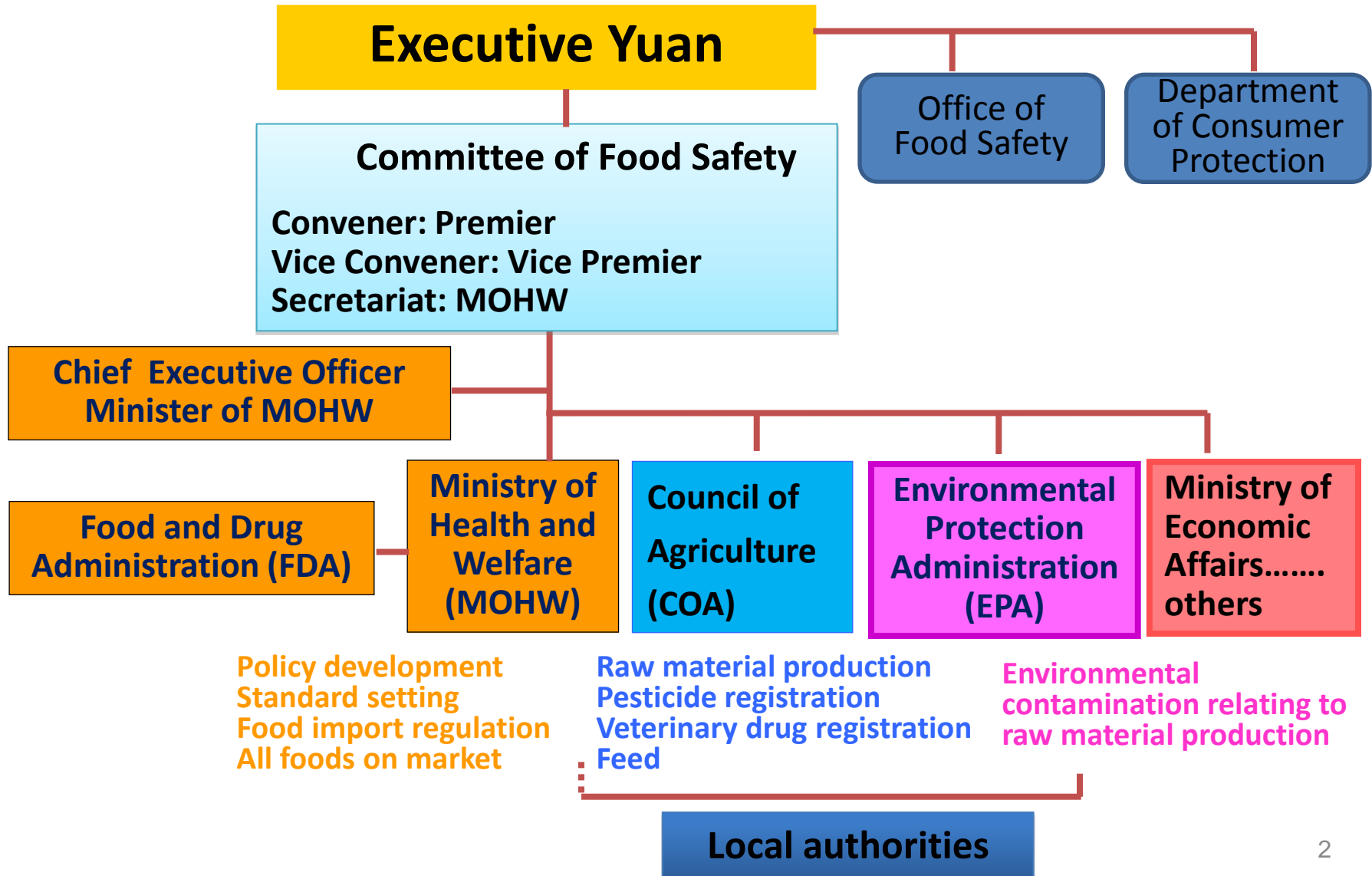


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# Imported Food Safety and Sanitation Management in Taiwan

Wu Tsung-Hsi  
TFDA

# Taiwan Food Safety Management Infrastructure



# Taiwan Food and Drug Administration

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- ❖ **TFDA was inaugurated on Jan. 1, 2010**
- ❖ **TFDA supersedes the following 4 bureaus of Department of Health :**
  - **Bureau of Food Safety**
  - **Bureau of Pharmaceutical Affairs**
  - **Bureau of Food and Drug Analysis**
  - **Bureau of Controlled Drugs**

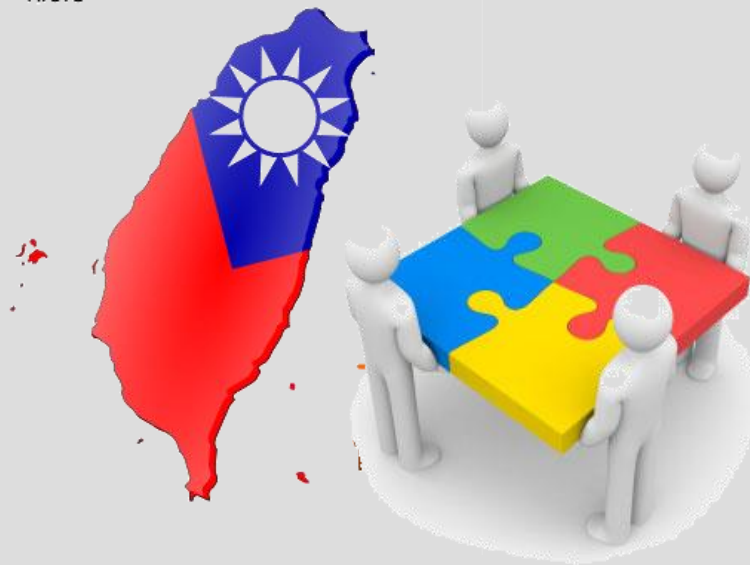


# Food and Drug Administration



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# Overview of Food Import Management in Taiwan



# Overview of the Food Import Management in Taiwan– Responsibilities of Competent Authorities

**(CA)**

**Customs Administration,  
Ministry of Finance**

clearance of  
goods

tariff duties

smuggling  
inspection

**(BOFT)**

**Bureau of  
Foreign Trade,  
Ministry of  
Economic  
Affairs**

foreign trade  
affairs

promulgate  
import  
requirements

**(BAPHIQ)**

**Bureau of  
Animal and  
Plant Health  
Inspection and  
Quarantine,  
Council of  
Agriculture**

animal and  
plant health  
inspection  
and  
quarantine

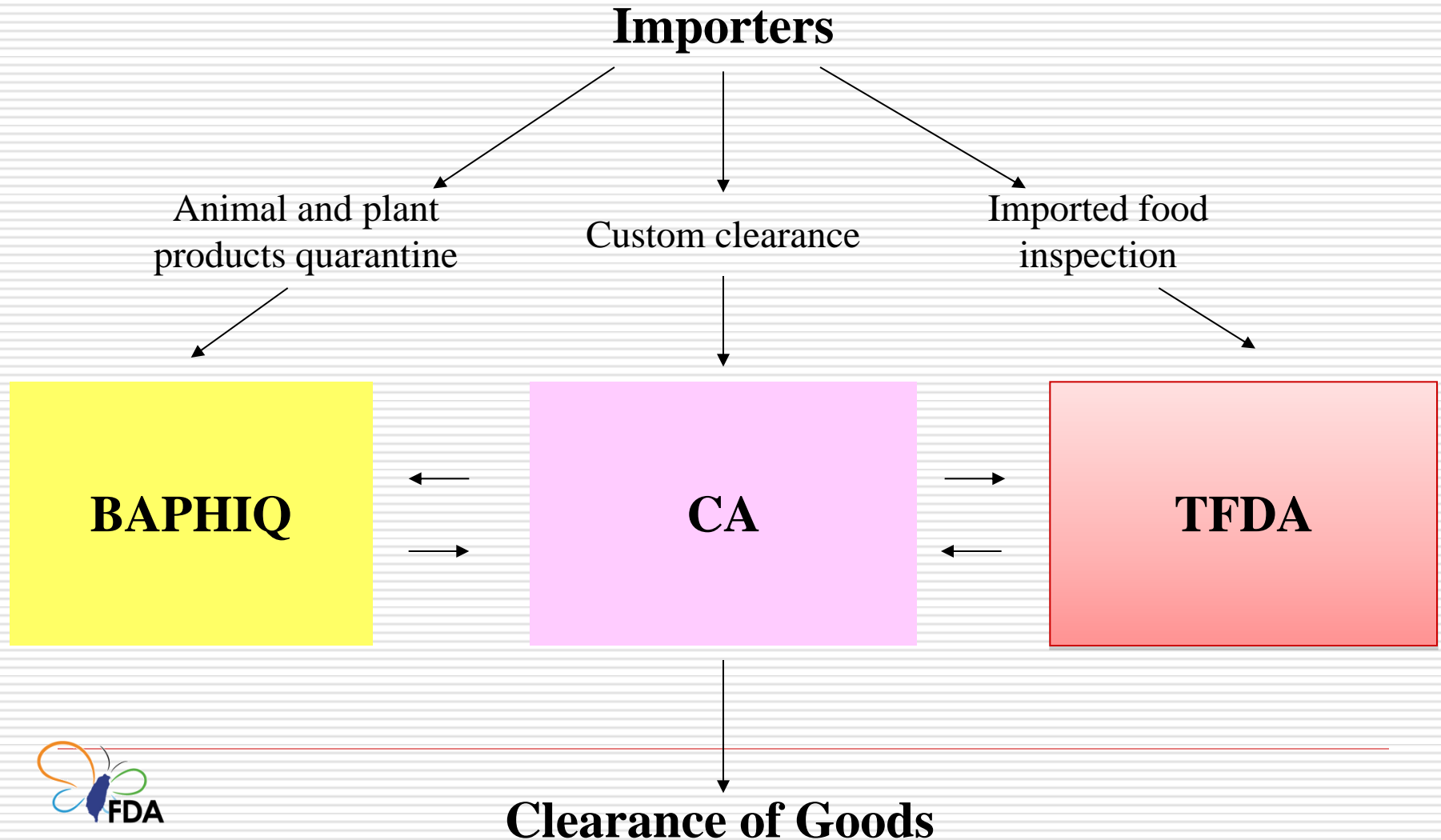
**(TFDA)**

**Food and Drug  
Administration,  
Department of  
Health**

food safety  
and  
sanitation  
inspection

# Procedure of customs clearance for imported food

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# Act Governing Food Safety and Sanitation

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- **Revised and promulgated on February 4, 2015 by Presidential Decree**
- **60+7 articles in 10 chapters**

- Ch. I General Principles (§1~3)
- Ch. II Risk Management for Food Safety (§4~6)
- Ch. III Sanitary Control of Food Businesses (§7~14)
- Ch. IV Food Sanitation Control (§15~21)
- Ch. V Food Labeling and Advertisement (§22~29)
- Ch. VI Food Import Control (§30~36)
- Ch. VII Food Testing (§37~40)
- Ch. VIII Food Examination and Control (§41~43)
- Ch. IX Penal Provisions (§44~56)
- Ch. X Supplementary Provisions (§57~60)



# Food Import Control Chapter in the Act

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## § 30

Application for inspection with the central competent authority and declaration of the relevant information of the product are required and shall be in accordance with the customs **commodity code and classification** when importing foods, genetically modified food raw materials, food additives, food utensils, food containers or packaging and food cleansers **designated by the central competent authority in a public announcement**.

The central competent authority may impose preferential measures to the food businesses with excellent performances in the import inspections referred to in the preceding paragraph.

The importation of products under Paragraph 1 that are not intended for sale and whose value and quantity are consistent with the public announcement of the central competent authority, or are approved by the central competent authority, **may be exempt from applying for inspection**.

# Border Inspection of Imported Food

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## Legal basis:

- Article 30 of the Act Governing Food Safety and Sanitation
- Regulations of Inspection of Imported Foods and Related Products

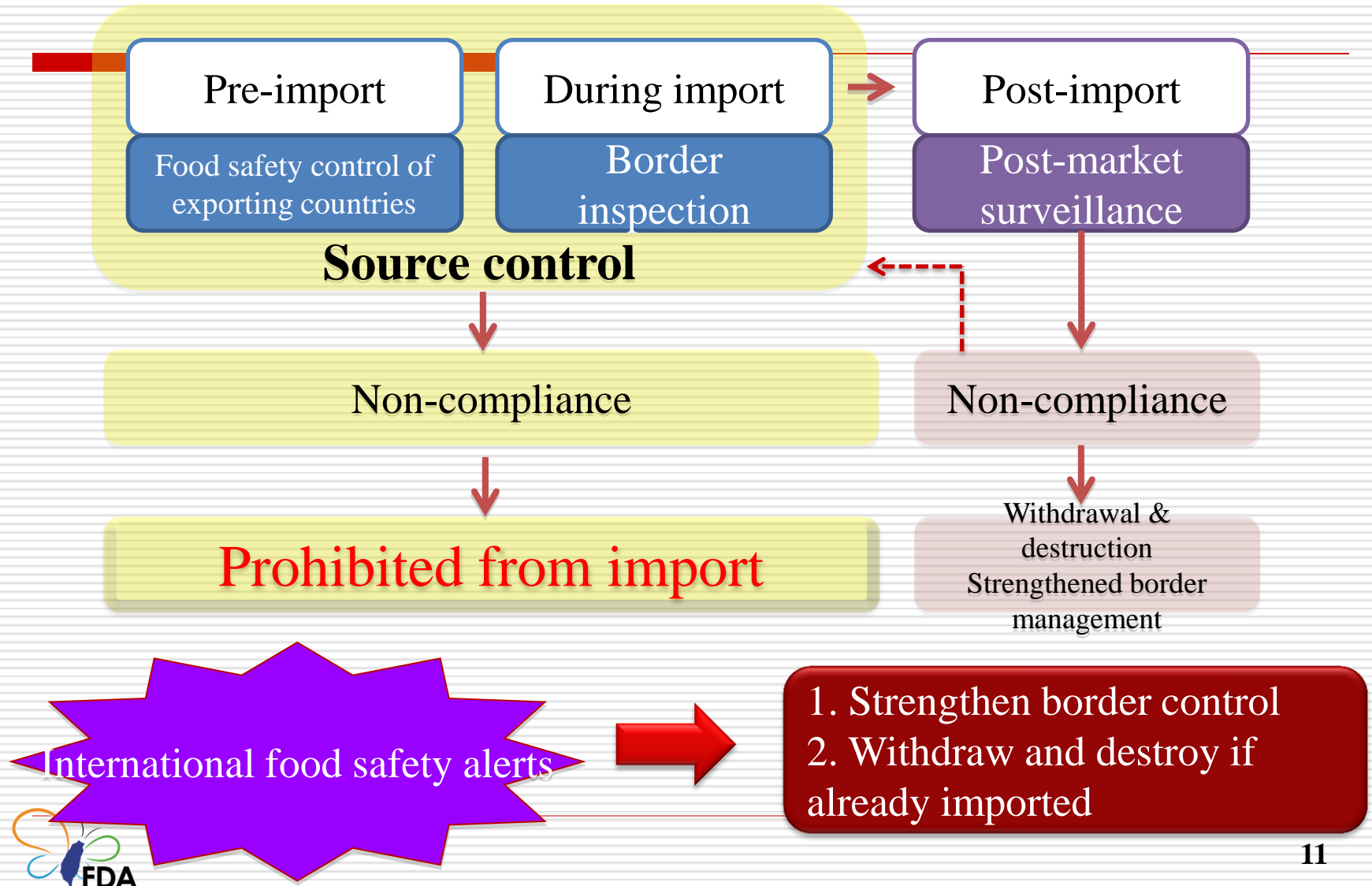
## Inspection scope:

The total number of codes of products subject to import inspection made public in announcements is **2363**.

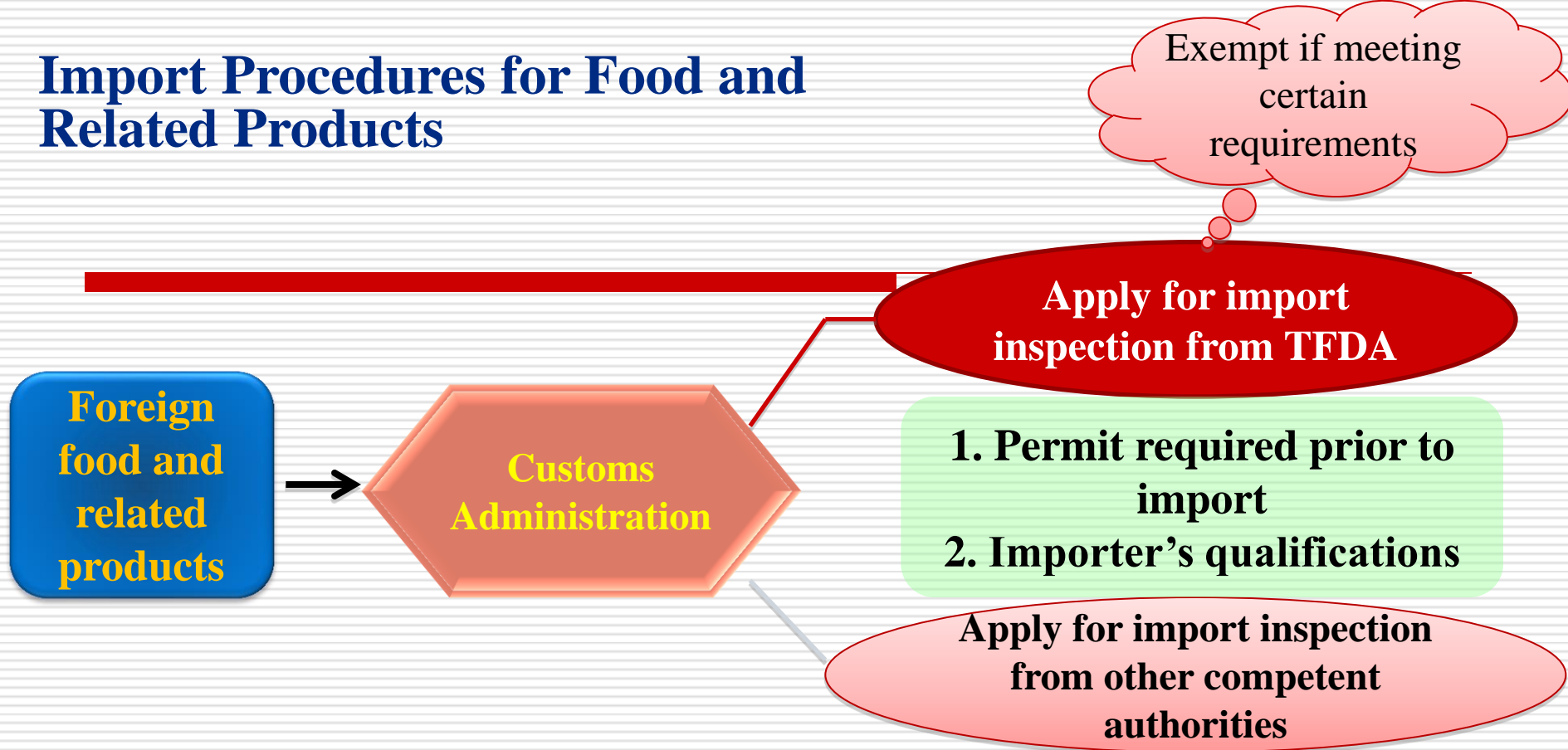
- Food
- Food additives
- Porcelain utensils
- Plastic baby bottles
- Disposable chopsticks
- Plastic microwavable lunch boxes, containers and cups for repetitive use
- Plastic sports water bottles for repetitive use

# Imported Food Control in Taiwan

## Triple Control: The Managements at Source/Border/Market



# Import Procedures for Food and Related Products



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- The **import regulations** designated by the product's **C.C.C. Code** (Commodity classification code of Republic China) determines from which competent authority the importer applies inspection.

# Import Regulation Examples

## TFDA of MOHW

**F01** : Apply for import inspection at TFDA according to “Regulations of Inspection of Imported Foods and Related Products”

**F02** : Apply for import inspection at TFDA according to “Regulations of Inspection of Imported Foods and Related Products” **if related to food or containing food**

## BAPHIQ

**B01** : Apply for import quarantine at BAPHIQ of COA

## BOFT of MOEA

**113** : Apply for import permit at BOFT when importing from the US

**MW0** : Importation of Mainland China products is prohibited.

**MP1** : (1) Importation of Mainland China products in this category is conditionally permitted. The importation should conform to the regulations of "Consolidated List of Conditional Import Items of Mainland China Origin and Regulations Governing Import of Mainland China Origin Commodities".(2) Importation of items on the "Consolidated List of Conditional Import Items of Mainland China Origin and Regulations Governing Import of Mainland China Origin Commodities" with "MXX" code requires Import Permit issued by the BOFT; Importation of items without "MXX" code shall be subject to the general code of import permit issuance.

**827** : 1. Importers of food and related products shall refer to F01. 2.Importers of medicines for human use shall refer to 503. 3. Importers of industrial oils shall refer to 251. 4. Importers of oils for biodiesel shall refer to 255. 5. Importers of feed and feed additives shall refer to 404. 6. Importers of oils which don't fall into the previous categories shall apply at BOFT. 7. Import permits are required prior to import.

◆ The CCC Code is designed for tax purposes

◆ **Not for food classifications**

CCC Code	Product name	Import regulations
0203.22.00.00-9	Hams, shoulders and cuts thereof, of swine, with bone in, frozen	<a href="#">B01</a> <a href="#">F01</a> <a href="#">MW0</a>
0206.21.00.00-7	Tongues of bovine animals, frozen	<a href="#">113</a> <a href="#">B01</a> <a href="#">F01</a> <a href="#">MW0</a>
0813.40.31.00-2	Chinese jujubes (red), dried. (incl. for Chinese drugs)	<a href="#">513</a> <a href="#">F02</a> <a href="#">H02</a>
1501.10.00.00-0	Pig lard, other than that of heading 02.09 or 15.03	<a href="#">827</a> <a href="#">A02</a>
2106.90.99.20-8	Food preparations, in capsule or tablet form	<a href="#">511</a> <a href="#">F01</a>
2834.10.10.00-4	Sodium nitrite	<a href="#">508</a>

# Important Articles of Regulations of Inspection of Imported Foods and Related Products

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- **§4-Documents for inspection**
  - An application form for inspection
  - A declaration form of product information
  - A photocopy of application for import declaration
  - Necessary certificated required by TFDA
- **§5-Pre-declaration of product information**
- **§24-Return or destroy**
  - Non-cleared products: applicant reports to the customs
  - Cleared products: applicant reports to local Health Department
- **§8-Inspection measures**
  - Batch-by-batch inspection
  - Reinforced randomly-selected batch inspection: 20~50%
  - Regular randomly-selected batch inspection: 2~10%
  - Batch-by-batch verification
  - Certification registration
  - Oversee inspection

# Pre-import Source Control

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- Official sanitary certificates of the export country
- List of FBOs qualified for export to Taiwan
- Pre-import systematic inspection
- Regular on-site inspection
- Bilateral agreements
- International alert monitoring

# Pre-import Systematic Inspection

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- §35 of Act Governing Food Safety and Sanitation (added in June 2013)
  - ✓ Paragraph 1: For the management and control of foods with a higher degree of safety risk, the central competent authority may perform systematic inspections before the importation thereof.
  - ✓ Paragraph 2: The regulations for the systematic inspections shall be prescribed by the central competent authority.
- **Systematic Inspection Mechanism**
  - ✓ Examine the equivalence of the food safety management system of the exporting country (territory) and that of Taiwan including (compulsory) document review and on-site inspection (if needed)
    - Management structure, regulations, monitoring programs and capabilities, and implementation of the exporting country
    - FBOs' self-management



# TFDA Review Processes for Import of Meat and Meat Products (Excluding Beef)

## Step 1 Application

- The applicant country which intends to export meat and related products to Taiwan shall apply at BAPHIQ.

## Step 2 Food Safety Questionnaire

- The applicant country shall fill out the food safety questionnaire for review by TFDA.
- TFDA requests the country to submit supplementary data if necessary.

## Step 3 On-site Inspection

- TFDA and BAPHIQ go to the country for on-site inspection.

## Step 4 Inter-agency Communication

- TFDA and BAPHIQ present inspection results.
- TFDA and BAPHIQ ask the country to provide supplementary data if necessary.

## Step 5 Confirmation and Open

- The following items are decided during interdisciplinary communication:
  - (1) Open scope
  - (2) Open timing
  - (3) Import conditions

Meat and meat products shall not come from endemic areas. Applicants shall contact BAPHIQ for application and review.

Note: TFDA reviews safety and risks associated with bovine derivative food products from BSE infected countries. Applicants from BSE infected countries shall provide relevant documents and apply at TFDA according to the procedures on TFDA website at <http://www.fda.gov.tw/TC/siteList.aspx?sid=223>

# Regular On-site Inspection

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- ❑ Paragraph 3 of §35: According to the needs for source control or due to a specific food sanitation and safety incident, the central competent authority may send personnel abroad to conduct on-site inspection of the sanitation and safety management of the imported foods.
- ❑ Based on bilateral agreements

# Post-import Market Surveillance

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- ❑ §41 of the Act
  - The municipal or county/city competent authority may take the following actions to ensure that foods, food additives, food utensils, food containers or packaging and food cleansers are in compliance with the provisions of this Act:
    - On-site examination and sampling and testing
    - FBOs are required to provide information, evidence and records and such may be reviewed, detained and copied.
    - FBOs may be ordered to suspend operations, cease sales and seal such products.
  - ✓ Where necessary, the central competent authority may also execute the measures described in the preceding paragraph.
- ❑ By annual monitoring or auditing plans, projects and whistleblowing

# Management of Food Importers

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- ❑ Registration of food importers
  - 8,887 importers completed registration as of June 30, 2015
  - Importers of food additives have been required to register since May 1, 2014
  - Importers of edible oils have been required to register since October 31, 2014
- ❑ Food Traceability Management Information System
- ❑ §7 of the Act: Self-management, food safety monitoring plan and self-testing
- ❑ Info sessions and seminars for food importers

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# Monitoring and Warning Mechanism

# Regular Announcements of Non-compliance

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- Weekly announcements of non-compliance according to §52 of the Act
- TFDA inspects imported food at border and publishes non-compliance at TFDA website. A total of 644 non-compliances were published in 2014.

# Monitoring International Food Alerts

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- ❑ Verify whether the food has been imported:
  - If no: TFDA reminds outbound travelers and importers
  - If yes: TFDA requests local health departments for withdrawal
  - If not sure: TFDA requests the importer to verify with the manufacturer; asks the embassy or official counterpart of the export country for verification; and requests local health departments for withdrawal if necessary
- ❑ Not yet imported but may be
  - TFDA calls domestic FBOs to attention
  - Through the embassy or official counterpart, TFDA requests the competent authority of the export country to verify and strengthen product control for export to Taiwan

# Other Border Control Measures for Imported Food

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## Managed separately according to the use purpose of the import:

- Imported products for human consumption shall be noted “for human consumption” in the field of Product Name on the Import Declaration Form. The batch number or information related to traceability shall be provided.
- Products with multiple usages shall be inspected by competent authorities according to import regulations designated by CCC code such as 8XX or 5XX.



# Change of Purpose of Import:

## From Industrial Use to Human Consumption

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In violation of Paragraph 13 of §47 of the Act:

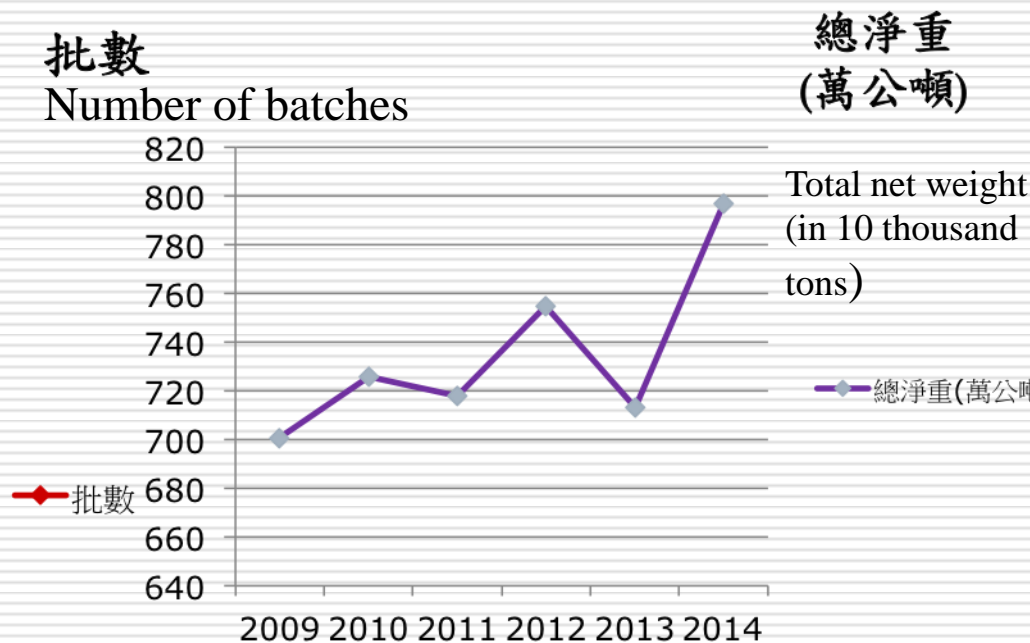
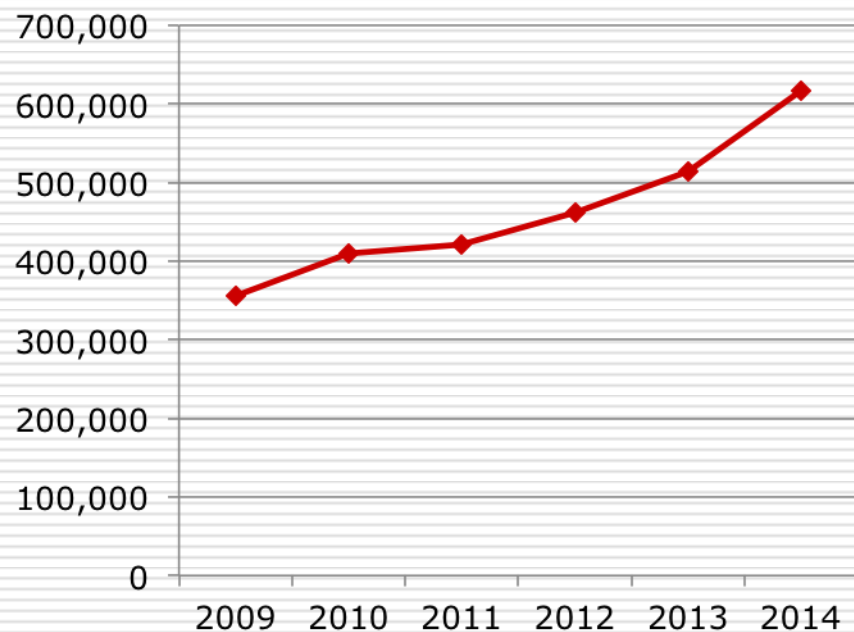
➤ If failing to declare the information of imported goods or the information declared is false:

- ✓ §47: In severe circumstances, the enterprise may be ordered to terminate business, suspend business for a certain period of time, revoke all or part of the items listed in the company registration, business registration or factory registration, or registration of the food businesses. If registration of the food businesses is revoked, re-application for new registration shall not be permitted within one year.
- ✓ §51: The application for inspection in accordance with Paragraph 1 of §30 from the food businesses or their representatives may be suspended.

➤ Product disposition:

- ✓ §52: The competent authority shall impose the punishment based on examination or testing results in accordance with §41
- ✓ §51: For the products which are already released, the food businesses may recall, destroy or return such products depending on the violation thereof.

# Quantity of Imported Food



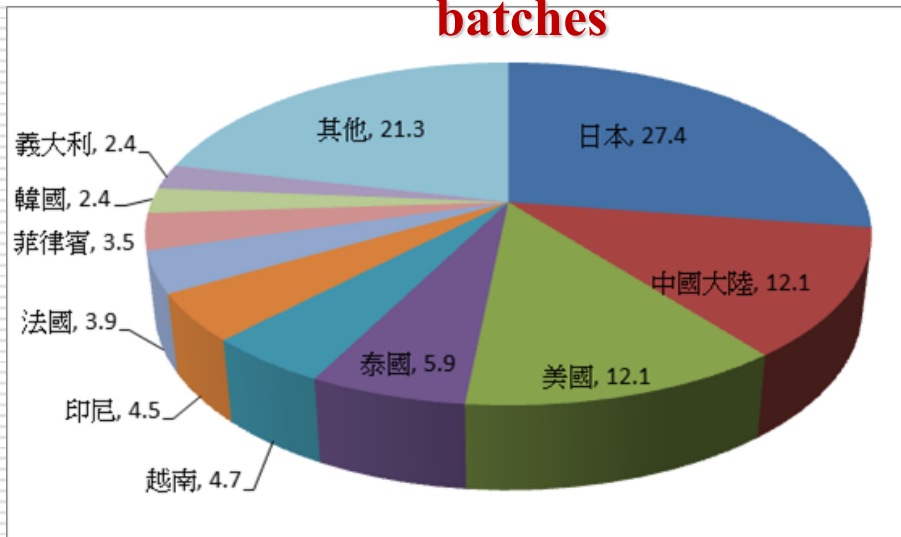
Year	2009	2010	2011	2012	2013	2014
Number of batches	355,455	409,408	420,601	461,665	514,710	616,286
Total net weight (in 10 thousand tons)	700.7	725.6	717.7	754.5	713.3	796.6

# Overview of Imported Food

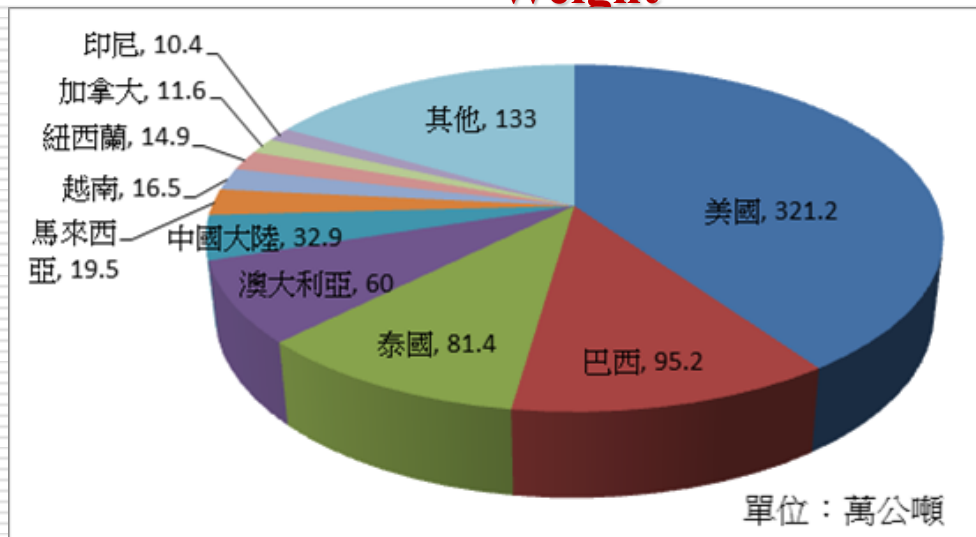
## □ Main Countries of Origin:

- By batch: Japan, US, China, Thailand and Vietnam
- By weight: US, Brazil, Thailand, Australia and China

**Number of  
batches**



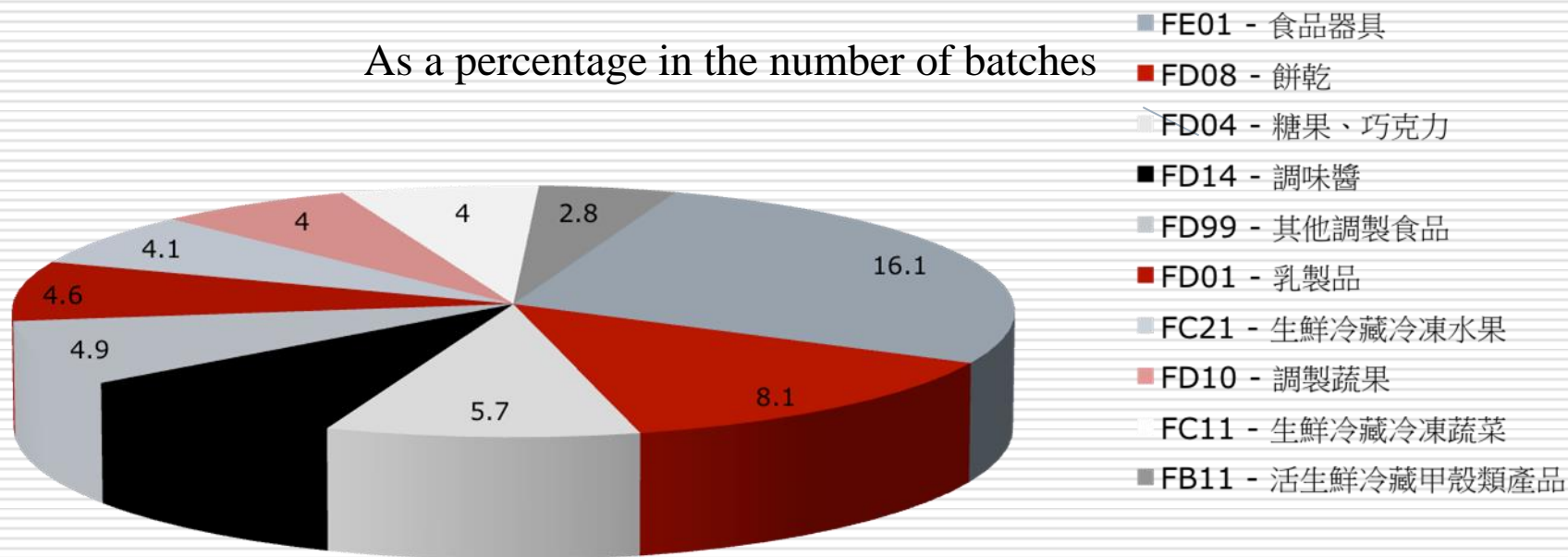
**Weight**



# Top 10 Classifications of Imported Batches in 2014

## 佔總輸入批數%

As a percentage in the number of batches



FE01: Food utensils

FD08: Biscuits

FD04: Confectionary and chocolate

FD14: Sauces

FD99: Other food preparations

FD01: Dairy products

FC21: Fresh, chilled, frozen fruits

FD10: Prepared vegetables and fruits

FC11: Fresh, chilled, frozen vegetables

FB11: Live, fresh, chilled crustaceans

# Overview of Food Import into Taiwan in 2014

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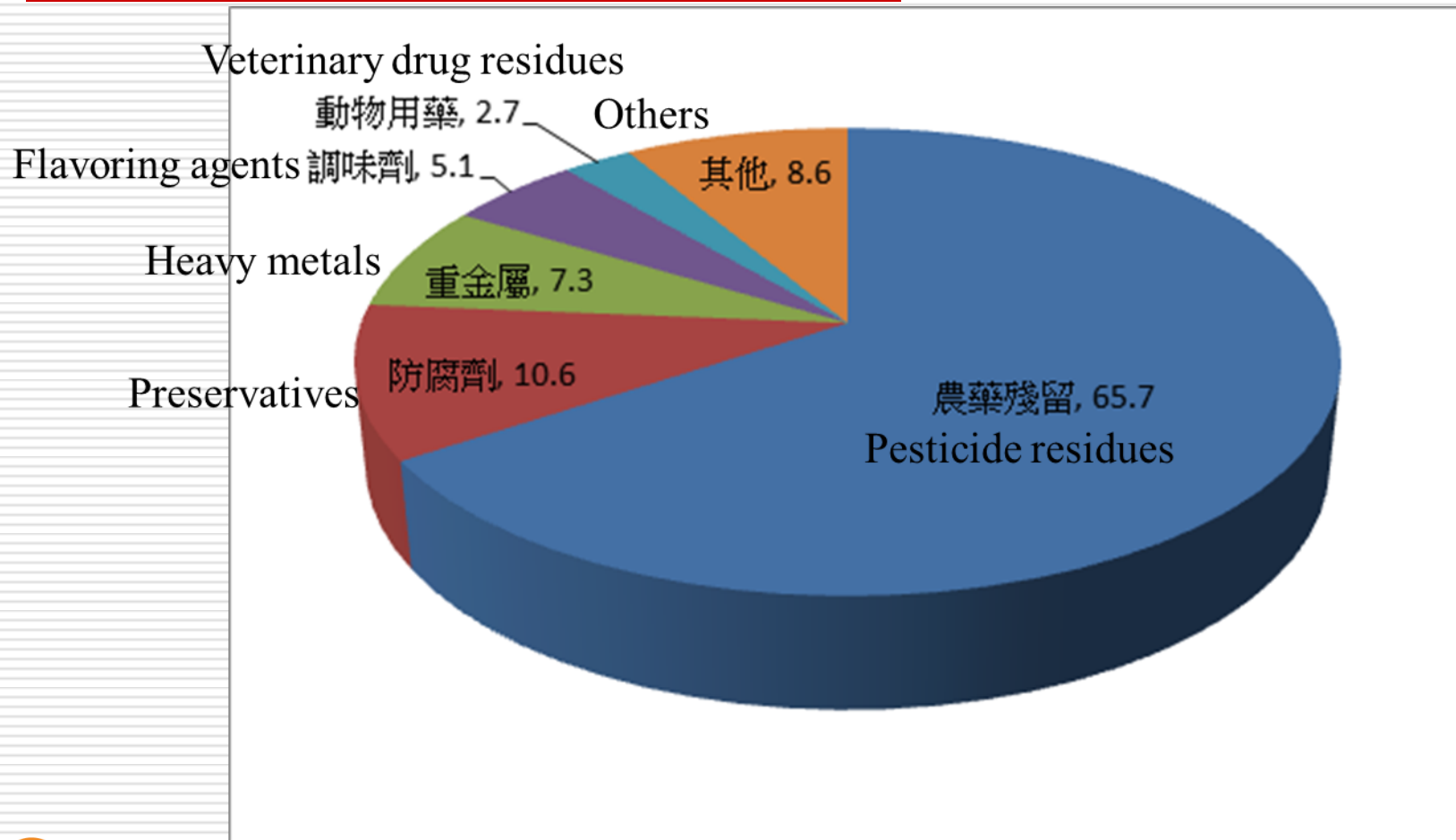
	2014
Application	616,286
Laboratory Analysis	48,704
Non-compliance(Content & Residual Standard)	664

Test ratio: 7.9% (tested batches/total inspected batches)

Non-compliance ratio: 1.4% (non-compliant batches/total inspected batches)



# Category of Standard Violation in 2014



# 2011~2013 Annual Imported Food Reports





# Thank you for your attention!

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For more information

Web site is at: <http://www.fda.gov.tw>

