



EU-Asia Cooperation on (Phyto-) Sanitary and Food Safety Regulation

**European approach to Official
Controls
applicable to FCM**

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Contracting Authority
Regional Team FPI

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Contractor





Legal basis

General food law

- The basic Union rules with regard to food and feed law are laid down in **Regulation (EC) 178/2002** of the European Parliament and of the Council

Specific law

- covers different areas
- aim: safety of food and feed
- framework legislation:
 - **Regulation (EU) 2017/625** on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products
 - **Regulation (EC) 1831/2003** on materials and articles intended to come into contact with food



Detailed legal basis – official controls

Regulation (EC)
1935/2004

Article 24
**Inspection and
control measures**

Member States shall carry out official controls in order to enforce compliance with this Regulation in accordance with relevant provisions of Community law relating to official food and feed controls.

EURL / NRL

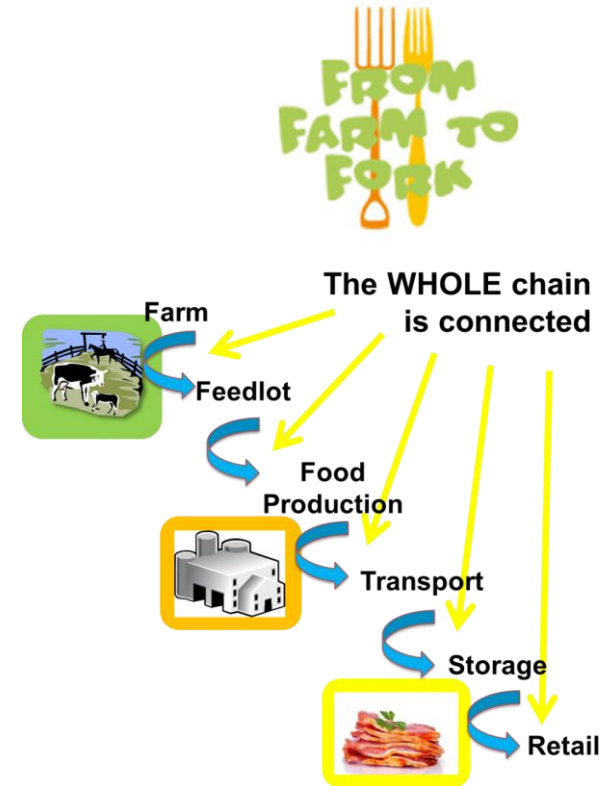
- assists to MS
- a high quality and uniformity of analytical results



Legal basis – official controls

Regulation (EU) 2017/625

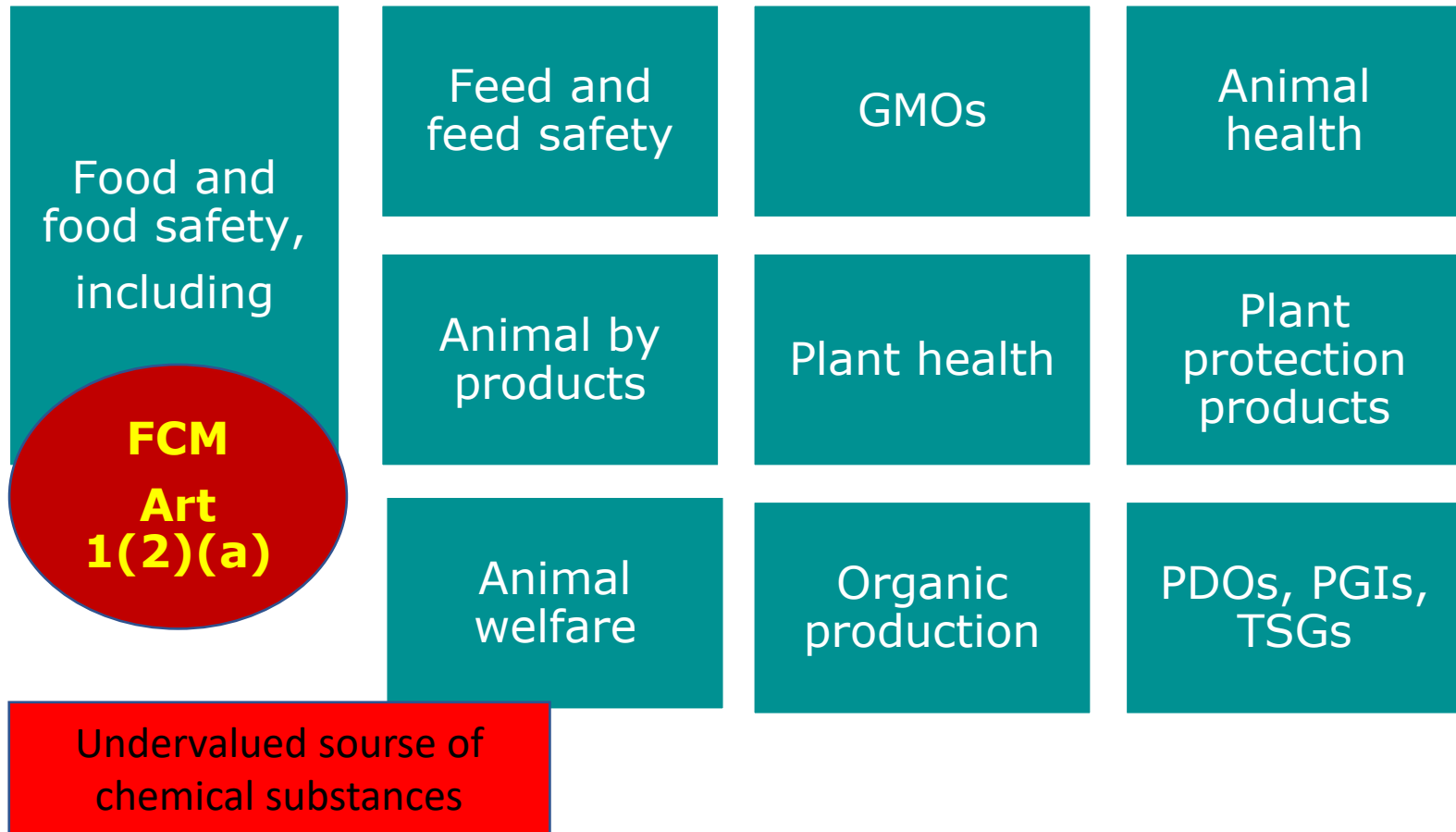
- Official controls are carried out by the competent authorities in the EU countries to verify business compliance with the requirements set out in agri-food chain legislation.
- The agri-food chain encompasses activities preceding and comprising the production of food, i.e. from farm to fork, stable to table.



The EU countries are responsible for the enforcement of agri-food chain legislation.



Scope of official control





FRAMEWORK REGULATION (EC) No 1935/2004

Article 24
Inspection and control measures

REGULATION (EC) No 1831/2003

SPECIFIC MEASURES (Article 5(i))

Covered by official control

Materials:

- Ceramic
- Recycled plastics
- Active and intelligent Materials

Substances:

- Nitrosamines
- Epoxy derivates: BADGE, BFDGE, NOGE
- Bisphenol A in plastic and varnished and coated FCM

Import controls:

- Melamine kitchenware
- Polyamine kitchenware

+ national provisions for non-harmonised FCM



Structure of Regulation 2017/625

General Principles **Articles 1 – 15**

Subject matter, scope & definitions, Competent Authorities general requirements

Sector Specific Requirements **Articles 16 – 27**

e.g. Products of animal origin, residues, animal welfare, plant health, GMOs, plant protection products, organic production, new risks

Art. 28 – 33 Delegation of tasks	Art. 34 – 42 Sampling, analyses, tests + Diagnoses	Art. 43 – 77 Import Controls	Art. 78 – 91 Financing OC + official certification	Art. 92 – 101 EURLs EURCs	Art. 102 – 108 Administrative Assistance + Cooperation
Art. 109 – 115 Planning + Reporting	Art. 116 – 124 Commission controls	Art. 125 – 129 Conditions for entry into the EU	Art. 130 Training (BTSF)	Art. 131 – 136 IMSOC	Art. 137 – 141 Enforcement

Common Provisions - **Articles 142 – 167**



Key Principles

Transparency

Harmonization

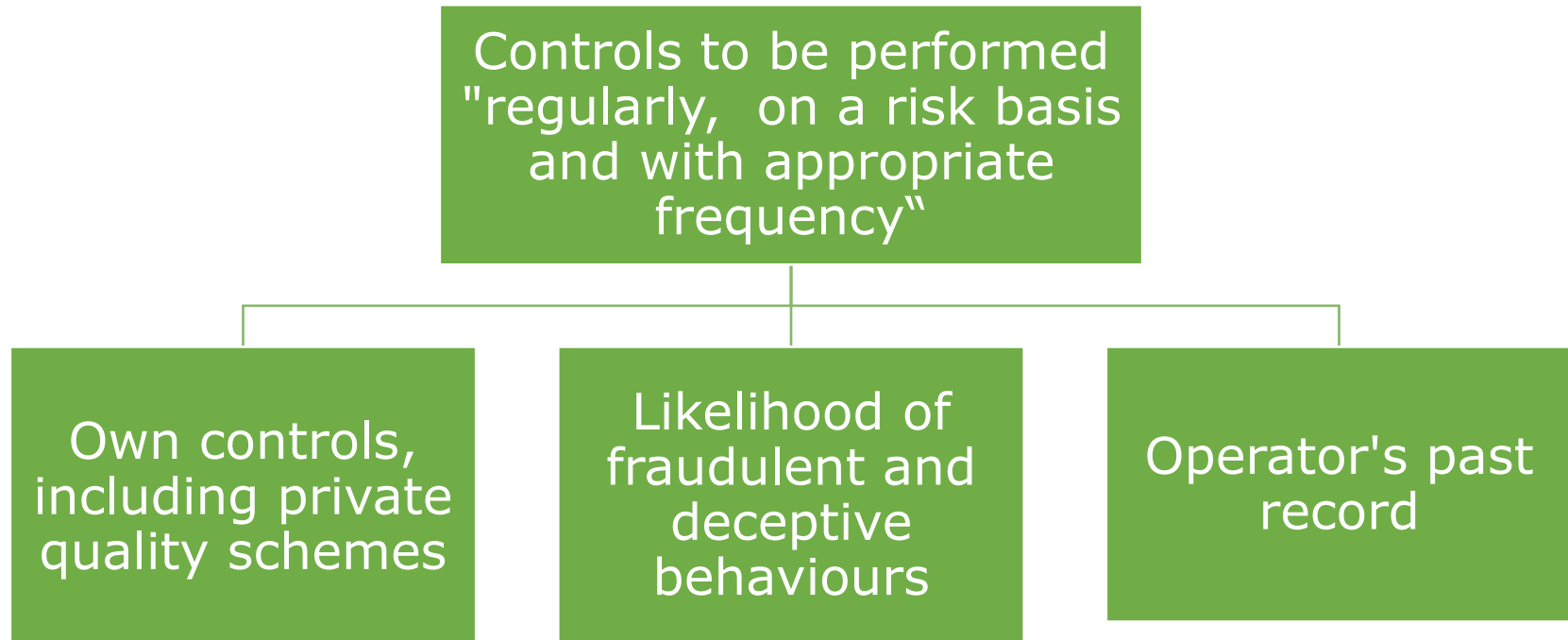
Simplification

Efficiency

Risk based approach



The risk based approach (Article 9) Performance & Frequency of Controls





The risk based approach (Article 9) Performance & Frequency of Controls

Without prior notice, unless necessary for the control to be carried out

The administrative burden of the operators to be minimised



Official Controls on the Operator's Processes and Activities

- Controls carried out at **all stages of production, processing, distribution and use of FCMs** (Article 10 (1)(b))
- **Register of operators** (including FCM operators –Article 10(2))
- Regulation requires Competent Authorities **to set up and keep an up-to-date register of operators subject to official controls.**



Specific Rules: Residues of relevant substances in food and feed (Article 19 (1))

At any stage of production, processing and distribution

Substances to be used in food contact materials, contaminants, non-authorized, prohibited and undesirable substances



Obligations of the operators (Article 15)

Provide information on their name, legal form and specific activities

Give access to computers and premises, to the extent necessary

Assist and cooperate with the staff of the competent authorities



Obligations of the authorities

Ensure the effectiveness, impartiality and quality of official controls and other official activities (Article 5)

Perform official controls in accordance with documented procedures; draw up written records of every control (Article 13)



General obligations concerning the competent authorities (Art. 5)

The competent authorities shall:

- a) have procedures and/or arrangements in place to ensure the **effectiveness and appropriateness** of official controls and other official activities;
- b) have procedures and/or arrangements in place to ensure the **impartiality, quality and consistency** of official controls and other official activities at all levels;
- c) have procedures and/or arrangements in place to ensure that **staff** performing official controls and other official activities are **free from any conflict of interest**;
- d) have, or have access to, an **adequate laboratory capacity** for analysis, testing and diagnosis



General obligations concerning the competent authorities (Art. 5)

- e) have, or have access to, a **sufficient number of suitably qualified and experienced staff** so that official controls and other official activities can be performed efficiently and effectively;
- f) have **appropriate and properly maintained facilities and equipment** to ensure that staff can perform official controls and other official activities efficiently and effectively;
- g) have the **legal powers to perform official controls** and other official activities and to take the action provided for in this Regulation and in the rules referred to in Article 1(2);
- h) have **legal procedures** in place in order to ensure that **staff have access** to the premises of, and documents kept by, operators so as to be able to accomplish their tasks properly;
- i) have **contingency plans** in place, and be prepared to operate such plans in the event of an emergency, where appropriate, in accordance with the rules referred to in Article 1(2) Reg. 2017/625.



Methods and Techniques for Official Controls

Article 14

Traceability

Labelling

GMP

Samples,
analysis

Cleaning and
maintenance

Relevant
packaging
materials
including FCMs

Advertising

Audits of
operators



Actions and Penalties

Actions non-compliance	Penalties
<ul style="list-style-type: none">• determine the origin and extent of non-compliance• correcting labels• restrict or prohibit placing goods on the market• order the BO to increase the frequency of own controls• order the recall, withdrawal, removal and destruction of goods• closing the website of the operator• etc	<ul style="list-style-type: none">• reflect operator's• economic advantage• turnover• protect whistle-blowers



Transparency of Official Controls

Publish, at least once a year, relevant information about the organisation and performance of official controls

Competent Authorities **must ensure a regular and timely publication of the outcome of official controls**

- the cases where enforcement measures were taken and penalties were imposed



Official Control Regulation and e-commerce

Article 35 on online sampling

- Sale via distance communication → CA can order samples from operators without prior identification
- **Article 138 (2) on measures**
- Where the non-compliance is established, the competent authorities shall:
 - (i) order the cessation for an appropriate period of time of all or part of the activities of the operator concerned and, where relevant, of the internet sites it operates or employs



Sampling and analysis (Article 34 + 37)

Off. laboratories to be accredited; ISO/IEC 17025



Decision to establish EURL (article 92)



Where the effectiveness of official controls depends on the quality, uniformity and reliability of methods and results of analysis

Where there is a recognised need to promote uniform practices in relation to the development or use of the methods

The Commission shall review their mandate regularly



Selection and designation of an EURL

The decision to establish an EURL will be taken by a delegated act

The designation will be implemented by the COM

- This will increase the openness and transparency of the selection process

The designation will be valid for a minimum period of five years



Responsibilities and tasks of EURLs (Article 94)

Proficiency testing

Reference materials to NRLs

Scientific and technical assistance to COM and NRLs (including Training Courses)

Establish and maintain reference collections of FCMs used to calibrate analytical equipment

Methods of analysis and tests to NRLs

To collaborate with labs of third countries and with EFSA



IMSOC

- Information Management System for Official Controls
- It's a concept to allow our EU systems to exchange information and share features (and with MS systems)
- Toward a better collective controls efficiency
- TRACES/ BOVEX/ ADNS/ EUROPHYT/ IRASFF/ AAC



Control activities

Control plan

means a description established by the competent authorities containing information on the structure and organisation of the official control system, and of its operation and the detailed planning of official controls to be performed, over a period of time, in each of the areas governed by the rules referred to in Article 1(2) Reg. 2017/625

part of MANCP



Control activities

How? Tools for controls:

- inspection
- monitoring
- sampling
- analysis
- documentary check (including audit of FCM producers)

Where?

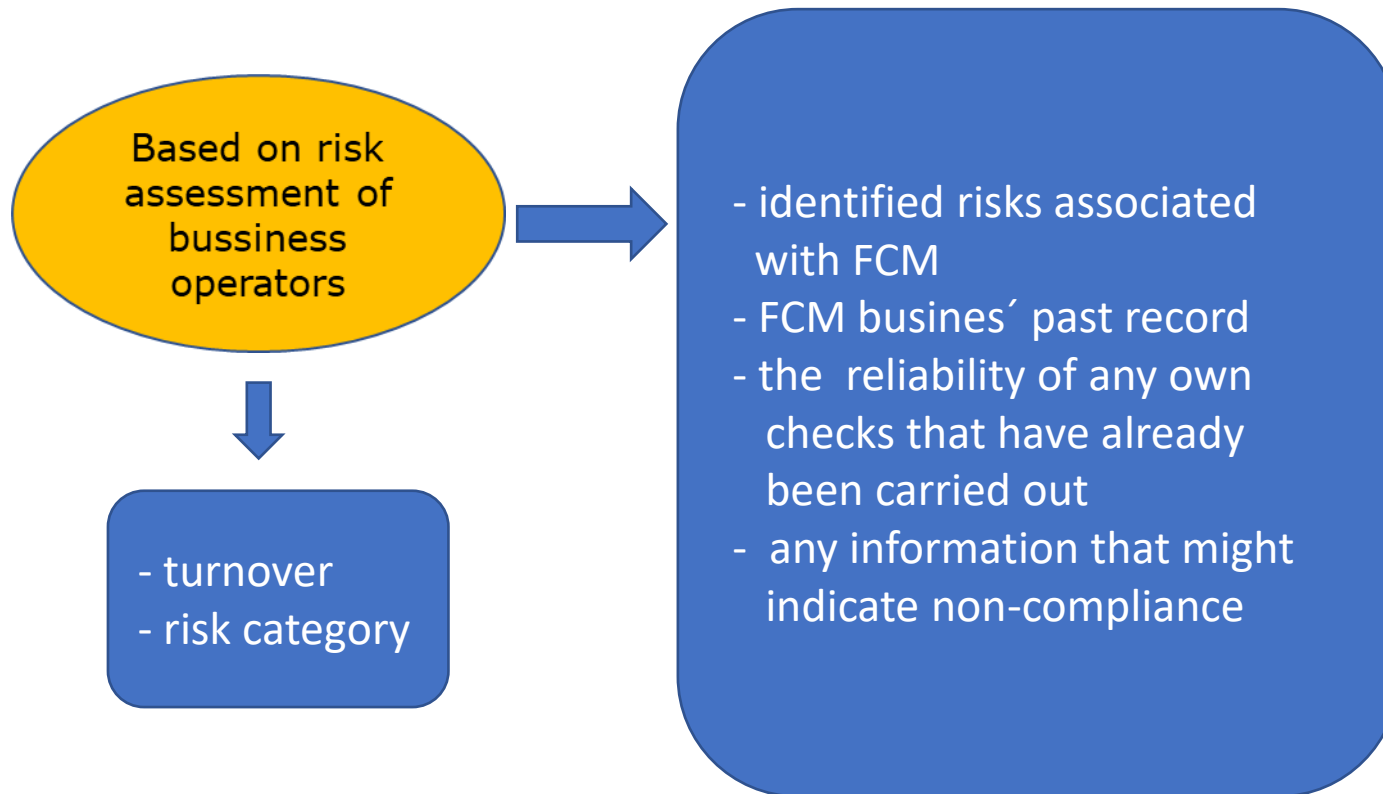
- in all stages of the supply chain of food contact material
- in the food industry
- at the point of entry in the EU
- at the point of distribution
- at retailers

Based on risk assessment of bussiness operators

- turnover
- risk category



Control activities





RASFF – the Rapid Alert System for Food and Feed - a key tool to ensure the cross-border follow of information to swiftly react when risks to public health are detected in the food chain





2021 Annual Report Alert and Cooperation Network

Total number of notifications: 4607

Area	Number of notifications
Food	4102
Feed	236
FCM	269

notifications on FCM are more than doubled compared to year 2020



Thank you for your attention!



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For more information on the project activities:



<https://eu-asia-sps.com/>
www.aets-consultants.com