
	廠址 Factory Address	
	負責人 Responsible Person	
	食品業者登錄字號 Food Business Registration No.	
	電話 Telephone No.	()
	工廠登記證編號 Factory Registration Certificate No.	
	統一編號 Unified Business No.	

一、健康食品查驗登記資料

Health Food Registration Information

品名 Name of Product	中文品名 Chines Name		
	英文(原文)品名 English Name (Source Language)		
食品外觀形態 (顏色、外觀、劑型) Appearance of Food (color, appearance, form)			
包裝 Packaging	材質 Materials	1. 內包裝 Inner Packaging :	外包裝 Outer Packaging :
		2. 內包裝 Inner Packaging :	外包裝 Outer Packaging :
		3. 內包裝 Inner Packaging :	外包裝 Outer Packaging :
		4. 內包裝 Inner Packaging :	外包裝 Outer Packaging :
		5. 內包裝 Inner Packaging :	外包裝 Outer Packaging :
	重量(容量) Weight (Volume)	1.	
		2.	
		3.	
		4.	
		5.	
保存方式 Preservation Method	保存方法 Storage Method		
	保存條件 Storage Conditions		
	保存期間 Shelf life		
食用方法 Usage Instruction	攝取量 Amount of Intake		
	注意事項 Precautions		
	警語 Warnings		

二、產品原料成分規格含量表

Specifications of the Raw Materials and Quantity of Ingredients of the Product

申請廠商 Applicant	
品 名 Product Name	
原料成分含量 Quantity of Ingredients	
成分規格含量 Specifications of Ingredients	

三、產品之成分規格檢驗報告摘要表

Summary Table of Ingredients Specification Test Report of a Product

申請廠商 Applicant	
品 名 Product Name	
第一批 1st (批號 Batch Number) :	
第二批 2nd (批號 Batch Number) :	
第三批 3rd (批號 Batch Number) :	

四、產品及其保健功效成分安定性試驗報告摘要表

Summary Table of Test Report on the Ingredient Stability of a Product
and its Health Care Effect

申請廠商 Applicant			
品 名 Product Name			
資料編號 Serial Number	試驗項目 Testing Items	試驗對象 Subject of Testing	試驗摘要及結果 Summary and Result of Testing
第一批批號 No. of 1st Batch :			
第二批批號 No. of 2nd Batch :			
第三批批號： No. of 3rd Batch :			

五、產 品 製 程 概 要

Summary of Manufacturing Process

申請廠商 Applicant	
品 名 Product Name	
製造加工流程 Manufacturing Process :	

六、良好作業規範之證明資料摘要表

Summary Table of Documentary Evidence of Good Manufacturing Practices

廠 名 Name of Factory	
品 名 Product Name	
合法工廠登記證 號 Official Factory Registration Certificate No.	
其他品管系統認 證資料清單 Checklist of Other Quality Management System Certification Information	
國外相關法規 (國產免填) Related Laws and Regulations of the Foreign Country (please ignore in case of domestically produced product)	
符合健康食品工 廠良好作業規範 相關資料清單 Checklist of Information Relating to the Compliance with the Good Manufacturing Practices for Health Food Manufacturer	製程管制文件 Manufacturing Process Control Document(s) : 1. 2. 3. 4. 品質管制文件 Quality Control Document(s) : 1. 2. 3. 4.

七、產品衛生檢驗規格及其檢驗報告摘要表

Summary Table of Sanitary Specifications and its Test Report

申請廠商 Applicant			
品 名 Product Name			
檢 驗 項 目 Items under Inspection	檢 驗 規 格 Inspection Specifications	檢 驗 結 果 Inspection Results	
第一批批號： No. of 1st Batch： 1. 2. 3. 4.			
第二批批號： No. of 2nd Batch：			
第三批批號： No. of 3rd Batch：			

八、一般營養成分分析報告摘要表

Summary Table of General Nutrients Analysis Report

申請廠商 Applicant					
品 名 Product Name					
檢驗項目 Items under Inspection	檢驗結果 Inspection Results	檢驗項目 Items under Inspection	檢驗結果 Inspection Results	檢驗項目 Items under Inspection	檢驗結果 Inspection Results
第一批批號 No. of 1st Batch		第二批批號 No. of 2nd Batch		第三批批號 No. of 3rd Batch	
產品每一份量 (公克/毫升)		產品每一份量 (公克/毫升)		產品每一份量 (公克/毫升)	
1. 熱量 Calorie 2. 蛋白質 Protein 3. 脂肪 Fats 飽和脂肪 Saturated Fats 反式脂肪 Trans Fats 4. 碳水化合物 Carbohydrates 糖 Sugar 5. 鈉 Sodium 6. 其他項目 Others		1. 熱量 Calorie 2. 蛋白質 Protein 3. 脂肪 Fats 飽和脂肪 Saturated Fats 反式脂肪 Trans Fats 4. 碳水化合物 Carbohydrates 糖 Sugar 5. 鈉 Sodium 6. 其他項目 Others		1. 熱量 Calorie 2. 蛋白質 Protein 3. 脂肪 Fats 飽和脂肪 Saturated Fats 反式脂肪 Trans Fats 4. 碳水化合物 Carbohydrates 糖 Sugar 5. 鈉 Sodium 6. 其他項目 Others	

九、產品包裝標籤及說明書（一）

Package, Label and Product Instruction Sheet (1)

申請廠商 Applicant			
品名 Product Name			
中文標示事項 Labelling in Chinese	產品標示內容 Product Label Content		
1. 品名 Product Name			
2. 內容物及食品添加物名稱；其為二種以上混合物時，應依其含量多寡由高至低分別標示之，混合二種以上食品添加物，以功能性命名者，應分別標明添加物名稱 Name of Ingredients & Food Additive(s); those that contain two or more ingredients shall indicate the respective ingredients in descending order of proportion; in the case of a mixture of two or more food additives which are named according to its function shall indicate the name of each additive separately.			
3. 淨重、容量或數量 Net weight, volume, or quantity			
4. 有效日期、保存方法及條件 Expiration Date, Storage Method and Conditions	有效日期 Expiration Date : 保存方法 Storage Method : 保存條件 Storage Conditions :		
5. 廠商名稱、地址。輸入者應註明國內負責廠商名稱、地址。 Name and address of the manufacturer. In case of an importer, please specify the name and address of the domestic manufacturer.			

九、產品包裝標籤及說明書（二）

Package, Label and Product Instruction Sheet (2)

申請廠商 Applicant		
品名 Product Name		
中文標示事項 Labelling in Chinese	產品標示內容 Product Label Content	
6. 核准之功效 The Approved Health Care Effects		
7. 許可證字號（樣板）、「健康食品」 字樣及標準圖樣（樣板） Reference number of the permit (sample), words of "Health Food" and standard logo (sample)		
8. 攝取量、食用時應注意事項、可能 造成健康傷害以及其他必要之警 語 Amount of Intake, precautions, possible health risks and other necessary warnings.		
9. 營養成分及含量（營養標示） Nutrient and its content (Nutrition facts)		
10. 保健功效成分及含量 Ingredients with Health Care Effect and its Content		

九、產品包裝標籤及說明書（三）

Package, Label and Product Instruction Sheet (3)

申請廠商 Applicant	
品 名 Product Name	

十、公司登記或商業登記之證明文件影本粘貼表

Table for Pasting of the Copy of Certificate of the Applicant's Corporation
or Business

申請廠商 Applicant	
品 名 Product Name	