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Official Controls Regulation (2017/625/EU)

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union

Explanatory Meeting on the Acquis

18/02/2019

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Outline

1) Background and entry into application

2) Basic principles and general rules

3) Administrative requirements

4) New system for border controls

5) Delegated and implementing acts

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Replacing Regulation 882/2004

15 June 2016: Political agreement

19 December 2016: Council common position

15 March 2017: European Parliament adoption

7 April 2017:

Official Journal of the European Union

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Main goals of the revision

- **Simplify and clarify the legislative context** to cover the **whole agri-food chain** (plants + animal-by-products included in the scope)
- **Increase the quality of official controls**
- **Modernise the legislation** (more coherent rules on imports, streamlined + digitalized exchange of information among Member States) and **strenghten** legal basis **against food frauds**

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Structure of Regulation 2017/625 (OCR)

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– 76 CONTROLS Entry into the Union	Art. 77-91 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

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Entry into force and application

Entry into force:
29 April 2017

Main date of application:

14 December 2019

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General rules

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Key objectives

Simplification

Harmonisation

Efficiency

Transparency

The risk based approach is maintained

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The risk based approach

Controls to be performed "regularly, on a risk basis and with appropriate frequency"

Own controls, including private quality schemes

Risks associated with animals and goods, activities, location…and the likelihood that consumers might be misled

Operator's past record

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Extended scope

- Food and food safety
- Feed and feed safety
- GMOs
- Animal health
- Animal welfare
- **Animal by-products**
- **Plant health**
- **Plant protection products**
- Organic production

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One size…

"Establish a harmonised Union framework for the organisation of official controls and official activities along the entire agri-food chain"

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...does not always fit all

"To avoid diverging enforcement practices which could generate uneven protection of human, animal and plant health, animal welfare and, as regards GMOs and plant protection products, also of the environment, disrupt the functioning of the internal market for animals and goods (…) and distort competition, the Commission should be able to supplement the rules (…) catering for the needs of controls of those areas."

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Example: The plant health sector

Article 22(3): Frequency of official controls of plants and plant products, as well as of professional operators authorised to issue plant passports and to apply the mark of wood packaging material

Article 92+93: Designation of five plant health European Union Reference Laboratories (for insects; nematodes; bacteria; fungi; viruses, viroids, and phytoplasmas)

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Member States responsible

"The responsibility to enforce Union agri-food chain legislation lies with Member States, whose competent authorities monitor and verify, through the organisation of official controls, that relevant Union requirements are effectively complied with and enforced".

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Obligations of the Member States

For each area under the scope of the OCR, designate the competent authority or authorities responsible for organising or performing official controls and other official activities

If more than one authority for the same area, ensure efficient coordination and designate a single authority responsible for contacts with the Commission and other Member States

Inform the Commission, and make publicly available, up-to-date contact details of the competent authorities

Obligations of the authorities

Ensure the effectiveness, impartiality and quality of official controls and other official activities

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

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Minimum disruption of business

Official controls shall be carried out in a manner that the administrative burden and operational disruption for operators are kept to the minimum necessary

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Planning, performing, reporting

Multiannual control plans, coordinated by a single body; publicly available; information for annual reports + reviews/updates

Risk based, regular controls at an appropriate frequency, performed without prior notice, unless necessary for the control to be carried out

**Annual reports by 31 August each year;
regular and timely publication of the outcome of official controls, incorrect information to be rectified**

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Administrative Assistance and Coordination

Member States should provide administrative assistance to each other, e.g. participation in on-the-spot controls

Member States must designate liaison bodies; a list to be published on the Commission's website

When receiving a reasoned request for assistance**, the competent authority must perform controls and indicate within 10 working days the estimated time necessary to provide an informed response**

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Operators are responsible too

"Union agri-food chain legislation is based on the principle that operators at all the stages of production, processing and distribution which are under their control are responsible for ensuring compliance"

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Obligations of the operators

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

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Financing

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Financing

No empowerments!

⇨ **Adequate resources for all types of controls!**

Mandatory fees:

- Slaughterhouses
- Cutting plants
- Milk products
- **Fishery products**

BCPs

- Animals
- Products of animal origin, germ. prod, ABP
- Plant + plant protection prod.
- Request of operators
- Follow-up non-compliance safeguard measures

Fees in Annex

Flat rate

Actual costs

Cost elements:

- Staff salary
- Facilities + equipment
- Consumables
- Services of delegated bodies
- Continuous training
- Travel
- Sampling + testing

TRANSPARENCY:

Make public e.g. the method and data used to establish fees, and the amount charged to each category of operators; stakeholders to be consulted on the general methods of calculation

Optional fees: to cover costs

(No fees = covered by states' general expenses/budget/tax

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Training

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Training requirements

Staff shall receive regular training in e.g. different control methods and techniques, such as sampling and **laboratory analysis**, testing and diagnosis as well as the evaluation of the application of **HACCP** procedures and of good agricultural practices

Competent authorities shall develop and implement **training programmes** for the purpose of ensuring that staff performing official controls and other official activities receive the training referred to above

+ Commission Delegated Regulation on the **training of staff at border control posts** (identity and physical checks, Art. 49.5)

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"Better Training for Safer Food"

The Commission organises training activities for the staff of the competent authorities and other authorities of the Member States, in cooperation with the Member States concerned

The training activities referred to above may be open to staff of the competent authorities of **third countries** and may be organised **outside the Union**

Activities aimed at disseminating such knowledge shall be included in the training programmes referred to in the earlier slide

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Laboratories

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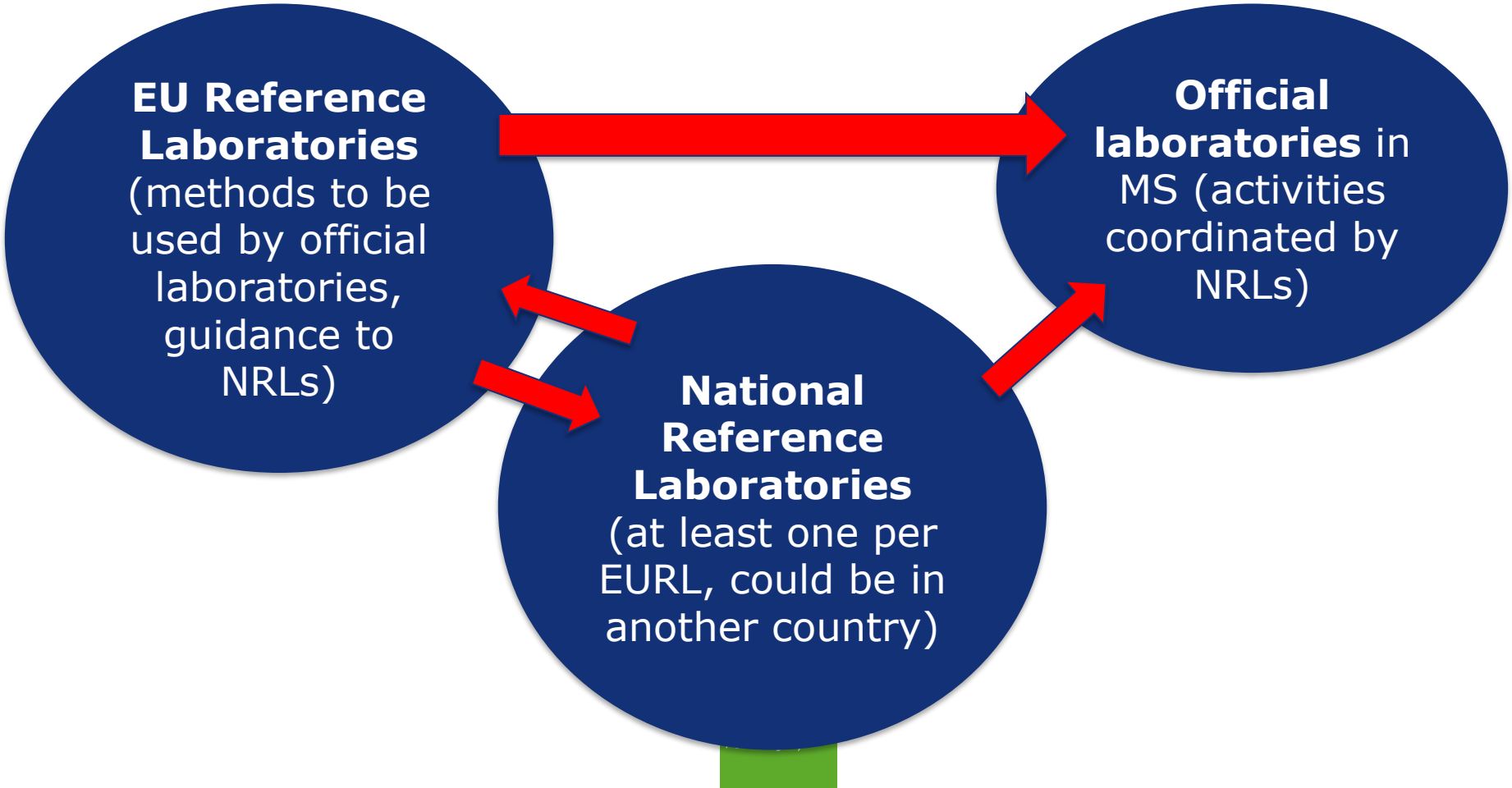
Network of laboratories



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EURLs shall be established where…

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

…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

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Responsibilities and tasks of EURLs

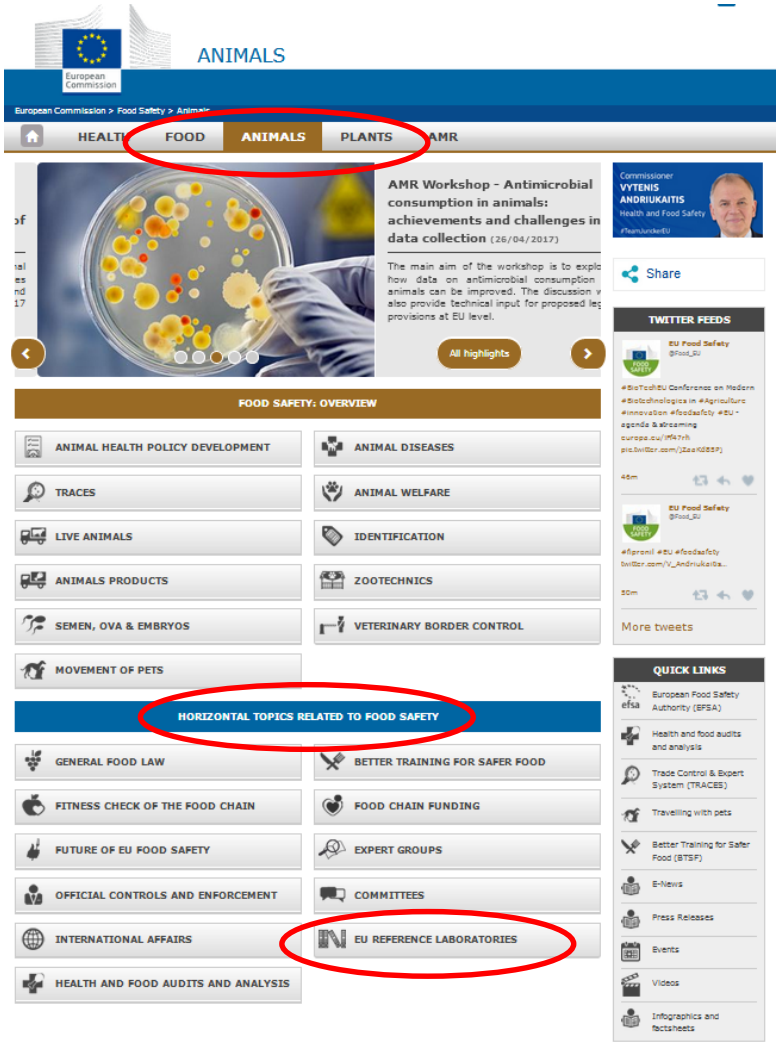
Methods of analysis and tests to NRLs (details and guidance, PT and new)

Reference materials to NRLs (including performance tests for the verification of quality)

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

To assist actively in the diagnosis of outbreaks in MS of foodborne diseases etc (confirmatory analysis)

To collaborate with labs of third countries and with EFSA



EURLs web section, including work programmes

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Responsibilities and tasks of NRLs

Collaborate with EURLs, participate in their training courses and inter-laboratory comparative tests

Coordinate the activities of official laboratories, incl. organise proficiency tests and training courses

Disseminate information from EURLs to competent authorities and official laboratories

Provide scientific and technical assistance to competent authorities for the implementation of multi-annual control programmes and coordinated control programmes

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Responsibilities and tasks of official laboratories

Competent authorities must designate official laboratories to carry out the laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities
(e.g. a monitoring programme)

May be located in another Member State or an EEA country

Immediately inform the competent authorities if the results indicate a risk

Upon request from the competent authorities make publicly available the methods used

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Main requirements for the laboratories

Impartial and free from conflict of interest

Accredited in accordance with **standard EN ISO/IEC 17025**

Suitably qualified staff and necessary infrastructure and equipment

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New system for border controls

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Entry into the Union – Main rules

"High risk"	"Low risk"
Animals, products of animal origin, germinal products, animal by-products, plant, plant products and certain feed and food of non-animal origin* = Designated **BCP** of first arrival	Animals and goods whose inherent risks do not require systematic border controls = An **appropriate place** within the customs territory of the Union
Always documentary checks; risk based identity and physical checks	**Regular, risk based controls with appropriate frequency (established by MS)**

New IT system. Same set of measures in cases of non-compliance, including enforcement measures

* A **list with CN codes** to be established

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A modernised system for border controls

A common, risk based framework for border controls on all animals and goods entering the EU

Border Control Posts (BCPs)
replace
- Border Inspection Posts (BIPs)
- Designated Points of Entry (DPEs)

Minimum requirements for

facilities - equipment - staff

Common Health Entry Document (CHED) single standard document for the prior notification of consignments

Data transmitted through **IMSOC** = integration of existing computerised systems
(including TRACES, RASFF, Europhyt)

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Border control process

Prior notification and exchange of information

CHED, IMSOC

Presentation and controls at the BCP

Mandatory documentary checks, but risk based identity and physical checks

Decision and follow-up on the consignment

CHED, IMSOC, customs' single window

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What is IMSOC?

Keywords	CONSOLIDATION-EFFICIENCY

Name:	Information Management System for Official Controls	
Is it a new IT application?	**NO!**	It's a concept to allow our EU systems to exchange information and share features (and with MS systems)
Will it add further burden to our activities?	**NO!**	It will be designed to make your life easier
Will it replace the current systems? (traces/bovex/europhyt/irasff/aac)	**NO/YES**	It will connect them and extend functionalities (some systems will be absorbed)
What is its purpose?	**Toward a better collective controls efficiency**	

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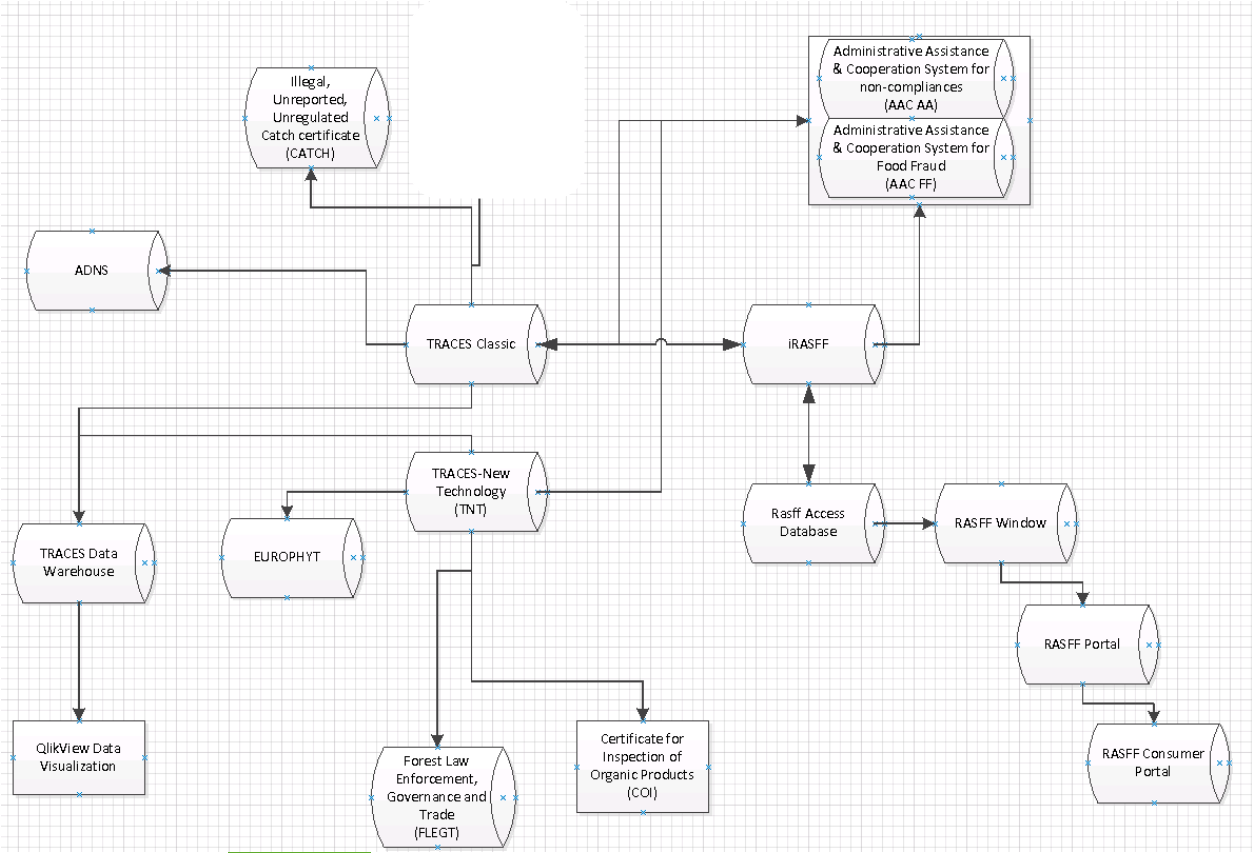
IMSOC and its system components (overview)

1. Administrative Assistance and Cooperation (AAC): Public health, Non compliances and Fraud suspicion
2. Certification (Animal, Animal products, Organic, Plants, Timber, Fish Catches …)
3. Alerts (Humans, Plants, Animals)
4. Identification (e.g. bovine)



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Delegated and implementing acts

(Main target date: 14/12/2019)

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Implementation of the OCR

EMPOWERMENTS are given to the Commission to ensure the implementation of the Regulation through…

Implemented Acts (IA): HOW?

(Uniform conditions for implementation)

Delegated Acts (DA): WHAT?

(Supplement or amend non-essential elements)

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Standard decision making process

Implementing Act (IA)

STAKEHOLDERS

Roadmap

Impact assessment

Concept paper

Draft 1

Draft 2

* Standing Committee
Plants, Animals, Food and Feed

Adoption

MS working group

Delegated Act (DA)

MS expert group

roadmap

Impact assessment

Concept paper

Draft 1

Draft 2 *

Adoption

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* Feedback mechanism (four weeks), see Better Regulation Guidelines: SWD(2015) 111 final

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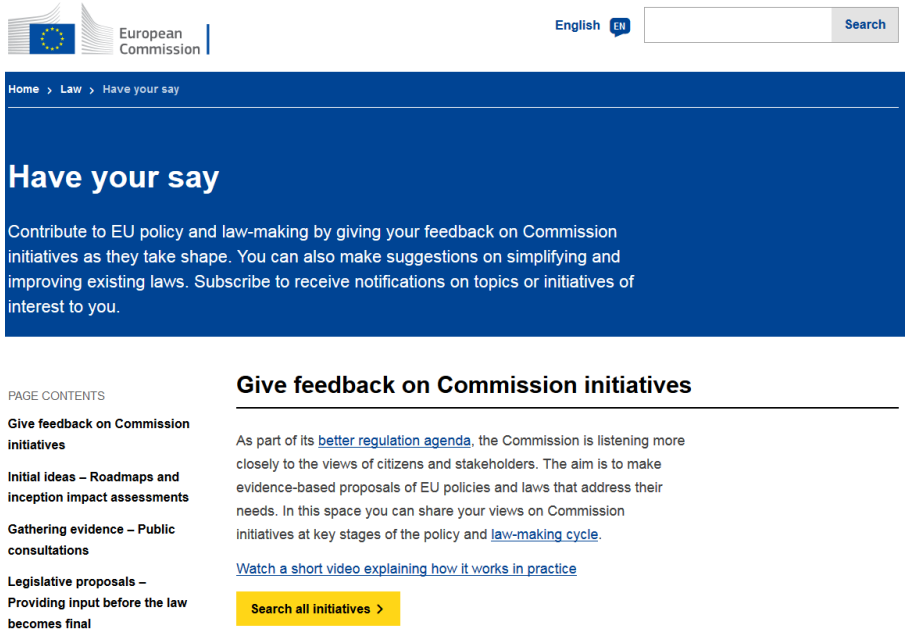
Public feedback on draft acts



Contribute to EU policy and law-making by giving your feedback on Commission draft delegated and implementing acts.

https://ec.europa.eu/info/law/better-regulation/have-your-say

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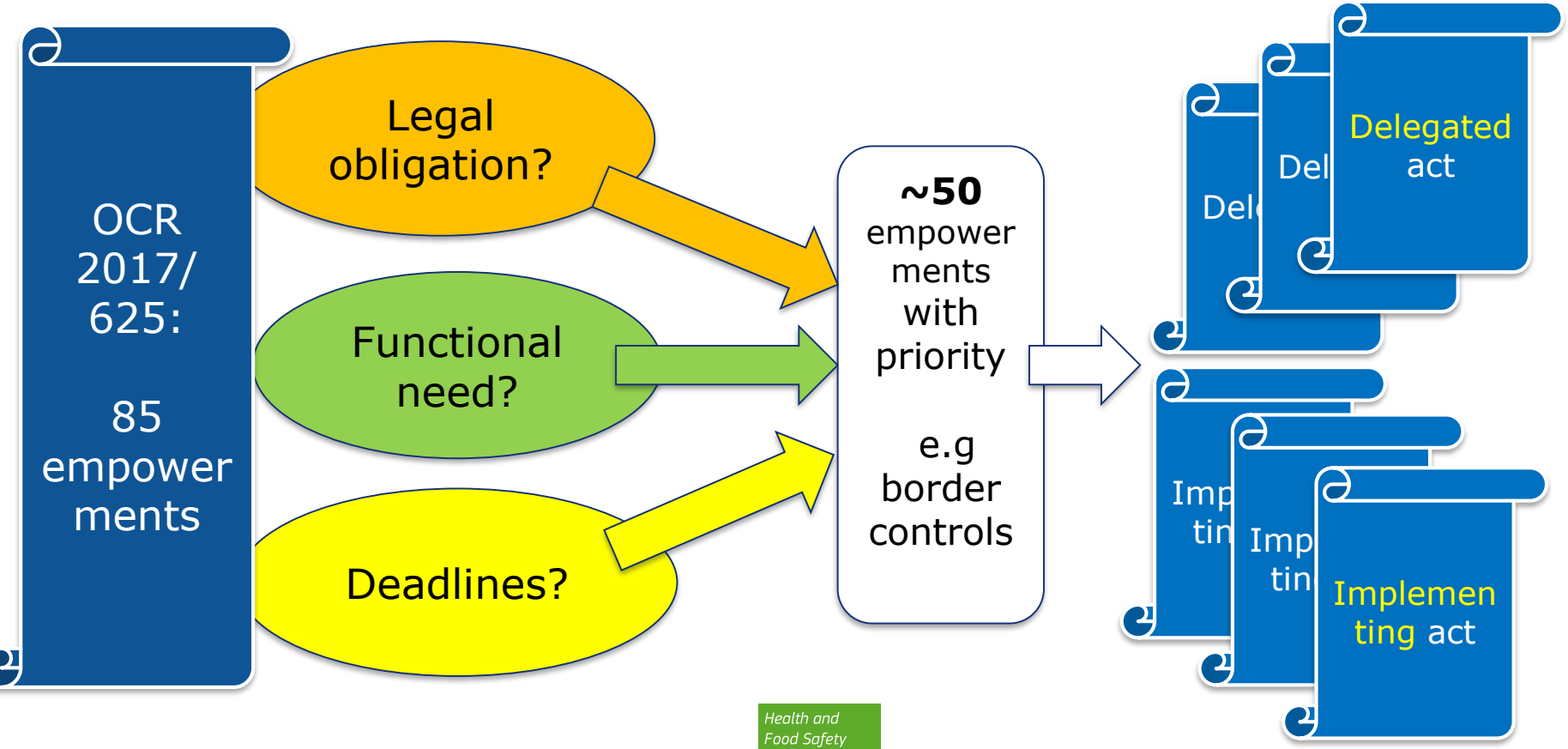
DG SANTE work plan on the OCR: some criteria for prioritisation



Unit in charge	***Topics***									
G.3	Certification for ship suppliers	List of animals and goods, with CN codes	Additional categories (composite products, hay and straw)	Animals and goods exempted from BCP controls	Training of BCP staff	CHED as an accompanying document	Transit, transhipment and onward transportation	Derogation from rules on documentary checks for plants in transit or transhipment	Details of checks performed at BCPs	Controls performed elsewhere than BCPs; controls by customs
	Frequency of identity and physical checks at BCPs	Prior notification	Listing of BCPs	Derogation from certain BCP requirements	BCP facilities	Intensified controls	Specific official controls and measures in cases of non-compliance	Monitoring of consignments from BCP to destination	Cases and conditions where competent authorities may request prior notification by operators	

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Unit in charge*	Topics				
D.2	Temporary measures on entry into the Union of certain goods				
E.2	Control programmes and reports on VMP	Measures in case of non-compliances related to VMPs	Import conditions for third countries for controls of VMP and pesticides residues and contaminants		
E.4	National control programs on pesticide residues				
F.6	Establishing standard model forms for the submission of the annual report on the operation of their multi-annual national control plan by MS	Establishing the (multi-)annual programme of controls carried out by Commission experts in the MS			
G.1	Minimum frequencies for plant health controls	Establishment of EURL	Designation of the 5 EURLs		
G.2	Specific animal health controls	Designation of an EU Reference Centre For Animal Welfare			
G.4	Meat inspection	Meat inspection practice	Model certificates for entry into the Union	Conditions to be respected by certain food entering the Union	Laying down lists of third countries allowed to enter products of animal origin on the Union market
G.5	Administrative Assistance and Cooperation	Rules for rapid exchange of information (AAC)	The functioning of the IMSOC	Exchange of information between authorities	Format of the CHED

*coordination G3

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Article 64(2) and 64(5)

Border Control Post designation - certain derogations

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Geographical Constraints - BCP at a distance from the point of entry into the Union

Derogation:

- Member States may designate a BCP not situated in the immediate vicinity of the point of entry

Conditions:

- Specific cases of geographical constraints (e.g. points of entry with a geographical configuration that imposes major constraints on the transportation system; points of entry subject to recurrent floods in certain periods of the year; maritime wharves surrounded by cliffs; etc.)
- BCP distance from the point of entry into the Union commensurate with the need to overcome the constraints of geography and it does not go beyond that need;
- BCP at an appropriate distance from establishments or places where animals, plants, plant products or other objects likely to be infected with transmissible diseases or pests are kept or grown;
- BCP and the point of entry are under the remit of the same custom authority.

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Geographical Constraints –BCP for unprocessed logs and sawn and chipped wood

Exemptions:

- Member States may designate the BCP exempted from certain minimum requirements (i.e. sufficient and suitably qualified staff, equipment/facilities, technology for the operation of IMSOC)

Conditions:

- arrangements in place to prevent at all times any undetected entry;
- BCP has access to a sufficient number of suitably qualified staff in the form of a competent authorities' mobile official control team able to reach the BCP before the arrival of the consignments;
- the competent authorities' mobile official control team provides or has immediate access to the equipment, premises and other facilities necessary for the performance of official controls;
- the competent authorities' mobile official control team provides or has immediate access to the technology and IT equipment necessary for the operation of IMSOC.

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Article 64(4)
Border Control Post facilities

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Detailed rules on minimum facilities

- **Common detailed minimum requirements for BCP infrastructure**

Example: areas or rooms where animals and goods are to be unloaded must be covered by a roof except non-containerised consignments of fishery products for human consumption, for ABP such as wool, loose manure, etc.

- **Common detailed minimum requirements for BCP equipment and documentation**

Example: equipment to unload, open and examine consignments

- **Specific minimum requirements for BCP designated for animals**

Example: area for the unloading of animals with adequate space and ventilation

- **Specific minimum requirements for BCP designated for POAO, ABP, etc.**

Example: inspection rooms with facilities to maintain temperature controlled environment where necessary

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Thank you for your attention!

Official Controls webpage on DG Health and Food Safety website:

http://ec.europa.eu/food/safety/official_controls/legislation_en