



EU-Taiwan Food Safety Seminar 20-21 June - Taipei

DG SANCO Food safety in the European Union An introduction

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EU Legislative framework for food safety management system

Legislative frame

- 1. The Food Law: roots and principals*
- 2. EU legislation framework: focus on hygiene*

Tools

- 3. EFSA*
- 4. Official laboratories*
- 5. Traces*
- 6. RASFF*

Imports

- 7. Import conditions for animal products*



1. The Food Law: roots and principals

■ Since 2000 the food safety policy has been reviewed and reinforced on the basis of the legislative program laid down in the White Paper on Food Safety



Food safety in the EU

► Why such an important overhaul of policy and legislation?

- Following a number of “food scares” (hormones in beef, BSE, dioxin, GMOs...) EU consumers had lost confidence in:
 - the food supply
 - the food scientists
 - the food legislators
 - the food controllers
- EU food legislation was incomplete, out of date, exceedingly complex, and largely not understood
- There was a need to provide a predictable regulatory environment for researchers, producers, importers, retailers

Food safety in the EU

► Structural reforms:

- Reorganization of Commission services (DG SANCO)
- Creation of FVO (Food and Veterinary Office)
- Creation of EFSA (European Food Safety Authority)
- Reform of regulatory committee
- Creation of advisory group of the food chain

► Procedural reforms:

- **RASFF (Rapid Alert System for Food and Feed)**
- Crisis management structure
- Emergency procedures
- **CRLs (Community Reference Laboratories)**
- **TRACES**

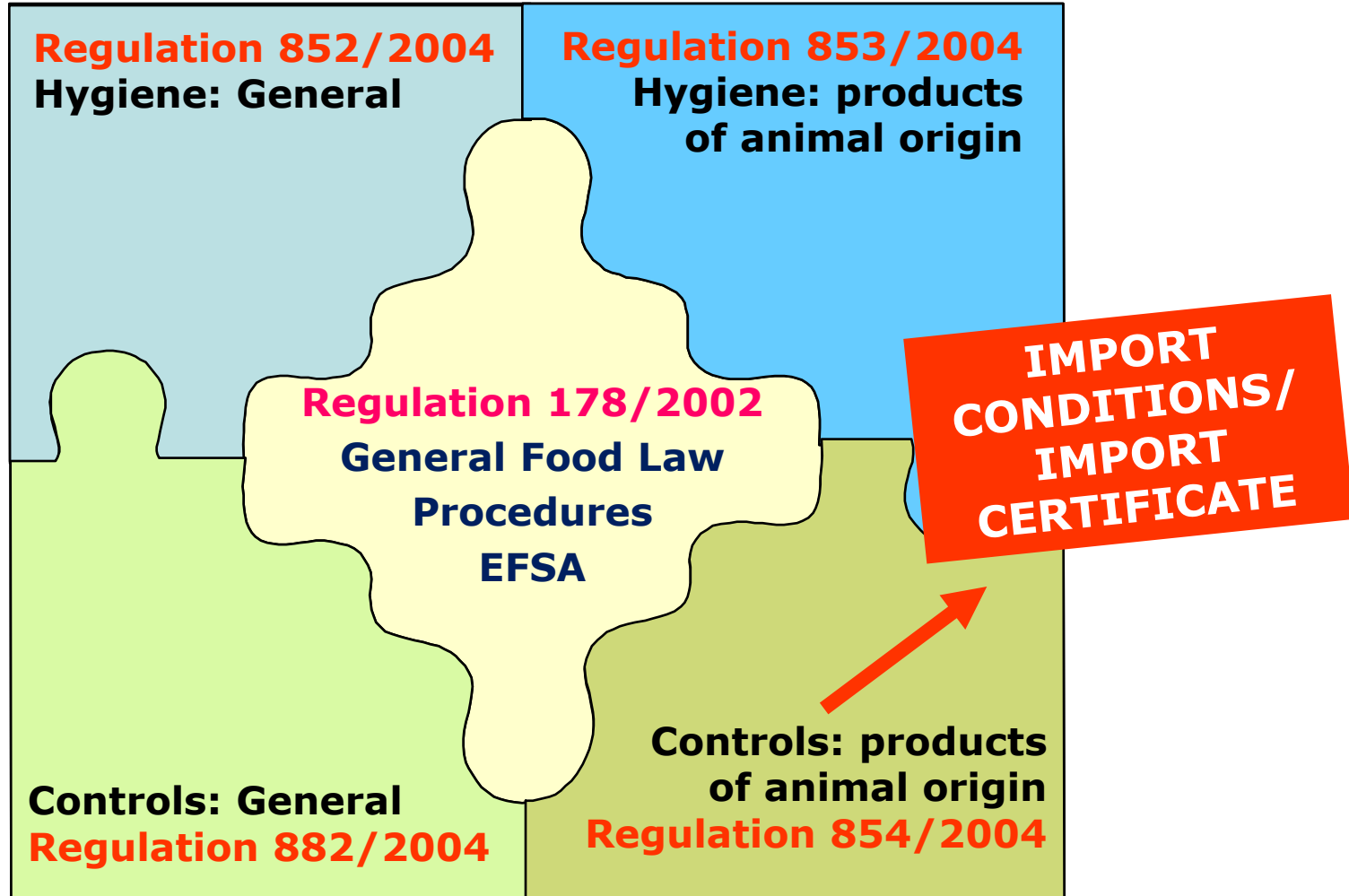
► Legislative reforms:

- New regulatory framework
- New legislation enacted (Regulations)
- Recasting (simplification) of existing legislation (Regulations)

Food safety in the EU

- ▶ **The new regulatory framework has been enacted in record times**
- ▶ **It is based on a coherent and comprehensive approach:**
 - “Farm-to-table” – traceability
 - Risk assessment based on best available science (EFSA)
 - Risk management – precautionary principle
 - Consultation of stakeholders – access to information
 - Clearly assigned responsibilities (producers – officials)
 - Equal treatment of domestic producers / importers
 - New emphasis on enforcement
 - New emphasis on communication (guidance documents)
 - New emphasis on training (“Better Training for Safer Food”)

Food safety in the EU



Food safety in the EU

Objectives (Article 5 – Regulation (EC) No 178/2002)

- ▶ **Food law shall pursue one or more of the general objectives of:**
 - a high level of protection of human life and health and
 - the protection of consumers' interests,
 - including fair practices in food trade;
- ▶ **taking account of, where appropriate:**
 - the protection of animal health and welfare,
 - plant health, and
 - the environment.
- ▶ **Food law shall aim to achieve the free movement of food and feed in the Union.**

Food safety in the EU

Scope (Article 1 – Regulation (EC) No 178/2002)

► **Applies to:**

- food, and
- feed.

► **at all stages of:**

- production,
- processing, and
- distribution.

► **Does not apply to:**

- to primary production for private domestic use, or
- to the domestic preparation, handling or storage of food for private domestic consumption.

Food safety in the EU

Principle of risk analysis (Article 6 – R. 178/2002)

- ▶ In order to achieve the general objective of a high level of protection of human health and life:
 - food law shall be **based on risk analysis**
 - **except** where this is not appropriate to the circumstances or the nature of the measure.
- ▶ **Risk assessment** shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.
- ▶ **Risk management** shall:
 - take into account the results of **risk assessment**, and in particular, the opinions of the **Authority** referred to in Article 22,
 - **other factors legitimate** to the matter under consideration, and
 - the **precautionary principle** where the conditions laid down in Article 7(1) are relevant.

Food safety in the EU

Other legitimate factor (Recital 19 – R. 178/2002)

► It is recognised that:

- **scientific risk assessment alone** cannot, in some cases, provide all the information on which a risk management decision should be based, and
- that **other factors relevant** to the matter under consideration should legitimately be taken into account
- including **societal, economic, traditional, ethical and environmental** factors and the feasibility of controls.

Food safety in the EU

Precautionary principle (Article 7 – R. 178/2002)

Paragraph 1 (principle)

- ▶ In **specific** circumstances where,
- ▶ following an **assessment** of **available** information,
- ▶ the **possibility of harmful effects** on health is identified
- ▶ but **scientific uncertainty persists**,
- ▶ **provisional** risk management measures
- ▶ **necessary** to ensure the high level of health protection chosen in the Community
- ▶ **may be** adopted,
- ▶ pending **further scientific information** for a more comprehensive risk assessment.

Paragraph 2 (limitations)

Measures under paragraph 1 should be:

- ▶ **proportionate**, and
- ▶ **no more restrictive of trade** than is required,
- ▶ regard being had to **technical and economic feasibility** and other factors
- ▶ **reviewed** within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

Food safety in the EU

Principles of transparency (Article 9 & 10 – R. 178/2002)

► **Public consultation:**

There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it.

► **Public information:**

Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.



2. EU legislation – framework

Focus on
hygiene



Regulation (EC) No 178/2002

General Food law

Competent authorities

Food business operators

Regulation (EC)
No 882/2004

General rules
for official controls

Regulation (EC)
No 854/2004

Specific rules for official controls
on products of animal origin

Regulation (EC)
No 852/2004

General rules
on hygiene

Regulation (EC)
No 853/2004

Specific hygiene rules
for products of animal origin

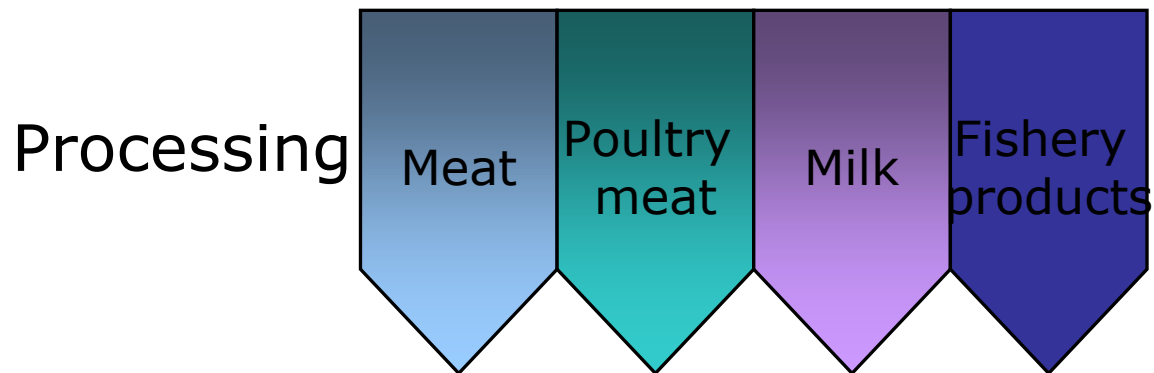
Regulation (EC)
No 2075/2005
Trichinella

Regulation (EC)
No 2074/2005
Other implementing rules

Regulation (EC)
No 2073/2005
Microbiological criteria

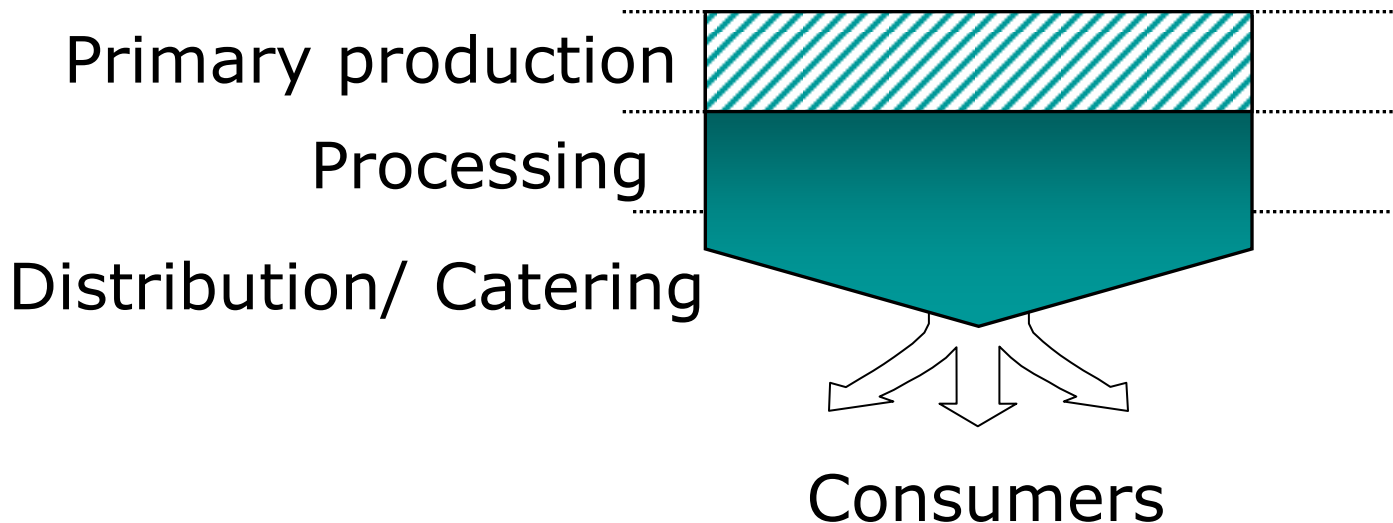
A revised hygiene legislation

= A more consistent approach
Previous rules on foods of animal origin



A revised hygiene legislation

A more consistent approach



Characteristics of R852/2004

All foods (plant and animal origin)

Stable to table (integrated approach)

All stages: primary production, processing,
distribution, exports, imports

Primary responsibility = food business operators

Requirements in R852/2004

Registration of all food businesses

Hygiene requirements

- ⇒ *Specific requirements for primary production*
- ⇒ *Minimum hygiene requirements for further stages*
- ⇒ *Microbiological criteria*
- ⇒ *Temperature control requirements*

HACCP (not compulsory for farms)

Guides to good practice

Requirements in R852/2004

Registration of all food businesses

Who? all food businesses should be registered
= from primary production to retail establishments

Why? to allow CA to know where FB are located
and what activities they carry out

How? simple procedure

Requirements in R852/2004

Primary production

Production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter

(includes fishing, harvesting wild products, associated operations)

all products (plant and animal origin)



Requirements in R852/2004

Primary production: which rules?

Protection against contamination,
Compliance with measures to control hazards
Cleanliness, use of water, use of medicinal
products, pesticides etc,
Record keeping
Guides to good practice
Note: no HACCP based procedures!

Requirements in R852/2004

Further stages:

Safe Food = Compliance with minimum
hygiene requirements

+

Implementation of procedures based on
HACCP

Requirements in R852/2004

Further stages: Minimum hygiene requirements

Covers premises, equipment, staff and environment without being specific for an establishment

Covers hazards in general without being specific for an establishment

= Foundation for HACCP implementation

Requirements in R852/2004

All food business operators since 1.1.2006:
Put in place, implement and maintain a
permanent procedure **based on the 7 HACCP
principles**

Provide the competent authority with evidence
of compliance

Ensure that documents describing procedures
are up-to-date all times

Retain documents for official controls.



Microbiological criteria

Main objectives of Reg. 2073/2005

To ensure a high level of human health protection

⇒ **Reduction of human cases of foodborne diseases**

To harmonise microbiological criteria in the EU

⇒ **Uniform rules for food business operators**



Microbiological criteria

Responsibility of FBOs

To demonstrate the compliance with MC

-Food safety criteria throughout the shelf-life

-Durability, challenge studies (Annex II)

To establish a sampling and testing scheme based on risk (HACCP)

To respond in case of non-compliance

To follow and assess trends



Microbiological criteria

Process hygiene criteria

Indicates the acceptable functioning of production process

Stage: during the process, not when placed on the market

Actions when unsatisfactory results: corrective actions defined in HACCP programme

Improvement of production hygiene

Better selection of raw materials

(e.g. E. coli for precut fruits and vegetables)

Microbiological criteria

Food safety criteria

Defines the acceptability of the product/batch

Stage: products placed on the market

Actions when unsatisfactory results:

- withdrawal or recall
- further processing (not yet at retail level)
- other corrective actions based on HACCP programme

(e.g. Salmonella for pre-cut fruits and vegetables)



Characteristics of R853/2004

One simplified text

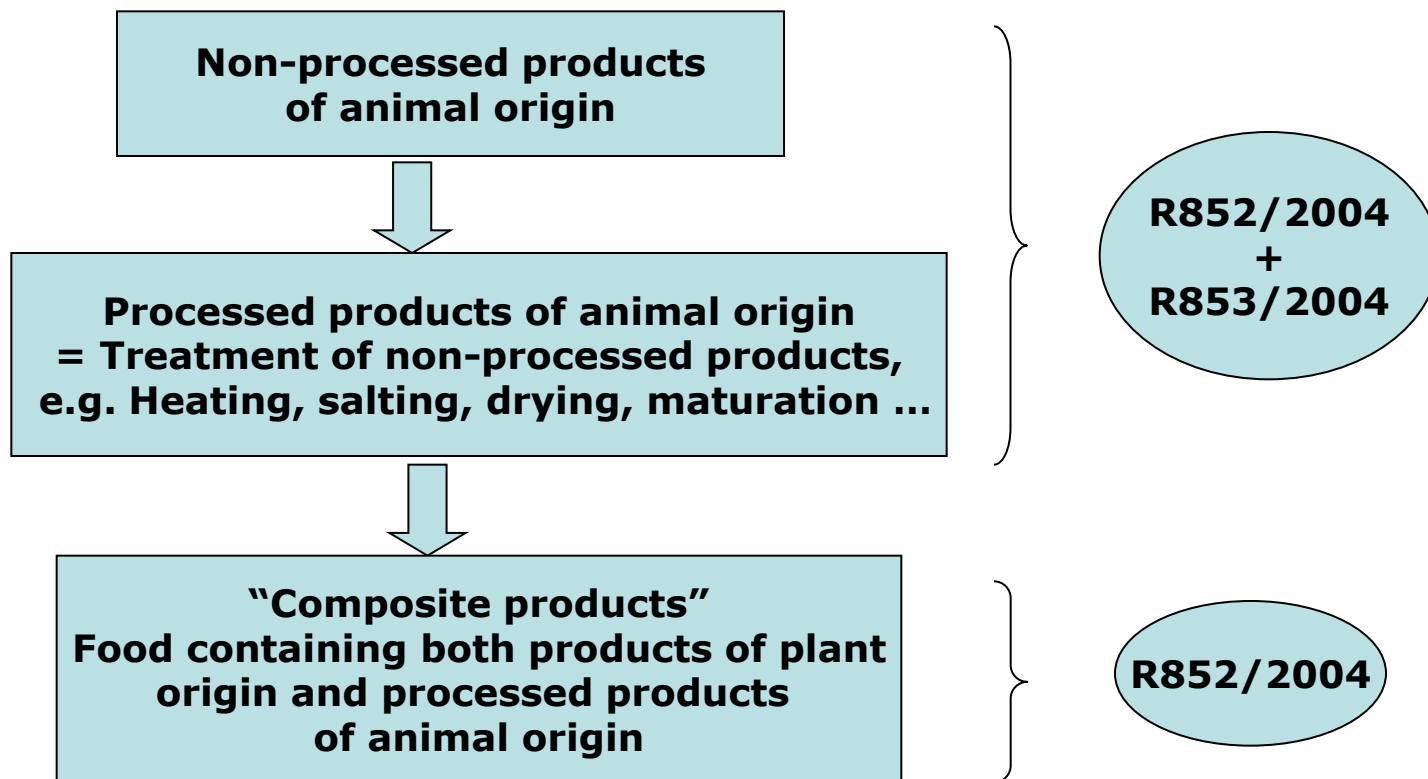
Unprocessed/processed food of animal origin

Does not apply to retail sale

Does not apply to composite products

Flexibility

Classification of products



Requirements in R853/2004

Approval of establishments

Identification/health mark

HACCP based

Level of details deemed necessary (15 Annexes)



Requirements in R853/2004

Approval



Who? All establishments handling products of animal origin for which requirements are laid down

Why? To be authorised to operate

How? After at least one on-site visit (but possibility for a conditional approval)



Requirements in R853/2004



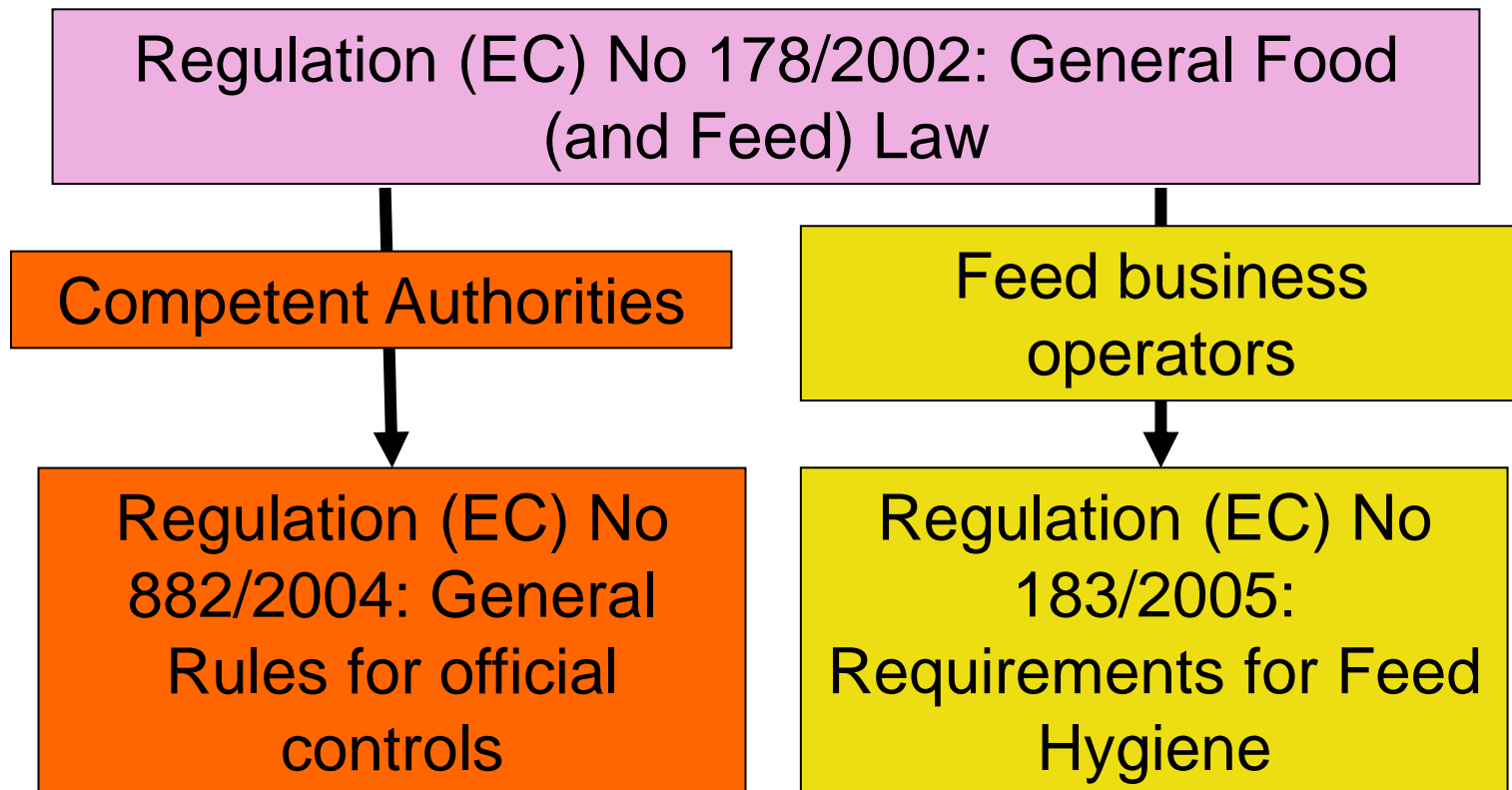
Identification marking

What? products of animal origin handled in establishments subject to approval under EU law and only if the product has been manufactured in compliance with EU rules

How? by food business operators

When? before the product leaves the establishment

Feed Hygiene: a similar approach





3. EFSA



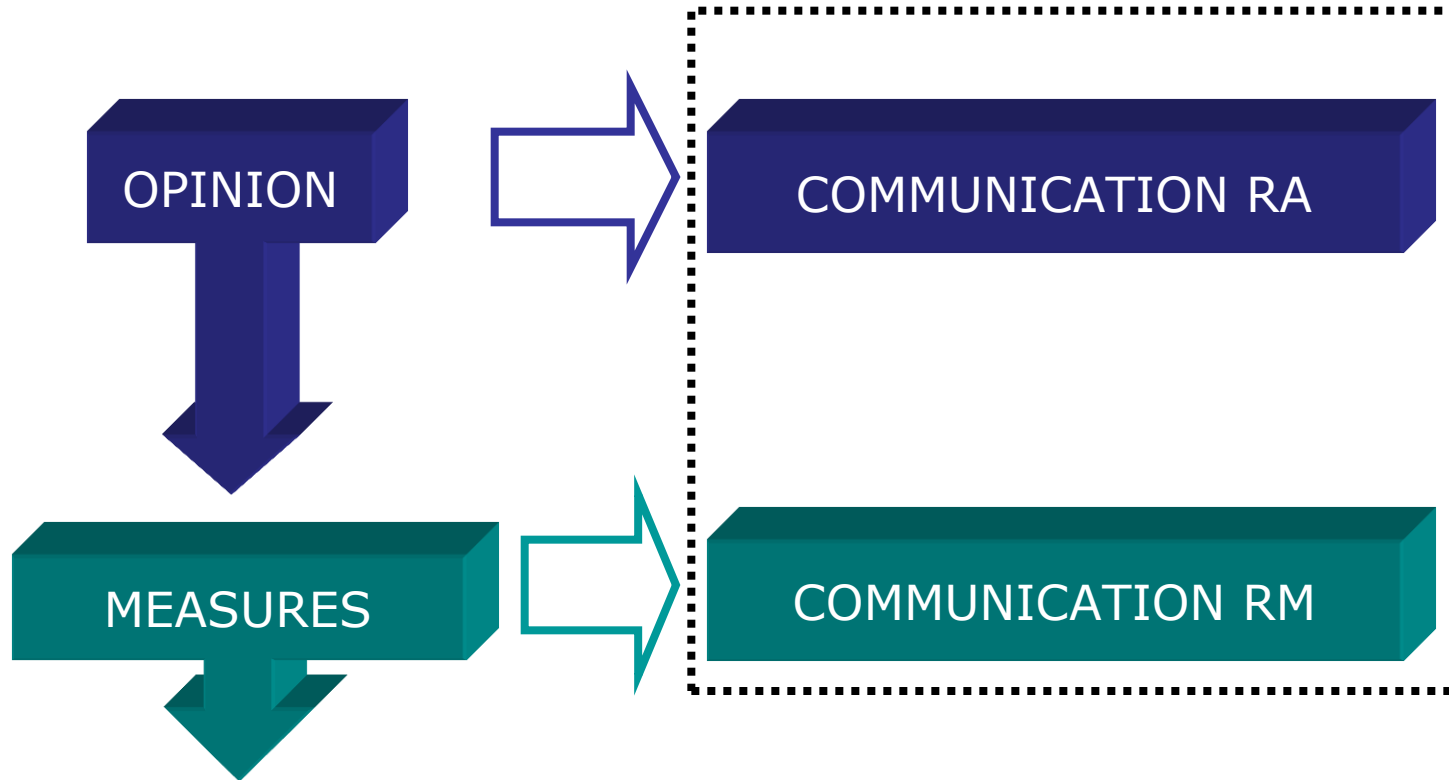
European Food Safety Authority

- Main task: Risk assessment
 - Collection and study of information
 - Scientific opinion: on request / self tasking
 - Network with scientific bodies / evaluation agencies in Member States
- Principles: Independance, excellence, transparency
- Risk management & communication: Commission, Member States...



European Food Safety Authority

Risk assessment



Risk management

Risk communication



4. Official Laboratories



Official laboratories

- accredited (EN ISO/IEC 17025)
- sampling/analysis methods complying with relevant EU rules or if no such rules exist, complying with internationally recognised rules or protocols (e.g. ISO, OIE, CEN) or those agreed in national legislation;
- or in their absence, fit for the intended purpose and developed in accordance with internationally accepted protocols.



EU Reference laboratories

- provide NRLs with details of analytical/diagnostic methods/techniques;
- coordinate the application of the methods/techniques and organise proficiency tests;
- inform NRLs about new methods/techniques;
- provide training courses for staff from NRLs and experts from developing countries;
- provide scientific and technical assistance to the Commission, assist actively in the diagnosis of disease outbreaks in MS;
- collaborate with laboratories in third countries.



National Reference laboratories

- Member States designate one (or more) National reference laboratory (NRL) for each EURL .
- collaborate with the EURLs;
- coordinate the activities of routine laboratories;
- organise comparative tests between the routine laboratories;
- ensure the dissemination of information that the EURLs supplies;
- provide scientific and technical assistance to the competent authority,



5. TRACES

TRACES : e-government system

- ***Functionalities***

- Certification (INTRA, IMPORT (CVED*), EXPORT)
- Notification
- Help to decision
- Control registration

- ***Availability to***

- Member states (compulsory from 1/01/2005)
- Third countries (Voluntary)

* Common Veterinary Entry Document Animal/Product

TRACES: Policy areas

- ***Animal Health***
- ***Animal Welfare (EU exclusive)***
- ***Veterinary Public Health***
 - Live animals
 - Semen and embryos
 - Products of animal origin
- ***Public Health***
 - Products of plant origin
- ***Plant health (2013)***

TRACES : Import certificates

- *Availability of all import certificates:140*
- *Last updated and in force version*
- *In 22 EU official languages*
 - ***NB: Annex VI R (CE) 854/2004***

TRACES : Import process

- *Electronic notification to the EU BIP*
- *Printing of certificates in desired EU languages*
- *Automatic transfer IMPORT to CVED*

TRACES : Import follow up

- *Direct access of the import decision CVED*
- *Electronic notification to the exporting country in case of rejection*
- *Indirect information via RASFF*

TRACES : Import and Help to decision

- *Basis legislation*
 - **Consolidated version**
 - **Available in all EU languages**

TRACES : Trade facilitation tool

- *Integration of private sector*
- *Integration of third countries*
- *Speed up of the border procedures*
 - **Automatic transfer from IMPORT to CVED**
 - **Interconnection with customs system**

TRACES : Anti fraud tool

- *Importation and false certificates*
- *List of all rejected consignments at the EU border*
- *Cross checks with customs data*

TRACES and benefits

- ☐ *Cooperation between services and sectors*
- ☐ *Fight against fraud*
- ☐ *Speed up of the border administrative procedures*
- ☐ *Provision to trade partners of updated and translated certificates*
- ☐ *Direct access to the EU decision*
- ☐ *Increase in security and speed of data transmission*
- ☐ *Work simplification for official services*



6. RASFF

Rapid Alert System for Food and Feed (RASFF)

The RASFF is:

- a **network**
- for the notification of direct or indirect **risks** to human health
- deriving from **food** or **feed**.

The RASFF involves:

- the Member States,
- the European Commission and
- the Authority (EFSA).

*Each of them designates a **contact point**, which is a member of the network.*

The European Commission is managing the network.

RASFF network members



Contact point in each Member Country

Austria	Greece	Poland	Iceland Norway Liechtenstein
Belgium	Hungary	Portugal	
Cyprus	Ireland	Slovakia	
Czech Republic	Italy	Slovenia	
Denmark	Latvia	Sweden	
Estonia	Lithuania	Spain	
Finland	Luxembourg	United Kingdom	
France	Malta	Bulgaria	
Germany	Netherlands	Rumania	



European Food Safety Authority



European Commission



EFTA Surveillance Authority

Rapid Notifications (Year/Number)



- ☐ Food or feed for which a risk has been identified
- ☐ Product is on the market
- ☐ Immediate action is required by members of the network

Information notifications (Year/Letter code)



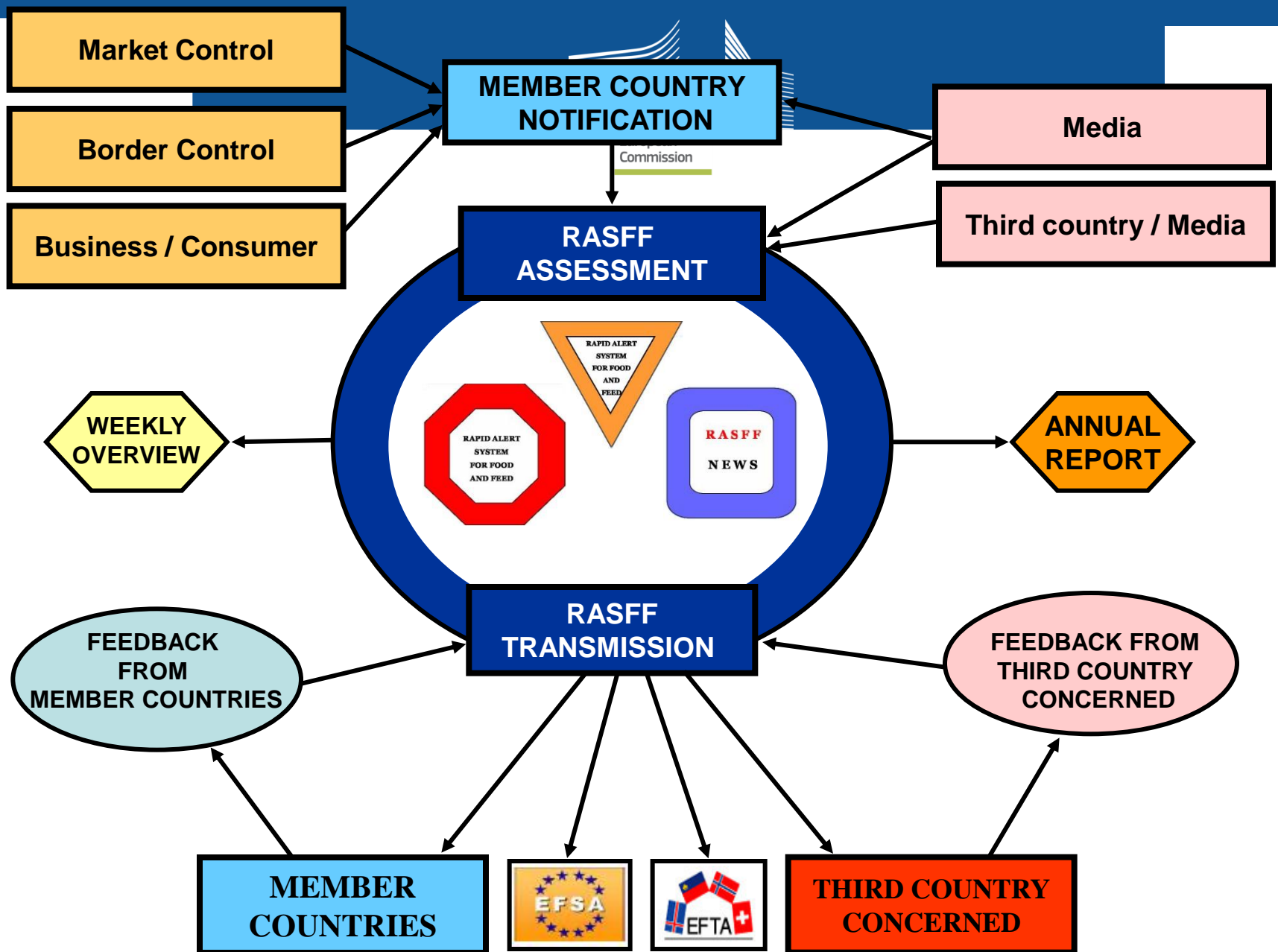
- ☐ Food or feed for which a risk has been identified
- ☐ Product has not reached the market

☐ Immediate action is not required by members of the network

News notifications



- Information related to the safety of food/feed
- Not communicated as an 'alert' or an 'information'
- But is judged interesting for the control authorities



The RASFF database



notification/hazard/product country/company news notifications

year **2006** Reference
Date between and
type

product or

and
brand
hazard category
hazard and
with hazard or
hazard definition
product category
☐ only news
☒ exclude news

notification/hazard/product country/company news notifications

origin
origin country type
☒ via origin
world region
notifying country
reaction by
reaction type
distributed to
company
country
type
name
AP-N°
☐ only news
☒ exclude news

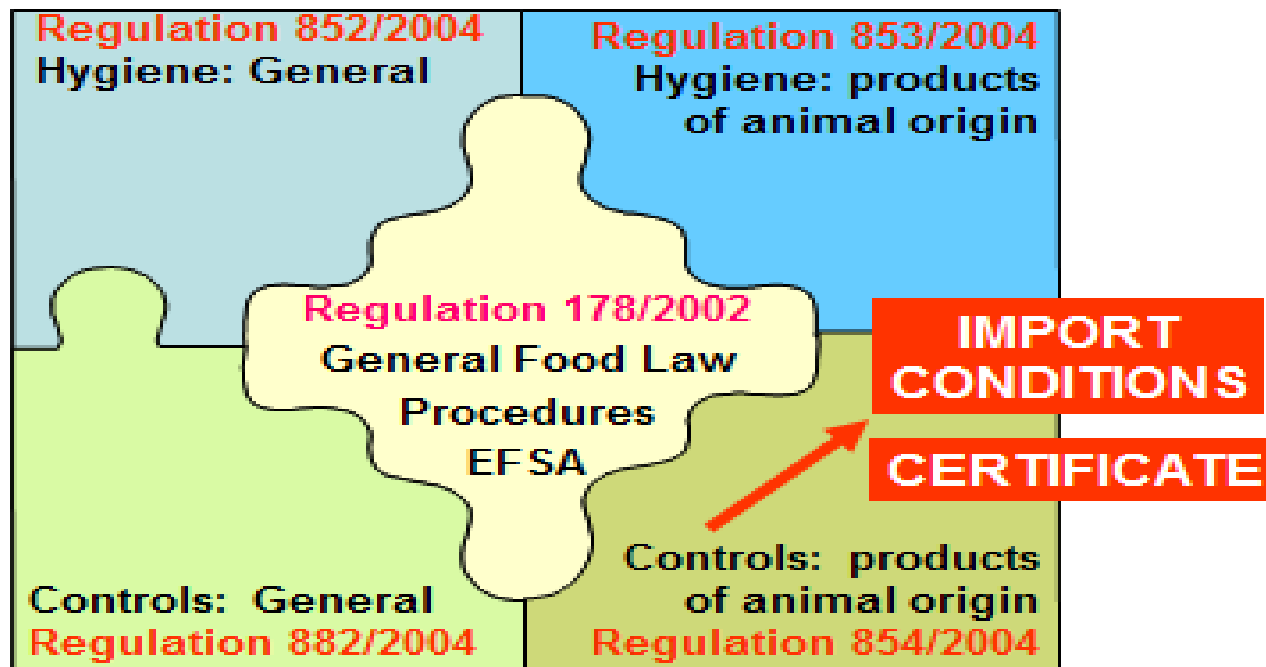
2006.BDY	15/05/2006	food	INFORMATION	border control - import rejected	GREECE	India
subject: altered organoleptic characteristics and bad temperature control of frozen squid (<i>Loligo duvaucelli</i>)					product category molluscs and products thereof	
2006.0310	12/05/2006	food	ALERT	market control	POLAND	Italy
subject: benzo(a)pyrene (13.26; 14.00 µg/kg - ppb) in grapeseed oil					product category fats and oils	
2006.0311	12/05/2006	food	ALERT	market control	CZECH REPUBLIC	Iran via Luxembourg
subject: aflatoxins (B1 = 64.1; Tot. = 71.9 / B1 = 106.3; Tot. = 111.3 µg/kg - ppb) in roasted and salted pistachio nuts in shell					product category nuts, nut products and snacks	
2006.0312	12/05/2006	food	ALERT	market control	ITALY	Spain
subject: mercury (1.56 mg/kg - ppm) in blue shark's slices (<i>Prionace glauca</i>)					product category fish and products thereof (other than crustaceans)	
2006.BDQ	12/05/2006	food	INFORMATION	border control - import rejected	ITALY	Egypt
subject: aflatoxins (B1 < 0.4; Tot. < 1.6 / B1 = 7.7; Tot. = 10.7 / B1 < 0.4; Tot. < 1.6 µg/kg - ppb) in peanuts in shell					product category nuts, nut products and snacks	
2006.BDR	12/05/2006	food	INFORMATION	border control - import rejected	LATVIA	Iran
subject: aflatoxins (B1 < 0.7; Tot. < 2.4 / B1 < 0.7; Tot. < 2.4 / B1 = 118; Tot. = 118 µg/kg - ppb) in pistachio nuts in shell					product category nuts, nut products and snacks	
2006.BDS	12/05/2006	food	INFORMATION	market control	ITALY	Greece
subject: too high count of <i>Escherichia coli</i> (790 MPN/100g) in venus clam (<i>Venus verrucosa</i>)					product category molluscs and products thereof	
2006.BDT	12/05/2006	food	INFORMATION	consumer complaint	CZECH REPUBLIC	Malaysia
subject: unauthorised food additive TBHQ - tertiary butylhydroquinone (76.3 mg/kg - ppm) in palm based					product category fats and oils	



7. Import Conditions for animal products

Import conditions of animal products at a glance

The regulatory framework



Import conditions (products of animal origin)

Imports of products of animal origin into the European Union are subject to official certification.

Official certification is based on the recognition of the competent authority of the non-EU country by the European Commission.

The competent authority of a non-EU country will only be recognised if:

- It has the necessary legal powers and resources;
- It is able to ensure credible inspection and controls throughout the production chain.



Import conditions - procedure in brief

- **Request to the Commission**
- **Pre-mission questionnaire**
- **Bilateral contacts to resolve outstanding issues**
- **On-the-spot inspection FVO / Report**
- **Draft legislation: third country / health certification / approval of residues monitoring program / initial list of establishments**
- **SCOFCAH – adoption – Official Journal**



Import conditions (products of animal origin)

- The importing third country appears on a list of countries from which imports are permitted (public health, animal health, residues ...)
- Imports are only authorised from approved establishments such as: processing plants, freezer or factory vessels, cold stores
which have been:
 - inspected by the competent authority of the exporting country
 - found to meet EU requirements.

List of approved countries

A list of approved establishments is:

maintained by the European Commission and its website.

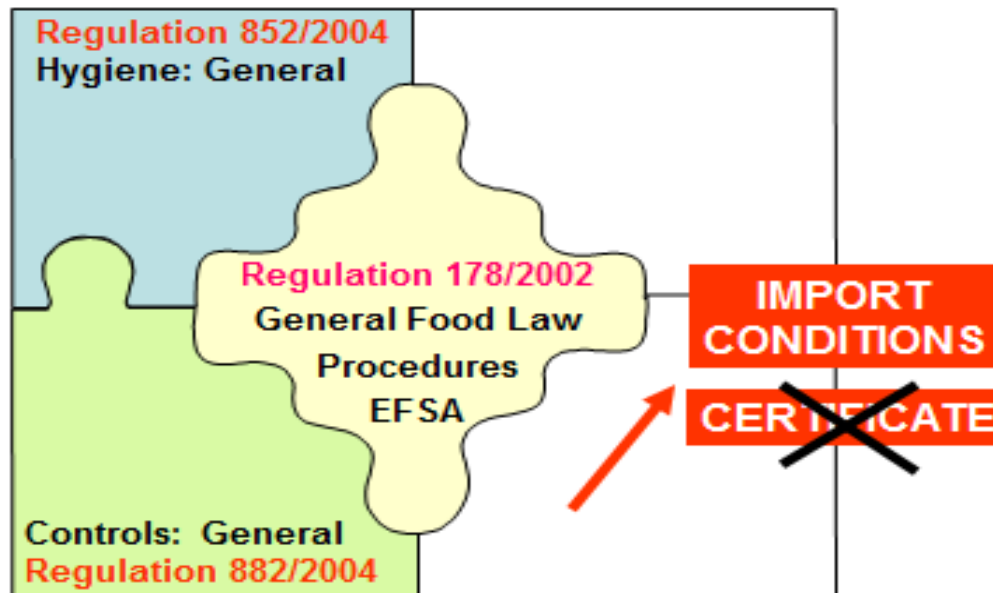


List of approved establishments

Taiwan

- [Section VIII : Fishery products \(25/02/2013\)](#)
- [Section XIV : Gelatine \(28/07/2007\)](#)
- [Section III : Other facility for the collection or handling of animal by-products \(i.e. unprocessed/untreated materials\) \(25/07/2012\)](#)
- [Section IV : Processing plants \(23/11/2012\)](#)
- [Section V : Petfood plants \(Including plants manufacturing dogchews and flavouring innards\)](#)

Other products (e.g. fruits and vegetables)



8



The importing conditions guarantee:

- **Uniform conditions**
- **Robustness**
- **Fairness / Openness**
- **Transparency / Predictability**
- **Experience**

Thank You!

Stéphane André
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