

# Questionnaires of Equivalence Information of Food Safety System in

## Dairy Products for Applying Import to Taiwan

### 申請乳製品輸入台灣之食品安全管理體系等效問卷

Please note prior to answer the questionnaire

#### 問卷作答須知

The purpose of this questionnaire is to obtain the general information about the food safety system in dairy products in your country. This information will be used to evaluate the food safety system in your country.

本問卷旨在瞭解貴國乳製品的安全管理狀況。這些資料將用來評估貴國之食品安全管理系統。

Please provide all the answers to the full extent if possible. Answers should be written in English or Chinese. Copies and electronic files of maps, tables and figures are preferred under the applicable questions.

請以英文或中文作答並力求完整，必要時請附上相關文件(地圖、圖表等)之影本和電子檔)

2018 年 2 月

## 0. Profile

### 0. 簡介

- 0.1 Before answering the following questions, please describe the profile of dairy product of the country, including history, geography, agriculture, forestry, fisheries, food import and export management and situation, and type of food industries including numbers of dairy factories, yearly production, types of dairy products and productivity.

請簡單介紹國家的乳品產業，包括歷史、地理、農林漁牧、食品進出口管理與進出口情形以及產業型態(國內乳品工廠數量、年產量、產品類型及其產量)

- 0.2 Please describe what kind of dairy products you want to export to Taiwan?

請選擇貴國欲申請輸入臺灣之乳製品

- ☐Milk 乳； ☐Whey 乳清； ☐Milk powder 乳粉；  
☐Cheese 乾酪(起司)； ☐Butter, Cream 奶油、乳脂； ☐Condensed milk 煉乳；  
☐Yoghourt 優格；  
☐Other products containing dairy material (please describe the detail\_\_\_\_)其他含乳產品

## 1. Laws and regulations

### 1. 法令規章

- 1.1 What laws and regulations address the control of food safety and prevention of disease and environmental contamination of dairy products? Please provide the materials in English or Chinese.

貴國有關乳製品之食品安全管控、預防環境污染及預防疾病的相關法令及規範為何？請提供英文或中文資料。

- 1.2 What laws and regulations mandate the dairy establishments to be responsible for the food safety management? Please describe the requirements in detail.

有那些法令及規範要求乳製品之生產廠場必須對其食品安全負責？請詳細描述這些要求。

- 1.3 What laws and regulations mandate to consider the source of dairy products for food safety? Please describe the requirements in detail.

有那些法令及規範要求乳製品之原料生產源頭端須符合食品安全？請詳細描述這些要求。

- 1.4 What food hygiene and safety laws and regulations mandate the labeling of dairy products (e.g food allergens, expiry/manufacturing date)? Please describe the requirements in detail.

有哪些法令及規範要求與食品衛生及安全相關之乳製品標示 (例如食品過敏原、保存期限/製造日期)?請詳細描述這些要求。

- 1.5 Other related laws and regulations about dairy products. Please describe the requirements in detail.

其他與乳製品相關之法令及規範。請詳細描述這些要求。

## 2. Control system and government organization

### 管理制度和政府組織架構

2.1 For each of the dairy products under this application, please describe your management system to control the source and food safety.

針對本次申請之個別產品，請說明貴國目前有關乳製品之來源管理及食品安全管理制度。

☐ Milk 乳：

☐ Whey 乳清：

☐ Milk powder 乳粉：

☐ Cheese 乾酪(起司)：

☐ Butter, Cream 奶油、乳脂：

☐ Condensed milk 煉乳：

☐ Yogourt 優格：

☐ Other products containing dairy material (please describe the detail\_\_\_\_)其他含乳產品

2.1.1 Please describe what governmental agencies enforce the relevant laws and regulations? Please include organization charts for each of these agencies.

請說明執行相關法令規範之政府機關為何。請列出這些機關之個別組織圖。

2.1.2 Please describe the functional relationship among the above governmental agencies at the national, provincial, or local levels? How do these agencies/authorities cooperate and work together?

請說明這些國家層級的、省級的或地方層級政府機關，其分別執行的任務為何。各級單位間如何分工？

2.1.3 In the field and at headquarters, please describe how many persons are assigned to the dairy products inspection programs? Please List the separate areas of responsibility and denote the number of persons in each area and organization charts for each field.

請說明有關貴國乳製品查驗計畫之中，隸屬於中央以及地方單位計有多少人。請列出各別的责任區域，並在各自別管轄區內註明人數及其職責與組織圖。

2.2 For each of the products under this application, please specify how your current

system can prevent dairy products from being polluted..

針對本次申請之產品，請說明貴國目前之管理制度如何預防乳製品受到環境污染。

2.2.1 Please describe what governmental agencies enforce the relevant laws and regulations? Please include organization charts for each of these agencies.

請說明執行相關法令規範之政府機關為何。請列出這些機關之個別組織圖。

2.2.2 Please describe what is the functional relationship among these governmental agencies at the national, provincial, or local levels? How do these agencies/authorities cooperate and work together?

請說明這些國家層級的、省級的或地方層級政府機關，其分別執行的任務為何。各級單位間如何分工合作？

2.2.3 Please describe what is the functional relationship among the food safety and environmental protection agencies/authorities? How do these agencies/authorities cooperate and work together to monitor and prevent food from environmental contamination and pollution.

請說明貴國之食品安全及環境保護機構/主管機關間之功能關係為何。這些單位間如何合作分工，以監督和預防食品遭受環境污染。

2.3 Please describe whether the dairy inspection agency/authority also responsible for other inspection programs? (For example, fishery products, meat and poultry products, non-meat food products and feed manufacture).

請說明負責乳製品查驗之機構/主管機關是否也負責其他產品之查驗計畫？（例如水產品、畜禽肉品，非肉類產品及飼料製造）。

### 3. Governmental control system

#### 政府管理制度

- 3.1 Please describe dairy products inspection programs at the national, provincial, or local levels. Is there any official control program for export establishments?

請說明貴國之國家層級、省級或地方政府的乳製品查驗計畫。針對出口廠場，是否有任何官方管制計畫？

- 3.1.1 Please indicate what products are covered under each inspection programs? These products should include products intended to export to Taiwan.

請指出在每一個查驗計畫下包含哪些產品，這些產品應包括想出口至台灣產品。

- 3.1.2 Please describe the budget/ funding sources of the above inspection programs?

請說明查驗計畫之經費來源為何？

- 3.1.3 Are there any other non-government inspection programs in place?

是否有其他非官方查驗計畫？

- 3.1.4 Please describe the execution frequency of the above government and non-government inspection programs?

請說明以上官方和非官方查驗計畫的執行頻率。

- 3.1.5 Please describe the training requirements for supervisors and inspectors personnel?

請說明相關查驗人員及督導人員有那些訓練要求。

- 3.1.6 Please describe the dairy products that export to other countries under any government or non-government inspection programs? Please describe the programs in detail. Is there any official or non-government inspection of these dairy products that have been exported to other countries so far, and what are the inspection plans?

請說明目前已出口至其他國家之乳製品是否有官方或非官方之查驗，其查驗計畫有哪些。請詳細描述這些查驗計畫。

- 3.2 Please describe the management program for dairy farm registration and animal identification.

請說明有關牧場登記和動物識別之官方管制計畫。

### 3.2.1 Please describe Farm registration

請說明牧場登記。

3.2.1.1 Please describe the registration system for livestock holdings. Any exemptions should be clearly state the rationale and pertinent regulations.

請說明畜牧場之登記系統，免除登記者應清楚說明其理由及相關規範。

3.2.1.2 Please describe the method used to identify individual holdings.

請說明個別牧場之識別飼養牲畜方法。

3.2.1.3 Please describe the farm registration system.

請說明牧場登記之記錄系統。

### 3.2.2 Please describe animal identification.

請說明動物識別。

3.2.2.1 Please describe the identification system for dairy cow. Any exemptions should be clearly state the rationale and pertinent regulations. Please provide information on identification systems. In particular, the details of what mark used (tags, tattoos etc), whether they allow individual animal or only farm identification, maximum age of animals at first identification, responsibility for application of marks, on-farm and official records of marks, re-application of lost marks, special marks for suspect or diseased animals etc.

請說明乳牛識別系統，免於識別者應清楚說明其理由及相關規範。請提供動物識別記錄系統之相關資訊，特別是所用標識形式之細節(如掛標記、刺青等)、是否要求個別動物識別或僅為牧場識別、動物進行識別紀錄之最晚年齡、申請標識之責任、標識之田間和官方紀錄、標識遺失之重新申請，以及疑似染病或已染病動物之特殊標識等。

3.2.2.2 Please indicate any special rules for identification of pedigree animals.

請闡明種畜識別之特殊規定。

3.2.2.3 Please describe the official controls and records maintained to monitor the operation of the animal identification systems.

請說明監測動物識別系統運作之官方管理制度和紀錄保存。

3.2.2.4 Please describe how the system trace back from the animals and products to their original farms. Please provide relevant regulations and competent authorities.

請說明此系統如何從動物及其產品追溯至來源牧場、相關法規以及權責機關。

3.3 Please describe the official control programs of the food additives, irradiation, packaging materials, detergents and sanitizing agents and etc.

請說明食品添加物、輻射處理、包裝材料、清潔劑和消毒劑等之官方管制計畫。

3.3.1 Please describe the relevant laws and regulations?

請說明其相關的法令規範為何。

3.3.2 Please describe the laws and regulations relating to testing, approval, and control the uses of these materials?

請說明這些物料檢驗、核准和使用管制之相關法令規範為何。

3.3.3 Please describe the procedures, inspection activity or criteria are used to determine whether these materials will not cause product deterioration and will comply with the applicable laws and regulations?

請說明政府藉由那些程序、查驗措施或標準判定所使用之物料不會引起產品變質且符合適用之法令規範。

3.3.4 Please describe what is the procedure to approve these materials to be legal food additives or food contact materials?

請說明這些物料成為合法食品添加物或食品接觸物質之核准程序為何。

3.3.5 Please describe how does the agency ensure or verify that dairy establishments only use legal food additives, irradiation, packaging materials, detergents and sanitizing agents.

請說明主管機關如何確保與確認乳製品生產廠場只使用合法之食品添加物、輻射處理、包裝材料、清潔劑和消毒劑等。



3.4 Please describe the official control activities to review the ingredients and methods of preparation for dairy products.

請說明官方對乳製品之成分和製備方法的管理措施。

3.4.1 Please describe what are the relevant regulations, requirements or guidelines to regulate the production and labeling of the dairy products.

請說明乳製品生產製造及標示之相關法規、要求及指引為何。

3.4.2 What governmental agencies or organization review the processed product ingredients and processing? What is the functional relationship among these agencies?

審核加工產品成分及製備方法之政府單位或組織為何？這些單位之分工關係為何？

3.4.3 Please describe what is the procedure to review the thermal and other sterilization processing?

請說明產品加熱和其他殺菌加工流程之審核程序為何。

3.4.4 Please describe is there any official document indicating the heating and other sterilization procedures.

請說明有無官方文件載明加熱或其他殺菌加工程序。

3.4.5 What agencies audit the processing process of the establishments?

負責稽核廠場加工過程的主管機關為何？

3.4.6 Please describe how do the agencies inspect the compliance of the materials used at the establishments?

請說明主管機關如何稽查廠場使用的原物料符合法規。

3.5 Please describe the HACCP (equivalent) inspection system in your country.

請說明貴國之 HACCP 或等效之查驗系統。

3.5.1 How does the government inspection system specify and mandate the HACCP system in dairy establishments must conduct hazard analysis, determine critical control point, establish control limit, conduct monitoring, implement corrective actions, maintain documents, and records and verify the effectiveness of the HACCP system?

政府查驗系統如何規定及強制要求乳品生產廠場的 HACCP 系統必需執行危害分析、決定重要管制點、建立管制界限、執行監測計畫、執行矯正措施、建立文件及紀錄及確認本系統執行之有效性？

3.5.2 Please describe what's the above system based on? Please provide the laws and regulations.

請說明此查驗系統是如何架構於政府的必要法令規範中，而這些法令規範為何。

3.5.3 How does the government inspection system verify the effectiveness of process control designed to ensure food safety?

政府查驗系統如何確認製程管控措施足以確保食品安全？

3.5.4 How does the government verify the effectiveness of the inspection system?

政府如何確認查驗系統之有效性？

3.5.5 In case the food safety incidents occur, would the authority take the following measures including sampling, traceability, publication of the test results and related information, recalling and withdraw from the market? Please specify how you work.

發現有危害食品安全事件時，政府所採取之措施為何(包括抽樣檢驗、追查來源及流向、公布檢驗結果、揭露資訊、回收下架等)？

3.5.6 In case of falsification of records, criminal prosecution, would the authority take the following actions including suspension, corrective action request, and follow-up inspection? Please specify how you work.

政府法令機構對偽造紀錄、違法有那些執法措施？包括暫時停工、限期改善、複檢等？

3.6 What regulations, directives or guidelines require establishments or export establishments to control the recall, destroy or reprocess products, raw materials, food additives, detergents and sanitizing agents or other materials that are not fitting for human consumption?

要求廠場或出口廠場控制應回收、銷毀或再製不宜供食用的產品、原物料、食品添加物、清潔劑、消毒劑或其他材料之法規、法令或指引為何？

3.7 Please describe what procedures are in place to certify acceptable products for export? What procedures do you follow to re-certify previously non-compliant

products for export?

請說明符合出口條件之產品的核准發證程序為何。之前不符出口條件之產品後續再次核准發證之程序為何？

### 3.8 Please describe the official management on food operating businesses.

請說明官方對食品業者之管理為何。

3.8.1 Please describe what regulations, directives or guidelines require food operating businesses including dairy operating businesses should register. Which agencies manage the registered? What activities will be taken by which agencies to audit and verify the correctness of the registrations?

請說明要求食品業者包括乳品業者應登錄(登記)之法規、法令或指引為何。負責管理食品業者登錄的主管機關為何？對於食品業者登錄情形之稽查與執行機關為何？有哪些措施確認食品業者正確之登錄？

3.8.2 Please describe what regulations, directives or guidelines require the dairy operating businesses to set up traceability system? What activities will be taken by which agencies to audit and verify the correctness of the traceability works conducted by the food businesses?

請說明要求乳品食品業者應建立追蹤追溯系統之法規、法令或指引為何。對於食品業者追蹤追溯辦理情形之稽查與查驗機關為何？有哪些措施確認食品業者正確之追溯追蹤？

3.8.3 Please describe what regulations, directives or guidelines require the dairy operating businesses to test their raw materials, semi-products and end products? What activities will be taken by which agencies to audit and verify the correctness of the test?

請說明要求乳品食品業者應自主檢驗其原物料、半成品及終產品之法規、法令或指引為何。對於食品業者是否正確執行自主檢驗之稽查與查驗機關為何？有哪些措施確認食品業者正確之自主檢驗？

#### 4. Self - control programs for dairy products at establishments

##### 廠場中乳製品之自主管理計畫

- 4.1 Please describe what regulations, directives, or guidelines mandate that the export establishments evaluate the sanitary conditions to prevent product from contaminations.

請說明有那些規定、指令及指引要求出口廠場必須評估其衛生狀態是否能避免產品受污染。

- 4.1.1 Please describe what regulations, directives, or guidelines mandate that the establishments address the sanitation standard operation procedures in written.

請說明要求廠場需有書面的衛生標準作業程序之規定、指令及指引為何。

- 4.1.2 Please describe what regulations, directives, or guidelines mandate that the establishments evaluate the sanitary conditions to prevent product from contaminations.

請說明要求廠場需評估可預防產品受污染之衛生條件之規定、指令及指引為何。

- 4.1.3 Please describe what regulations, directives, or guidelines mandate that the establishments establish cleaning procedures, including cleaning frequency.

請說明要求廠場建立清潔作業標準，包括清潔頻率等之規定、指令及指引為何。

- 4.1.4 Please describe what regulations, directives, or guidelines mandate that the establishments take correction actions.

請說明要求廠場採取矯正措施之規定、指令及指引為何。

- 4.2 Please describe what regulations, directives, or guidelines mandate that the establishments address the control and prevention of contaminations in constructing ground, building and facility for processing, personnel dormitory, dining room, resting area, toilet and water supply etc.

請說明有哪些管制及預防污染之規定、指令及指引要求廠場在食品作業場所之廠區、建築與設施、員工宿舍、餐廳、休息室、廁所及用水等處須有管控及預防產品受污染之措施。

- 4.3 Please describe what regulations, directives, or guidelines address the control and prevention of contaminations of facility and utensil cleaning, personal hygiene

and health, waste disposal and pests control programs.

請說明有哪些規定、指令及指引規範設備與器具之清洗衛生、作業人員衛生及健康、廢棄物及病蟲害管制計畫，需能管控及預防產品受污染。

- 4.4 Please describe what regulations, directives, or guidelines require establishment to perform processing and quality controls? Including the following questions 4.4.1-4.4.13.

請說明有哪些規定、指令及指引要求廠場需執行加工製程及品質管制，包括以下 4.4.1-4.4.13 各項提問。

- 4.4.1 Please describe in-coming materials, intermediate goods and product receiving inspection and control.

請說明原物料、半成品及成品之驗收與管控措施。

- 4.4.2 Please describe food additives receiving inspection and control.

請說明食品添加物之驗收與管控措施。

- 4.4.3 Please describe processing control, including processing temperature, humidity, pH, water activity, pressure, flow rate and time.

請說明加工過程之溫溼度、酸鹼值、水活性、壓力、流速和時間等之管控措施。

- 4.4.4 Please describe operation, handling and maintenance of the processing equipments, utensils and containers.

請說明加工過程中所使用之設備、器具及容器，其操作、使用與維護方式。

- 4.4.5 Please describe effective measures to prevent metal or other foreign materials mixing into products.

請說明防止金屬或其他外來雜物混入食品之有效措施。

- 4.4.6 Please describe control of water supply (including potable water and cleaning water) and relevant records.

請說明用水(包括飲用水及清洗用水)之管控措施及相關紀錄。

- 4.4.7 Please describe control of packaging, packaging material or recycle of containers.

請說明包裝、包裝材料或容器回收使用之管控措施。

- 4.4.8 Please describe pre-shipment control.  
請說明出貨前之管控措施。
- 4.4.9 Please describe process and quality nonconformity control.  
請說明製程與品質不合格者之管控措施。
- 4.4.10 Please describe corrective and preventive actions.  
請說明矯正與預防措施。
- 4.4.11 Please describe labeling and traceability.  
請說明標示與追蹤追溯。
- 4.4.12 Others.  
其他。
- 4.4.13 Please describe records of the above items.  
請說明以上各項的紀錄。
- 4.5 Please describe what regulations, directives, or guidelines mandate dairy establishments to take responsibility for the warehouse and transportation controls.  
請說明要求乳製品生產廠場應進行倉儲和運輸管控措施之法規、指令或指引為何。
- 4.6 Please describe what regulations, directives, or guidelines mandate establishments to take responsibility for testing and measurement, customer complaints, product recall and record-keeping controls.  
請說明要求廠場應進行檢驗與量測管制、客訴、產品回收和保存紀錄控管的法規、指令或指引為何。
- 4.7 Please describe the frequencies to implement the control programs listed in 4.1 – 4.6.  
請說明廠場執行問題 4.1 到 4.6 管制計畫的頻率。
- 4.8 Please describe what regulations, directives, or guidelines mandate low-acid canning establishments taking control of programs listed in 4.1 – 4.6.  
請說明要求低酸性罐頭工廠執行問題 4.1 至 4.6 管制計畫之相關法規、指令

或指引為何。

- 4.9 Please describe how governmental agencies confirm that establishments carryout the above Self- Control Programs.

請說明政府機關如何確認廠場執行上述自主管理計畫之情形。

## 5. Chemical residues, contaminants and microbial control programs

### 化學殘留物、污染物和微生物管理制度

#### 5.1 Chemical residues and contaminants.

##### 化學殘留物及污染物

5.1.1 Please describe the control programs of veterinary drugs, feed additives, food additives, pesticides, herbicides, detergents, sanitizing agents, industrial and environmental pollution (e.g dioxin, heavy metal) and irradiation.

請說明動物用藥、飼料添加物、食品添加物、殺蟲劑、除草劑、清潔劑、消毒劑、工業及環境污染物(例如戴奧辛和重金屬)及輻射處理的管制計畫。

5.1.1.1 Please describe the chemical residue control programs at the national, provincial, and/or local levels. Is there any export program in place? Which agencies are responsible for planning and implementing the national control programs?

請說明國家層級、省級和/或地方層級之化學殘留物的管制計畫。是否有任何出口管制計畫。負責規劃及執行國家管制計畫之政府機關為何？

5.1.1.2 Please list the chemical residues, pollutants and the maximum residue limits in each chemical residue control plans and samples to be analyzed, for each specific residue compounds.

請列出在化學殘留物管制計畫中所監測之每一項化學殘留物、污染物及其最大容許量以及每一特定殘留化合物之分析樣品。

5.1.1.3 Please submit a copy of your annual residue programs/plans/projects, which might be monitoring, surveillance or other special testing programs/plans/projects in place.

請提供貴國年度化學殘留物管制方案/計畫/項目 1 份，此管制方案/計畫/項目可能為監測、調查或其他現行特殊檢測計畫。

5.1.1.4 Please describe the design of the residue programs/plans/projects for dairy products to be tested for residues, including sampling size and location. Indicate whether the sampling is based on random sampling and/or the statistical significance expected of the residue conclusions or whether the sampling plan is based on non-statistical design



principles. In both cases, indicate the objectives of the residue programs/plans/projects.

請說明針對乳製品的化學殘留物檢測之管制方案/計畫/項目，有關樣本量及取樣地點等之設計原理，並指出是否依隨機原理做取樣，化學物質殘留之結果是否為可預期的或統計學的結果作為判定標準，或者該取樣計畫是以非統計學原理為基準來執行，同時說明該方案/計畫/項目之目的。

5.1.2 Please describe the government enforcement programs for chemical residues and the government's activities to prevent dairy products from chemical residues contamination.

請說明政府對化學殘留物的執法計畫及預防乳製品受到化學殘留物污染危害之行動。

5.1.2.1 Please describe how are test results reported? What agencies will receive the report when test results violate the standards?

請說明檢測結果如何通報。當違規時，哪些機關會收到這份報告？

5.1.2.2 Please describe what actions are taken when positive or violate results determined the chemical listed in 5.1.2.2.1-5.1.2.2.5? In addition to the product recall, destroy and other disposition, what other actions will be taken? Such as personnel prosecute or penalty?

請說明當 5.1.2.2.1-5.1.2.2.5 中之化學殘留物檢測結果為陽性或超出標準時，將採取什麼行動。除了可能的產品回收或銷毀等處置外，還會採取其他什麼行動呢？如人員起訴或刑罰等。

5.1.2.2.1 Please list the drugs permitted for the therapeutic and preventative use in animals produced raw milk.

請列出允許使用在生產生乳動物上之治療性及預防性藥品。

5.1.2.2.2 Please list the prohibited and permitted substances for food safety.

請列出基於食品安全禁用及准用的物質。

5.1.2.2.3 Please list agricultural chemicals permitted for crops used in feed production and in grazing.

請列出使用於飼料生產及放牧作物之農業用化學物質。

5.1.2.2.4 Please list environmental or industrial chemicals that are potential contaminants to dairy production.

請列出可能污染乳製品生產之環境或工業之化學物質。

5.1.3 Please provide the organization chart of the agencies responsible for chemical residue programs/plans/projects and explain the relationship in the dairy products monitoring programs for compound approval, residue programs design, sample collection, laboratory and enforcement.

請提供負責化學殘留物之監測方案/計畫/項目之政府機構組織架構圖，並解釋這些機關在乳製品監測計畫中之化合物准用、殘留物監測計畫設計、採樣、實驗室及執行面的關係。

5.1.4 Please identify the regulations, directives and guidelines concerning the chemical residues.

請指出有關化學殘留物之相關法規、指令及指引。

## 5.2 Microbial control -programs

微生物管制計畫

5.2.1 Please describe the national microbial monitoring programs/plans/projects for dairy products including further processed products in your country at the national, provincial, and/or local levels. Is there any export program in place? What agency is responsible for the planning for national control programs and what agency is responsible for implementation?

請說明貴國在國家層級、省級和/或地方層級之乳製品(包括再加工者)微生物監測方案/計畫/項目。是否有任何出口管制計畫?負責規劃及執行的政府機關為何?

5.2.1.1 Please describe what does the microbial monitoring programs/plans/projects work as an effective indicator for process control. How to analyze these data?

請說明微生物監測方案/計畫/項目在製程管控上之有效指標為何。如何分析這些數據。

5.2.1.2 Please describe the indicator microorganisms and microbial standards for corresponding product category.

請說明相對應的產品類別之指標微生物和微生物標準。

5.2.1.3 Please submit a copy of your annual monitoring, surveillance or other special testing programs/plans/projects?

請提交 1 份年度監測、調查或其他特殊的檢測方案/計畫/項目。

5.2.1.4 Please describe what is the statistical basis for the sampling program. What sample categories are covered in these programs /plans /projects?

請說明抽樣計畫的統計基礎為何。這些方案/計畫/項目所涵蓋之產品類別為何？

5.2.1.5 Please describe the design of the sampling programs/plans/projects for product category to be tested. Indicate whether the sampling plan is based on random sampling and the statistical significance expected of the microbial monitoring conclusions or whether the sampling plan is based on non-statistical design principles. In both cases, indicate the objectives of the residue programs/plans/projects.

請說明針對產品類別之抽樣方案/計畫/項目，並指出是否依隨機原理做取樣，微生物監測之結果是否為可預期的或統計學的結果作為判定標準，或者該取樣計畫是以非統計學原理為基準來執行，同時說明該方案/計畫/項目之目的。

5.2.2 Please describe how are test results reported. What agencies will receive the report when test results violate the standards? Please describe what are the corrective actions for the noncompliant incidents obtained in these testing and monitoring programs/plans/projects.

請說明檢測結果如何通報。當違規時，哪些機關會收到這份報告？請說明針對這些檢測和監測方案/計畫/項目所獲得不符合情事之矯正措施為何。

5.2.3 Please provide the organization chart of the agencies responsible for microbial monitoring programs/plans/projects and explain the relationship in the dairy products monitoring programs design, sample collection, laboratory and enforcement.

請提供負責微生物監測方案/計劃/項目之政府機構組織架構圖，並解釋這些機關在乳製品監測計畫設計、採樣、實驗室及執行面的關係。

5.2.4 Please identify the regulations, directives and guidelines concerning the

microbial monitoring programs/plans/projects.

請指出有關微生物監測方案/計劃/項目之相關法規、指令及指引。

## 6. Laboratory

### 實驗室

- 6.1 Please identify the analytical methods used for the microorganisms, veterinary drugs, food additives or other chemical compounds for dairy products including further processed products. Please use Table 1. to list the analytical methods you used.

請說明乳製品(包括再加工者)之微生物、動物用藥、食品添加物或其他化學物質等分析方法(請列於表一)。

- 6.2 Please describe the the laboratory management.

請說明實驗室管理制度。

- 6.2.1 Please identify how many laboratories perform the tests.

請說明有多少實驗室執行檢測。

- 6.2.2 Please indicate what the governmental, private or other laboratories are and the correspondent tests are performed in these laboratories. Please list the private and governmental laboratories performing tests for these tests for dairy products including further processed products in Table 1.

請指出這些實驗室有那些是官方、民間或其他類型。請於表一列出這些執行乳製品包括加工產品之檢測的民間和官方實驗室檢測項目。

- 6.3 Please describe how do the quality control or quality assurance programs carryout in approved laboratories to ensure accurate and consistent analyses.

請說明核可實驗室之品質管制和品質保證計畫如何確保其分析結果的準確性與一致性。

- 6.3.1 Please describe how the government ensures the correctness of quality control programs and analytical results.

請說明政府如何確保品質管制計畫與分析結果的正確性。

- 6.3.2 Please describe the records keeping system for the analytical events.

請說明分析結果之紀錄保存系統。

- 6.3.3 Are these laboratories accredited? If yes, please list them in Table 1.

這些實驗室是否經過認證？如果是，請列於表一。

- 6.3.4 Please provide the name of the accreditation bodies for the approved

laboratories.

請提供這些實驗室的認證機構名稱。

6.3.5 What items are the approved laboratory accredited for? Please list in Table 1.

這些實驗室其認證項目為何？請列於表一。

6.3.6 Does the laboratory participate in proficiency testing? Please list in Table 1.

這些實驗室是否參加能力測試？請列於表一。

**Table 1** Please list the governmental laboratories and designated private laboratories performing national monitoring programs/plans/projects for chemical and microbial tests for dairy products including further processed products.

表一、請列出官方及指定民間實驗室，針對乳製品(包括再加工者)所執行之國家化學物質及微生物監測方案/計畫/項目

Laboratories 實驗室	Testing item 檢測項目	Testing Method 檢測方法	Does the testing item being accredited? 檢測項目是否經過認證?	If the testing item is accredited, please specify the accreditation body 如檢測項目經過認證，請列出認證單位	Does lab participate in the PT test for this testing item? 此檢測項目是否參加過能力測試?
<b>ex: Veterinary Drug 動物用藥</b>					
AAA	OTC	LC-MS-MS	YES	TFDA	<input type="checkbox"/> Yes <input type="checkbox"/> No
BBB	OTC	LC-MS-MS	No	N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>ex: Food Additives, etc. 食品添加物等</b>					
AAA	Benzoic acid	HPLC	YES	FDA	<input type="checkbox"/> Yes <input type="checkbox"/> No
Environmental Contaminants (Environmental agent, Heavy metal, Dioxin, PAH, etc) 環境污染物(環境用藥、重金屬、戴奧辛、多環芳香族碳氫化合物等)					

Laboratories 實驗室	Testing item 檢測項目	Testing Method 檢測方法	Does the testing item being accredited? 檢測項目是否經過認 證?	If the testing item is accredited, please specify the accreditation body 如檢測項目經過認證，請列出認證單 位	Does lab participate in the PT test for this testing item? 此檢測項目是否參加過能 力測試?
AAA	Mercury	ICP-MS	YES	FDA	<input type="checkbox"/> Yes <input type="checkbox"/> No
					<input type="checkbox"/>
Microorganisms 微生物					
CCC	<i>Staphylococcus aureus</i>	FDA	YES	FDA	<input type="checkbox"/> Yes <input type="checkbox"/> No
Mycrotoxin 黴菌毒素					
CCC	Aflatoxin	FDA	YES	FDA	<input type="checkbox"/> Yes No
ex:Virus 病毒					
BBB	Norovirus	RT-PCR	YES	FDA	<input type="checkbox"/> Yes <input type="checkbox"/> No

(Please prepare a table using this format) (請使用此格式製作表格)



## 7. Control of import and export

### 進出口管理

- 7.1 Please describe your export inspection system of dairy products, including the assurance of food safety and the inspection procedures

請說明貴國針對乳製品之出口查驗制度，包括貨品食品安全的確保及查驗程序。

- 7.2 Please describe your import inspection system of dairy products, including the assurance for food safety and the inspection procedures.

請說明貴國針對乳製品之進口查驗制度，包括貨品食品安全的確保及查驗程序。

- 7.3 Please describe what actions are taken when deceptive labeling, packaging, invoices or other documentation are discovered.

請說明發現標示、包裝、單據或其他文件不實時，需採取什麼行動。

- 7.3.1 Please describe what government authority is responsible for taking this action.

請說明那個官方單位負責採取這個行動。

- 7.3.2 Please describe how do you ensure the accuracy of packaging, labeling, invoices, and export documentation. Please describe the process in detail.

請說明貴國如何確保產品之包裝、標示、單據及出口文件的正確性。請詳述其過程。

- 7.3.3 Please describe what regulations, policies, guidelines, and other requirements pertain to the labeling and invoicing of products. Please briefly describe the intent of each regulation, policy, guideline, and requirement.

請說明產品的標示與單據之相關規定、政策、指引及其他要求為何。請概述其內容。

- 7.4 Please describe the certification programs for dairy products exporting to Taiwan.

請說明乳製品出出口到台灣的發證制度。

7.4.1 Please describe official inspection measures when products are shipped for exports.

請說明當產品要出口到台灣前的官方查驗措施。

7.4.2 Please describe authorized officers (a list and samples of signatures) and export official certification procedures (required documents, test results and so on).

請說明授權簽證檢查人員(清單及簽名樣張)及出口發證程序(必要之文件、檢測報告和其他)。

7.4.3 Are there any measures to prevent from fabrication of certificates?

是否有任何方法防止偽造證明文件?

7.5 Please describe the notification mechanism for illegal dairy products exported to other countries.

請說明不合法令規範之產品如有出口至其他國家之通報機制。

7.6 Please describe how to request the food operating businesses to recall or off-shelf non-compliance products, and to notify the downstream companies and agencies. Please also list related regulations.

請說明要求食品業者回收或下架不合法令規範產品，並要求廠商通知下游業者和主管機關之管制措施以及列出其相關規定。

7.7 Please describe the traceability of the exported products.

請說明產品出口後之追溯追蹤制度。

7.8 Please describe the management or control program for dairy products exporter.

請說明乳製品出口商管制計畫。

7.9 Please describe and list Memoranda of Understanding or other agreements for the import and export of dairy products with other countries.

請說明並列出是否有和其他國家簽訂與乳製品輸出入相關之合作瞭解備忘錄或其他協議。