



# 輸銷美國罐頭食品管理制度

財團法人食品工業發展研究所 技術服務及推廣中心 |  
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113年



# 大綱

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- 美國FDA訪廠查核重點

# 美國FDA 食品安全管理-發展路徑

## 法規-電子文件

- ✓ **2011 FSMA 7 rules** : Produce Safety rule , Foreign Supplier Verification Programs (FSVP), Sanitary Transportation rule , Protection Against Intentional Adulteration (IA), Accredited Third-Party Certification , Preventive Control Rule for Human and Animal Food , Voluntary Qualified Importer Program (VQIP)
- ✓ 17 類別 QA on FSMA
- ✓ 73 個 Guidance for Industry
- ✓ FSMA Training 標準化培訓講義、線上課程
- ✓ FSMA Technical Assistance Network

## 數位工具

- ✓ Agricultural Water Assessment Builder
- ✓ Food Defense Plan Builder 2012/2019
- ✓ Food Safety Plan Builder 2018/2020
- ✓ Product Codes and Product Code Builder
- ✓ FEI Portal
- ✓ Import Program Tools
- ✓ Prior Notice System Interface (PNSI)
- ✓ Product Code Builder

## 數位資料庫

- ✓ Food Defense Mitigation Strategies Database
- ✓ FDA Poisonous Plant Database
- ✓ Inspection Classification Database
- ✓ GRAS Substances Database

## 公開數據

- ✓ Import Alert
- ✓ FDA Data Dashboard

381 GRAS substance、SCOGS report number、CAS Reg. No.(ID code)、year of report、SCOGS Type of conclusion、21CFR regulation、NTIS accession Numbers 與NTRL報告資料連結  
<https://ntrl.ntis.gov>

Inspections
Compliance Actions
Recalls
Import Summary
Import Refusals
Imports Entry
Facility Information

2020~  
2030

## 智慧食安新時代2020

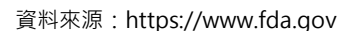


- ✓ 引用科技內涵的追溯追蹤
- ✓ 智慧化工具於預防與應對食品事件
- ✓ 新商業模式與現代化銷售
- ✓ 食品安全文化

## Food Defense Plan Builder 2.0

## 食品防禦計畫產出工具2019更新版

- 增加風險評估要素資料內容
- 納入食品業者註冊碼及識別碼
- 刪除原有的共通性防禦模組及資料內容



# 美國FDA 食品安全管理-發展路徑-數位工具

## Food Safety Plan Builder

Food Safety Plan Builder - New\*

File Edit View Tools Help

Facility Information Preliminary Steps **GMP & Other Prerequisite Programs** Hazard Analysis & Preventive Controls Determination Process Preventive Controls Food Allergen Preventive Controls

**Current Good Manufacturing Practices: Personnel**

1. Personnel

1a. In accordance with 21 CFR 117.4(b), all personnel must receive training in the principles of food hygiene and food safety, and the training must be documented in accordance with 21 CFR 117.4(d). As a convenience, you may choose to store records of employee training in the Supporting Documents tab.

1b. The management of an establishment must ensure that all individuals

1c. The management of the establishment must take reasonable measure

1d. The management of the establishment must take reasonable measure

2. Plant and Grounds

2a. The grounds about a food plant under the control of the operator must

2b. The plant must be suitable in size, construction, and design to facilitat

3. Sanitary Operations

3a. Buildings, fixtures, and other physical facilities of the plant must be ma

3b. Substances used in cleaning and sanitizing, and storage of toxic mate

3c. In accordance with 21 CFR 117.35(c), pests must not be allowed in an

3d. All food-contact surfaces, including utensils and food-contact surfaces

3e. Non-food-contact surfaces of equipment used in the operation of a fo

3f. Cleaned and sanitized portable equipment with food contact surfaces e

4. Sanitary Facilities and Controls

4a. The plant's water supply must be adequate for the operations intende

4b. The plant's plumbing must be of adequate size and design and is ade

4c. The plant's sewage must be disposed of into an adequate sewerage s

4d. Each plant must provide employees with adequate, readily accessible

4e. Each plant must provide hand-washing facilities designed to ensure th

4f. Rubbish and any offal must be so conveyed, stored, and disposed of e

5. Equipment and Utensils

5a. All plant equipment and utensils used in manufacturing, processing, p

5b. Seams on food-contact surfaces must be smoothly bonded or maintai

Supplementary Information:

Zoom(-) Zoom(+)

☐ Yes ☐ Not Applicable

### 食品安全計畫產出工具

- 僅於GMP項目納入條文並以問項方式列出內容及勾選**符合或不適用**
- 可由問項瞭解美國FDA的GMP要求
- 只有FS面向，未納入PCHF之經濟動機攙偽

# 美國FDA 食品安全管理-發展路徑-數據應用

- Data Modernization Action Plan (DMAP) 聚焦於數據的管理、安全、品質、分析及實時使用，加速保障食品供應鏈的安全
- 進口水產品既有數據分析-含被拒絕入境、加強現場檢查、標籤檢查或樣品採樣實驗室分析、線上註冊登錄資訊、境外查核結果及食品擋關或回收事件等數十年巨量數據
- 機器學習與人工智慧，以大數據分析預測，提高效率



2019 第一期概念驗證  
篩選有疑慮的進口水產品  
效率較人工篩選提高3倍



2021 第二期  
從數據挖掘/識別風險水產品  
，擴展FDA的預測分析能力，  
以降低食源性風險



2022 第三期  
加強邊境進口篩檢，提高/快速識別可能  
被病原菌污染、分解變質、殘留藥物  
或其他危害的進口水產品的能力

# 美國GMP強調之重點

美國cGMP章節	強調重點
1.從業人員衛生管制 (Personnel)	<p>1.美國允許從業人員在手部外傷時可使用“不可滲透材質”手套遮蓋傷口後執行工作，並指出此彈性作法是參考食品法典而更新</p> <p>2.要求從業人員之衣著整潔外，從業人員衣著必須要防止過敏原交叉接觸</p>
2.廠房與地面 (Plant and Grounds)	<p>1.美國要求廠區外地面要空出道路，碼頭和停車場，以避免該區域汙染食品，廠區外部的地面，需要病媒防治措施</p> <p>2.在廠房建造時，要考慮防止過敏原交叉接觸的動線問題，且有關集塵系統、氣流系統等要考慮其造成過敏原交叉接觸的可能性</p>
3.衛生作業 (Sanitary Operations)	<p>1.美國增列避免過敏原交叉接觸，器具及設備的食品接觸面必須被頻繁清潔，以防止過敏原交叉接觸，另外，非食品接觸面也必須要防止過敏原交叉接觸</p> <p>2. 要求購買的清潔劑、消毒劑、有毒化學物質及病媒防治用藥劑必須要有保證(guarantee)或證明(certification)</p> <p>3. 提出可以置放於食品作業場所內的物品：</p> <ul style="list-style-type: none"><li>(1)需要用來保持清潔和衛生條件的物品</li><li>(2)用於實驗室檢測程序所必需的物品</li><li>(3)工廠與設備維護及運作所必需的物品</li></ul>

# 美國GMP強調之重點

美國cGMP章節	強調重點
4.設施衛生管制 (Sanitary Facilities and Controls)	<p>1.美國cGMP增加器具必須防止過敏原交叉接觸</p> <p>2.要求食品接觸面的<b>接縫必須維持平滑</b>以減少食物顆粒，污垢和有機物質的積聚，減少微生物生長和過敏原交叉接觸的機會</p> <p>3.21CFR 178.1010 對消毒劑有規範，每種消毒溶液在使用時，對成分濃度有嚴格限制。例如，含氯的溶液濃度不得超過200ppm；含碘的溶液濃度不得超過25ppm等。完整規範列出多達40多種消毒劑的具體成分及其使用條件，並對特定使用場景提供詳細說明。</p>
5.設備與器具衛生 (Equipment and Utensils)	<p>1.要求設備必須使用不會與食品發生化學反應的材料，並且容易清洗、消毒</p> <p>2.移動設備必須設計可移動或拆卸，便於清洗和維護</p>

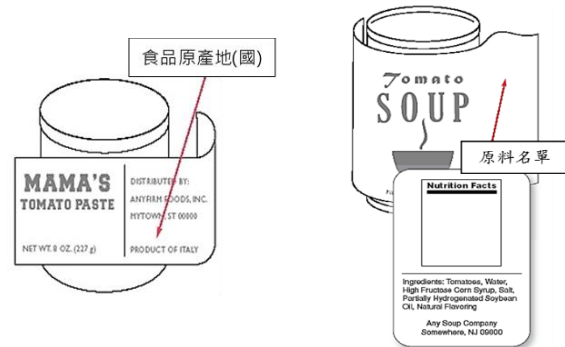
# 美國GMP強調之重點

美國cGMP章節	強調重點
<b>6.製程管理</b> (Processes and Controls)	<p>1.美國cGMP要求製程中所有被摻雜污染的食物必須被報廢或酌情處理以消除污染。</p> <p>2.美國cGMP針對受汙染的食品之處置有較清楚的說明：</p> <p>(1)受汙染的食品，原材料和其他成分必須被處置妥當以避免汙染其他食品</p> <p>(2)如果受汙染的食品可以重工，必須</p> <p>a.使用已被證明有效的方法進行修復</p> <p>b.在聯邦法案的定義下重新審查</p> <p>3.原材料和其它成分屬於食品過敏原者，及重工包含過敏原成分時，必須被標示並避免過敏原交叉接觸</p>
<b>7.倉儲及運銷</b> (Warehousing and Distribution)	<p>1.美國cGMP要求將過敏原及非過敏原料儲存時做區分以避免交叉接觸，且要避免生物、物理及化學性之危害</p> <p>2.原物料驗收時要確認其是否含有過敏原及盤點過敏原成分，液態或乾燥的原材料和其它成份以散裝型式接收和儲存者，必須防止過敏原交叉接觸</p>
<b>8.缺陷行動級別</b> (Defect Action Levels)	<p>美國FDA允許一些食品包含些微天然及不可避免的缺陷，在cGMP規定下生產並不會傷害健康</p>
<b>9.副產品做為動物用飼料之保存與運送規定</b> (Holding and distribution of human food by-products for use as animal food)	<p>1.運送副產品作為動物食品的容器和設備，運送前必須進行清潔，並防止副產品受汙染</p> <p>2.副產品的運送必須在防止汙染源(垃圾)的汙染下進行</p> <p>3.副產品保存期間，必須明確的識別辨識</p>

# 罐頭食品包裝標示規範

## □ 標示方式：分為主展示面與訊息面

- 所有法規要求的項目標示於主展示面，或主展示面標示食品名稱與淨重，其他內容標示於訊息面
- 訊息面標示項目包括製造商、包裝商或經銷商的名稱和地址、內容物清單、營養成分以及過敏原
- **不得於訊息面標示無關之資訊**
- 食品原產地(國)標示必須醒目。如果所標示的國內公司為經銷商，則必須將食品原產地(國)標示在緊鄰公司名稱和地址處
- 如果使用外語，則**所有必須標示項目應同時有英文標示**
- 當食品中添加核准的化學防腐劑時，必須包含該**防腐劑名稱及功能**，如“防腐劑”、“防腐劑”、“保鮮”等
- 原料中含有需FDA上市前認可的色素時，需以具體或縮寫名稱標註，比如“紅色40號”。若使用不需認證之色素，則以“人工色素”、“人工著色劑”或採用具體或通用名稱比如“焦糖著色劑”以及“甜菜汁著色劑”等名稱標示



# 罐頭食品包裝標示規範



Almonds  
Artificial nuts  
Beechnut  
Brazil nuts  
Butternut (white walnut)  
Cashews  
Chestnuts  
Chinquapin nut  
**Coconut**  
Filberts  
Gianduja (a creamy mix of chocolate and chopped toasted nuts found in premium or imported chocolate)  
Ginkgo nut  
Hazelnut spread  
Hazelnuts  
Hickory nuts  
**Litchi, lichee, or lychee nut**

Macadamia nuts  
Mandelonas (peanuts soaked in almond oil)  
Marzipan or almond paste  
Nangai nut  
Natural nut extract  
Nougat  
Nut butters (for example, cashew butter or almond butter)  
Nut milks, such as almond milk or cashew milk ice cream  
Nut oil, nut pieces, or nut meal  
Nut paste, such as almond paste  
Pecans  
Pesto  
Pili nut  
Pine nuts (pignolia)  
Pistachios  
Praline  
Shea nut  
Walnuts

1. Include the name of the food source in parenthesis following the common or usual name of the major food allergen in the list of ingredients in instances when the name of the food source of the major food allergen does not appear elsewhere in the ingredient statement for another allergenic ingredient.

OR

2. Place the word "Contains," followed by the name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients, in a type size that is no smaller than that used for the ingredient list.

## Nutrition Facts

**Ingredients:** Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, partially hydrogenated cottonseed oil, high fructose corn syrup, whey, eggs, vanilla, natural and artificial flavoring, salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin, mono- and diglycerides.

**Contains:** Wheat, Milk, Egg and Soy.

Any Cookie Company  
College Park, MD 20740

### EXAMPLE 1

In parentheses following the name of the ingredient.

lecithin (soy)

flour (wheat)

whey (milk)

### EXAMPLE 2

Immediately after or next to the list of ingredients in a "contains" statement.

Contains: Wheat, Milk, and Soy.

Some foods carry a voluntary "may contain" label statement (e.g. "May Contain Peanuts") because there is a chance that a food allergen is present. FDA guidance says these statements should not be used as a substitute for following current good manufacturing practices, and must be truthful and not misleading.

# 罐頭食品輸銷美國流程概述

## ① 申請報告

### 低酸罐頭食品

- pH>4.6、水活性>0.85
- 事先密封於任何容器再經加熱處理殺菌的食品



### 酸化罐頭食品

- 在低酸性食品中加入酸或酸性食品使其pH≤4.6、水活性>0.85的食品



- 1) 殺菌設備熱分布測試評估報告
- 2) 熱穿透測試報告 (產品)

- 1) 酸化殺菌設備評估報告
- 2) 酸化產品殺菌值評估報告

## ② 進行註冊

美國FDA 產業系統登錄(FDA Industry System , FIS)

美國FDA食品設施註冊 (Food Facility Registration , FFR)

低酸/酸化罐頭食品工廠註冊 (Food Canning Establishment , FCE)

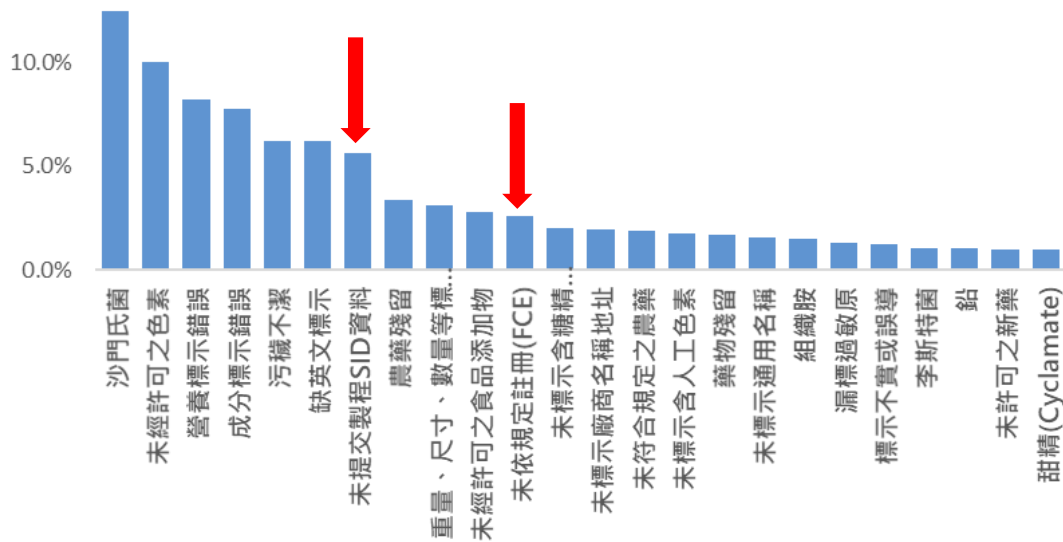
罐頭產品註冊識別碼申請 (Submission Identifier number, SID)

註冊前須先準備  
a) 鄧白氏環球編碼申請 (DUNS)  
b) 美國代理人 (U.S. Agent)

臺灣  
(FIRDI)

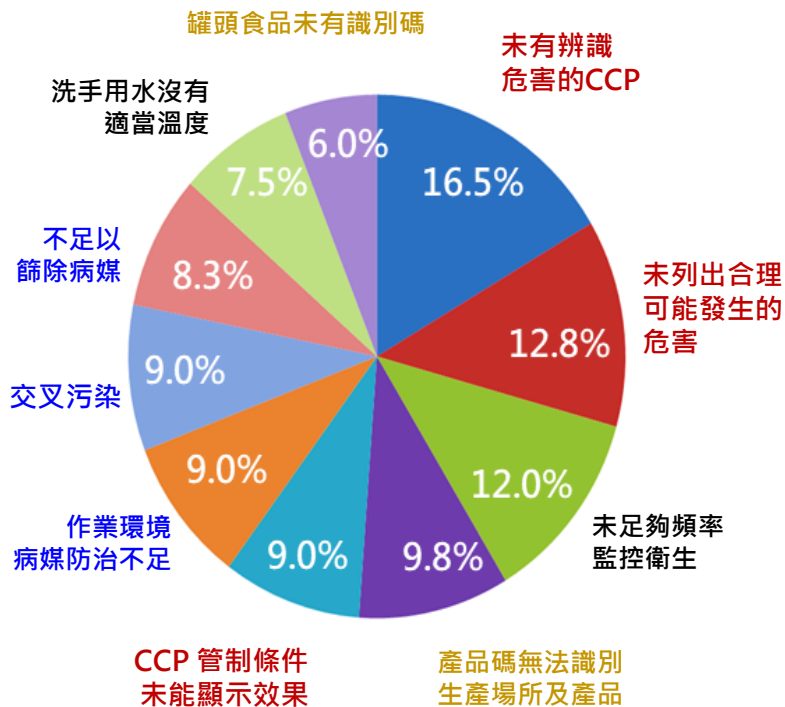
美國FDA官網

# 由開源資料看美國FDA訪廠查核重點



臺灣輸美食品擋關事件主要違規事由

# 由開源資料看美國FDA訪廠查核重點



美國FDA查核臺灣食品工廠常見缺失

# 美國FDA訪廠查核重點-產品碼與編碼產出工具

Product Code: 38BEE27

Example 1 - Food Product Code					
Structure	Industry	Class	Subclass	Process Identification Code (PIC)	Product
Format	Number	Letter	Letter or Hyphen (-)	Letter or Hyphen (-)	Letter or Number
Sample	38	B	E	E	27
Meaning	Soup	Soup, Conc	Metal	Commercially Sterile	Tomato Soup, Concentrated

產品碼組成:產業類別、產品大類、產品次類、製程鑑別、產品名稱

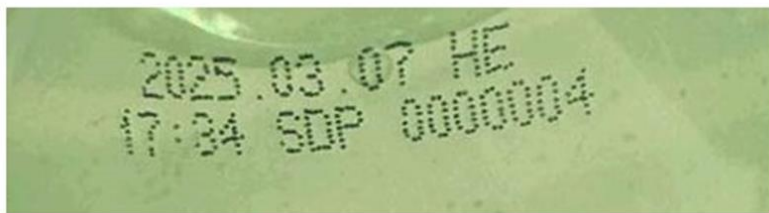
# 美國FDA訪廠查核重點-罐頭食品未有識別碼、產品碼無法識別生產場所及產品

## 產品編碼113.60(c) 的規定

- 低酸性加工食品的密封容器應標有識別代碼，該代碼應**永久肉眼可見**
- 當容器不允許壓印或墨水印代碼時，標籤可清晰地打孔或以其他方式標記，前提是標籤牢固地粘附在產品容器上
- 識別代碼應標明 **製造廠、產品、包裝年份/日期/期間**
- 包裝期間的代碼應足夠頻繁更換，以便**識別批次**，例如4~5小時的間隔；人員輪班更換；或批次不超過一個人員輪班的時間

YYYY.MM.DD(EXP.) / Factory code

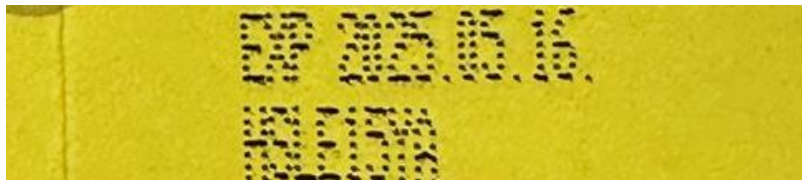
Production time / Production code / serial number



EXP YYYY.MM.DD

HS (factory) L (product) E15 (Month date), Y (year 2024)

A (production time AM)



# 美國FDA訪廠查核重點-未列出合理可能發生的危害

- 已知或合理可預期的危害
- Appendix 1: Known or Reasonably Foreseeable Hazards( “Potential Hazards” ) · 2024版所明列的潛在危害已較2016版者少很多
- 參考的指引 請自FDA網站下載
  - Tables 1A ~ 1Q 類別食品潛在的生物性危害
  - Tables 2A ~ 2Q類別食品的潛在的化學性危害

## Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry<sup>1</sup>

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan>.

### Appendix 1: Known or Reasonably Foreseeable Hazards (“Potential Hazards”)

# 美國FDA訪廠查核重點-未列出合理可能發生的危害

Table 1H: Known or reasonably foreseeable (“potential”) food-related biological hazards for Fruits and Vegetables

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>S. aureus</i>	Parasites	Viruses	Comments
Fruits	1	Whole RAC	Ambient or Refrigerated						X	X	X		X <sup>1</sup>	X <sup>2</sup>	All whole RAC fruits
Processed Fruits	2a	Fresh-cut	Refrigerated						X	X	X		X <sup>1</sup>	X <sup>2</sup>	All fresh-cut fruit, including individual fruit and mixed fruit
Processed Fruits	2b	Whole or Cut	Frozen						X	X	X		X <sup>1</sup>	X <sup>2</sup>	All frozen fruit
Processed Fruits	2c	Heat Treated Fruit Products	Ambient <sup>3,4</sup> or Refrigerated						X	X	X				Includes individual and mixed fruit (e.g., fruit and mixed fruit in juice or syrup)
Processed Fruits	2d	Dehydrated Fruit Products	Ambient						X	X	X				All dried/dehydrated fruits
Processed Fruits	2e	Jams, Jellies, Chutneys <sup>4</sup>	Ambient												All varieties

# 美國FDA訪廠查核重點-未列出合理可能發生的危害

Table 1J: Known or reasonably foreseeable (“potential”) food-related biological hazards for Grains, Pulses, Flours, and Starches

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>S. aureus</i>	Parasites	Viruses	Comments
Grains	1	Whole, grains	Ambient	X <sup>1</sup>	X <sup>1</sup>				X	X	X				All whole grains
Grains, Milled Products	2a	Flours (other than rice flour, corn flour, and root flour)	Ambient	X <sup>1</sup>	X <sup>1</sup>				X	X	X				All flours from grains (except as noted in the subcategory); includes gluten
Grains, Milled Products	2b	Rice and rice products	Ambient	X <sup>1</sup>		X <sup>1</sup>				X					Includes all varieties of rice and rice-based noodles
Grains, Milled Products	2c	Malt	Ambient							X					Includes all malted grain products
Grains, Milled Products	2d	Corn	Ambient	X <sup>1</sup>						X					Cornmeal, corn flour
Grain-based Cereal Products	3a	Cereal Product: Ready-to-Eat	Ambient							X					Includes cereal products with and without inclusions <sup>2</sup>
Grain-based Cereal Products	3b	Breakfast food, dried	Ambient	X <sup>1</sup>						X					Includes products such as oatmeal, farina, oat bran, cream of wheat, grits
Grain-based Pasta Products	4a	Unfilled Pasta	Refrigerated or Frozen	X <sup>1</sup>	X <sup>1</sup>				X	X	X				All varieties

# 美國FDA訪廠查核重點-未列出合理可能發生的危害

**Table 2H: Known or reasonably foreseeable (“potential”) food-related chemical hazards for Fruits and Vegetables<sup>1</sup>**

Category	# <sup>1</sup>	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Fruits and vegetables	All	Whole RAC or processed	Ambient or Refrigerated						X	All fruits and vegetables
Fruits and vegetables	All	Whole RAC or processed	Ambient or Refrigerated			X				Includes spinach, lettuce, potatoes, beets
Fruits and vegetables	All	Whole RAC or processed	Ambient or Refrigerated				X			Includes sweet potatoes, carrots, spinach, dried plums (prunes), potatoes, mushrooms, garlic
Fruits and vegetables	All	Whole RAC or processed	Ambient or Refrigerated					X <sup>2</sup>		Includes apple products, dried fruits, dried beans and peas

<sup>1</sup> Known or reasonably foreseeable (“potential”) chemical hazards generally apply to a raw agricultural commodity regardless of whether and how it is processed. Therefore, each row in **Table 2H** applies to “fruits and vegetables,” regardless of whether they are whole RACs or processed as described in **Table 1H** regarding known or reasonably foreseeable (“potential”) biological hazards. The difference between each row is the chemical hazard that is listed as a known or reasonably foreseeable (“potential”) chemical hazard.

<sup>2</sup> For apples and apple products, the applicable mycotoxin is patulin. For dried fruits the applicable mycotoxins are aflatoxin (dried figs) (FDA Import Alert 23-14; see Table 5 in section VI of the Introduction of this guidance) or ochratoxin A (raisins, dried figs) (FDA Compliance Program 7307.001; see Table 5 in section VI of the Introduction of this guidance). For dried vegetable (beans and peas) the applicable mycotoxin is ochratoxin A (FDA Compliance Program 7307.001; see Table 5 in section VI of the Introduction of this guidance).

# 美國FDA訪廠查核重點-未列出合理可能發生的危害

**Table 2J: Known or reasonably foreseeable (“potential”) food-related chemical hazards for Grains, Pulses, Flours, and Starches**

Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Grains, Non-Rice	1	Whole and milled grains (e.g., flour and bran)	Ambient					X <sup>1</sup>	X	Wheat, Rye, Sorghum, Oats, Barley, Triticale, Buckwheat, Corn, Amaranth, Millet, Quinoa (RACs and milled grain products)
Rice, Milled Rice Products	2b	Rice (whole and milled) and rice products	Ambient		X	X		X <sup>2</sup>	X	White or Brown Rice, Rice protein, Sticky/sweet Rice, Basmati Rice, Jasmine Rice, Arborio rice, Rice-based noodles, Rice-based cereal
Other Milled Products	5a	Root flours	Ambient					X <sup>3</sup>		Potato flour, Cassava flour
Other Milled Products	5a	Root flours	Ambient						X	Sweet potato flour, yam flour
Pulses	6a	Whole (dried) or processed	Ambient					X <sup>4</sup>	X	Soybean, Kidney, Pinto, Navy, Azuki, Mung, Black Gram, Dried Peas; Chickpea; Cowpea/Black-eyed Pea; Lentil; Winged Bean

<sup>1</sup> The applicable mycotoxins are ochratoxin A (oats, wheat, barley), aflatoxin (dried corn), fumonisin (dried corn), and deoxynivalenol/ vomitoxin (wheat, barley) (See CPG Sec. 555.400 (in Table 3 in section VI of the Introduction of this guidance); Advisory Levels for Deoxynivalenol (DON) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed (in Table 4 in section VI of the Introduction of this guidance); FDA Compliance Program 7307.001 (in Table 5 in section VI of the Introduction of this guidance); and Import Alert 23-14 (in Table 5 in section VI of the Introduction of this guidance).)

<sup>2</sup> Aflatoxin is the applicable mycotoxin (only for raw brown rice).

<sup>3</sup> Cassava contains cyanogenic glycosides that produce cyanide. Depending on the level of cyanogenic glycosides, cassava is detoxified by heat processing alone, or by a combination of heat processing and food preparation techniques such as peeling, soaking, sun-drying, and scraping off the outer layer to leach out the cyanide (Canadian Food Inspection Agency, 2019).

# 美國FDA訪廠查核重點-未列出合理可能發生的危害

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receiving refrigerated ingredients – liquid pasteurized egg	B Vegetative pathogens such as <i>Salmonella</i>	X		While pasteurization minimizes the likelihood of <i>Salmonella</i> USDA recommends the product be used in cooked foods. <b>Experience has shown <i>Salmonella</i> occasionally occurs in this ingredient.</b>			
	C Allergen – egg	X		Egg is an allergen that must be labeled to inform consumers. <b>Cross- contact is not an issue – all products contain egg.</b>			
	P None						

# 美國FDA訪廠查核重點-未辨識危害的CCP

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Receiving refrigerated ingredients – liquid pasteurized egg	B Vegetative pathogens such as <i>Salmonella</i>	X		While pasteurization minimizes the likelihood of <i>Salmonella</i> USDA recommends the product be used in cooked foods. Experience has shown <i>Salmonella</i> occasionally occurs in this ingredient.	Process Control - subsequent cook step		X
	C Allergen – egg	X		Egg is an allergen that must be labeled to inform consumers. Cross-contact is not an issue – all products contain egg.	Allergen Control – allergen labeling at other steps		X
	P None						

# 美國FDA訪廠查核重點-未辨識危害的CCP

(1) Ingredient/ Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Receiving packaging	B	None						
	C	Undeclared allergens – egg, milk, soy (wheat in biscuit only)	X		Labeled cartons must declare allergens present in the product and print errors have occurred	Allergen Control –label review for allergen information	X APC	
	P	None						
Receiving shelf stable ingredients – salt	B	None						
	C	None						
	P	None						
Receiving shelf stable ingredients – pan release oil	B	None						

# 美國FDA訪廠查核重點-未辨識危害的CCP

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? <i>Process including CCPs, Allergen, Sanitation, Supply- chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Assemble, wrap	B Introduction of environmental pathogens such as <i>L. monocytogenes</i>	X		Recontamination may occur if sanitation controls are not in place	Sanitation Controls – prevent recontamination	X	
	Growth of vegetative pathogens such as <i>Salmonella</i> and <i>L. monocytogenes</i>		X	Time is too short for growth to be reasonably likely.			
	C Allergen cross- contact from other products handled at this step; e.g., Cheese Omelet Biscuit	X		Biscuits could introduce wheat allergen to other products without control	Sanitation and Allergen Controls – prevent allergen cross-contact	X	
	D None						

# 美國FDA訪廠查核重點-未足夠頻率監控衛生

## 組裝、包裝桌面衛生清潔

目的：去除潛在過敏原並減少微生物交叉污染或環境病原菌污染，避免影響產品安全性  
頻率：

清潔：中午休息，品項生產結束後、每日生產結束時

消毒：作業開始前、中午休息，品項生產結束後、每日生產結束時

執行者：生產人員

程序：

例如使用特定清潔工具清潔製程結束後的區域，以降低潛在過敏原交叉接觸可能性

清潔：

1. 將未使用的包裝材料移至工作結束時的區域，防止其弄濕
2. 使用刮刀移除顯著污垢
3. 用浸泡清潔溶液的乾淨布擦拭桌面
4. 用清水沖洗桌面

消毒：

1. 用200 ppm濃度的四級銨鹽溶液噴灑桌面，確保整個表面覆蓋
2. 表面自然風乾，約5分鐘。

監控：

檢查桌面是否有殘留的污垢和潔淨度

糾正措施：

1. 如果發現桌面有殘留的污垢，重新清潔並消毒
2. 如果濃度不正確，製作新的溶液

確認：

主管在7個工作日內檢查並簽署每日衛生清潔表

# 美國FDA訪廠查核重點-未足夠頻率監控衛生

## Daily Sanitation Control Record – Omelet Line

DATE:						
Sanitation Area and Goal	Pre-Op Time:	Start Time:	Lunch Break Time:	Post-Op Time:	Comments and Corrections	Operator Initials
Condition & Cleanliness of Food Contact Surfaces						
• Equipment cleaned and sanitized (S/U)*						
• Sanitizer type and strength: <u>Quaternary ammonium compound, 200 ppm</u>						
Omelet line (ppm)+						
Dish room dip tank (ppm)+						
Prevention of Cross-Contact						
• Cleaning after Cheese Omelet Biscuit (S/U/NA)&						
Condition & Cleanliness of Non-food Contact Surfaces						
• Floors and wall splash zones cleaned and sanitized (S/U)						
• Sanitizer type and strength: <u>Quaternary ammonium compound, 400-600 ppm</u>						
Floors and wall splash zones (ppm)+						
* S = Satisfactory, U = Unsatisfactory + Enter ppm measured per test strip & NA = not applicable because Cheese Omelet Biscuit run after other products						
Verification signature:		Date:				

## 清洗衛生確認

- 證明清洗消毒程序有正確被執行
- 使用的方法可能會根據食品、設施及食品安全系統而異
- 使用方式範例：
  - 測量化學清洗消毒劑濃度
  - ATP檢測、快篩試片、微生物塗抹檢測
  - 對環境進行病原菌監測
  - 紀錄審查

# 美國FDA訪廠查核重點-未提交製程SID資料

## 美國食品現代化法案( FSMA ) 對於低酸罐頭食品法規變更的重點

### □ 美國FDA對罐頭食品登錄SID的變更

- 每個容器尺寸將有其個別的SID，更便於追蹤產品狀況
- 替換的SID現在標記為“取消SID”，系統保留3年後歸檔
- 容器尺寸四捨五入，少於1/16英寸的尺寸會進行四捨五入，僅影響尺寸紀錄，不影響其他提交內容

### □ 影響之前以紙本提交資料的業者

- 若收到新SID，未來與FDA的溝通使用新的SID編號
- 如果提交多容器尺寸的產品，將收到不同SID的通知
- 業者無需提交新資料，只需注意SID變更後的溝通

# 美國FDA訪廠查核重點-cGMP與LACF

## 21 CFR part 117-人類食品的現行良好製造規範和基於風險的預防控制

- LACF製造商需遵守的培訓要求，包括確保參與製造、加工、包裝或儲存食品的人員及監督活動的主管是合接受食品衛生和食品安全的基礎培訓的合格人員，必須建立並維持培訓紀錄
- LACF製造商如果確認食品過敏原為危害，必須建立預防控制措施
- LACF製造商 對於生物性危害的清洗衛生控制措施不是必需的。但如果存在過敏原危害，則可能需要清洗衛生控制措施來防止交叉接觸
- FSMA的IA法規適用於所有食品製造廠，包括LACF必須制定和實施針對蓄意污染的緩解策略，以減少風險



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謝謝聆聽  
敬請指教