

# The Official Controls Regulation (EU) 2017/625 of the European Parliament and the Council (OCR)



27 November 2019



## Please note:

In the presentation the following abbreviations will be used:

OC(s) - Official Control(s)

CA(s) – Competent Authorities

MS(s) – Member State(s)

OCR – Official Controls Regulation

OV(s) – Official Veterinarian(s)

NC – non-compliance

# Summary

- Introduction
- Background of Regulation 2017/625
- General principles (art. 1 – 15)
- Sector specific requirements (art. 16 – 27)
- Delegation of tasks (art. 28 – 33)
- Laboratories, sampling, analysis, diagnosis (art. 34 – 42 and 92 – 101)
- Financing of controls (78-85)



# Summary

- Administrative Assistance and Cooperation (**AAC**) and Integrated Management System for Official Controls (**IMSOC**)
- Planning and reporting
- Commission controls and Enforcement

**SUMMARY**

# Reg 178/2002 lays down the Food Law overall objectives which MSs shall pursue by means of the OCs system

a high level of protection of human life and health



the protection of consumers' interests, including

fair practices in food trade



The protection of animal health and welfare\* *to be taken into account where appropriate*



The protection of plant health and the environment

\* *to be taken into account where appropriate*



# The “Food Hygiene Package” Regulations

Clearly specify the **FBOs obligations** in respect to the **general hygiene requirements** of foodstuffs (Reg. EC n. 852/04) and specific rules on the hygiene of **food of animal origin** (Reg. EC n. 853/04)

**Further specifications** of the requirements laid down in these Regulations and implementing measures have been adopted by mean of other Regulations (Reg. EC n. 2073/05, Reg. EC n. 2074/05, Reg. EU 2015/1375, etc.)





# Two different regulations



Laid down the **general rules for the performance of OCs** (Reg EC. n. 882/04) - and the **specific rules** for the organisation of official controls on **products of animal origin** intended for human consumption (Reg. EC n. 854/04) - to verify compliance with rules aiming at:

- **preventing, eliminating or reducing** to acceptable levels **risks** to humans and animals, either directly or through the environment and
- guaranteeing **fair practices** in feed and food trade and **protecting consumer interests**, including feed and food labelling and other forms of consumer information

# Member States obligations are defined

Establish and maintain a system of official controls

To verify 1) compliance with rules by operators at all stages of the food chain, and 2) that animals and goods fulfil the requirements set by EU food chain rules

To enforce food law implementing, whenever necessary or appropriate, the relevant penalties

To maintain a system of public communication on food and feed safety and risk.



# Since 2004, many things happened...



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 8.7.2009  
COM(2009) 334 final

Among others:

- The Commission submitted a **report to the European Parliament and the Council** reviewing the experience gained from the application of the Regulations (2009)
- **E-commerce** in ascending trend
- **Food fraud** summoned more attention from the public and competent Authorities

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND TO THE COUNCIL

on the application of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules

Alibaba.com

amazon

ebay



# ...Pushing the Parliament, the Council and the Commission

To **review Reg. 882/2004 on Official Control** to respond to the new context and to reassess some items **in the light of the experience gained**



**SOMETHING!**

# Actually

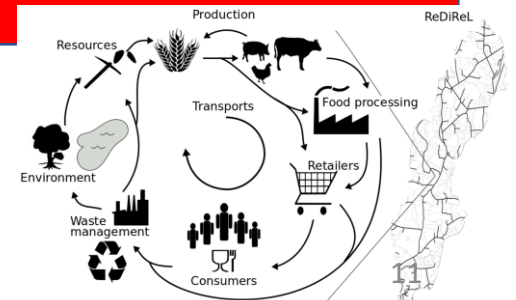
The same Commission report on the application of Reg. 882/2004 clarified that gained experience [MS CAs, FVO (now Directorate F)] showed that **adjustments of Reg 882/2004** were necessary in a number of areas aiming to:

Simplify the legal framework

Clarify some aspects

Expand its field of application

Consolidate the integrated approach



# Reg. (EU) 2017/625

7.4.2017

EN

Official Journal of the European Union

L 95/1

Adopted on March,  
15<sup>th</sup> 2017, constitutes  
the answer of the EU  
Parliament, the  
Council and the  
Commission to these  
needs.

I

*(Legislative acts)*

## REGULATIONS

REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2017

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, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)

# Reg. (EU) 2017/625

- **Confirms** principles laid down in Reg (EC) 882/2004



- **Clarifies** some aspects

- Introduces some **novelties**



# The scope of the new Regulation has been extended (art. 1)

- and will now cover OCs to verify compliance with food and feed law, animal health and welfare, plant health, plant protection products, animal-by products, organic, quality schemes, marketing standards (fraud) rules.
  - Animal by-products, under Reg. 1069/2009
  - Plant health including plant protection products, Reg. 2016/2031
  - Animal Health, Reg. 2016/429





# The scope of the new Regulation has been extended (art. 2)

Official activities are to include “Other Official Activities” beyond Official Controls



- **other official activities** *other than OCs, which are performed by the CA, or by the delegated bodies or the natural persons to which certain other official activities have been delegated ..., including activities aimed at verifying the presence of animal diseases or pests of plants, preventing or containing the spread of such animal diseases or pests of plants, eradicating those animal diseases or pests of plants, granting authorisations or approvals, and issuing official certificates or official attestations.*



# It is clarified

- That OCs include the verification of compliance for the issuance of an **official certificate** or official attestation (art. 2.1)
- A new definition - **official attestation** – is added to include some activities carried out in the framework of OCs

Official certificate

Part I: Details of dispatched consignment	I.1. Consignor		I.2. Certificate reference number		I.2.a			
	Name							
	Address		I.3. Central Competent Authority					
	Tel.N°		I.4. Local Competent Authority					
	I.5. Consignee		I.6.					
	Name							
	Address							
	Postal code							
	Tel.N°							
	I.7. Country of origin		ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10.
	I.11. Place of origin		Approval number		I.12.			
	Name							
	Address							
	I.13. Place of loading		Approval number		I.14. Date of departure			time of departure
	Address							
I.15. Means of transport		Aeroplane <input type="checkbox"/>		Ship <input type="checkbox"/>	Railway wagon <input type="checkbox"/>	I.16. Entry BIP in EU		
Road vehicle <input type="checkbox"/>		Other <input type="checkbox"/>		I.17. No.(s) of CITES				
Identification:								
Documentary references:								
I.18. Description of commodity		I.19. Commodity code (HS code)		01.06.39			I.20. Quantity	
I.21.				I.22. Number of packages				
I.23. Identification of container/seal number				I.24.				
I.25. Commodities certified for:		Slaughter <input type="checkbox"/>						
I.26.				I.27. For import or admission into EU <input type="checkbox"/>				
I.28. Identification of the commodities		Species (Scientific name)		Breed/Category	Identification system	Identification number	Quantity	

# Definitions (art. 2)

The following definitions are **no longer** part of the OCR:

- **Inspection**
- **Monitoring**
- **Surveillance**

[even if inspection is recalled at art. 14 on  
*“Methods and techniques for official controls”*]



# Official controls notice

## Clarification

Reg. 2017/625 makes clear the principle according to which, in general, OCs must be performed without prior notice, **except where such notice is necessary** to the performance of the OC itself and **duly justified** for the official control to be carried out (as in case of **OCs** performed in slaughterhouses **during slaughter operations**)

Even in case of **OCs upon request from the operator**, the CA may decide whether to give prior notice or not

Anyhow, OCs with prior notice **shall not preclude** OCs without prior notice



# A stronger coordination among different CAs required (art. 4,2)

*“Where, for the same area, a MS confers the responsibility to organise or perform OCs or other official activities on **more than one CA** (...) the MS shall (...) designate **a single authority**, ... , **responsible for coordinating the cooperation and the contacts with the Commission** and with other MSs in relation to the OCs and other official activities performed in each of the areas governed by the rules referred to in Article 1 (2).”*



# General obligations concerning the CAs (art. 5)

(including the organic CAs) **are confirmed:**

- ensure the **effectiveness and appropriateness** of OCs and other official activities as well as their **impartiality, quality and consistency** at all levels by mean of a **sufficient number of suitably qualified and experienced staff** ;
- ensure that staff performing OCs and other official activities are free from any **conflict of interest**;
- have, or have access to, an **adequate laboratory capacity** for analysis, testing and diagnosis;
- have, or have access to appropriate and properly maintained **facilities and equipment**;



# General obligations concerning the CAs



- have the **legal powers to perform OCs** and other official activities and to take the relevant enforcement actions
- have **legal procedures** in place in order to ensure that staff **have access** to the premises of, and documents kept by, operators;
- have **contingency plans** in place and be prepared to operate such plans in the event of an emergency, where appropriate.

So **no particular problem** should be encountered by MS in ensuring the fulfilment of these requirements, at least when considering **CAs are already operating in the perimeter of Reg (EC) No 882/2004**

# Training (art. 5.4)

**I WANT YOU**



Staff performing OCs shall receive appropriate training  
“*enabling them to undertake their duties competently  
and to perform official controls and other official  
activities in a consistent manner*”

Commission Delegated Reg. (EU) 2019/624 lays down  
minimum training requirements for the **OVs**, official  
auxiliary and the **staff designated by the CAs**

The **Commission** may organise training activities for the  
staff of the CAs & other authorities (art. 130)



# Concept and practice of confidentiality (art. 8)

These are updated. Differently from Reg. 882/2004, laying down the principle according to which **information covered by professional secrecy** acquired in the framework of OCs was **not to be disclosed** to third parties, unless “**in duly justified cases**”, Reg. 2017/625 specifies what a “duly justified case” is: information shall not be disclosed “Unless there is **an overriding public interest**”



# An overriding public interest

To be assessed taking into consideration the **possible risks to:**

- Human health,
- Animal health,
- Plant health,
- Environment,

and the nature, severity and extent of such **risks** (art. 8.4)



# Reg. (EU) 2017/625

Confirms a **risk-based approach** to OCs including risks connected to possible cases of fraudulent or deceptive practices (**FRAUD**)



# Food fraud control



Clearly part of the principles of Reg. 178/2002 (the General Food Law):

*Food law shall pursue one or more of the general objectives of ... the **protection of consumers' interests**, including **fair practices in food trade***

...

and was already taken into consideration by Reg. 882/2004:

*This Regulation lays down general rules for the performance of OCs to verify compliance with rules aiming, in particular, at:*

*... guaranteeing **fair practices in feed and food trade** and **protecting consumer interests***

# Reg. (EU) 2017/625

Emphasizes the importance of **food fraud control**, in relation to

- **a dedicated set of controls (9.2)**
- **OCs frequency** (art. 9.2 , 65.4, 73.2),
- Frequency of Com controls in third countries (art.121)
- **official certificates** principles (90),
- designating **EU reference centers for the authenticity and integrity of the agri-food chain** (97, 98), and
- the general rules for **Administrative Assistance and Cooperation** (102)
- **penalties (139.2)**



# Reg 2017/625 poses great attention to transparency

Art. 11 is entirely dedicated to **transparency of OCs**.

Among others, CAs shall, at least once a year, **make available to the public relevant information** concerning the organisation and the performance of OCs and shall ensure that any **inaccuracies** in the information made available to the public are **appropriately rectified**.





# Additional requirements for official controls and other official activities in certain areas

A whole section is dedicated to **OCs** and other official activities to be performed **in specific areas** (art. 16 -27)

The Commission is to adopt **delegated and implementing acts** laying down specific requirements for these sectors

Delegated and implementing acts **substitute** or **update** the repealed **technical regulations** (eg. Reg. EC 854/2004)





## Articles 16 - 27

Lay down **specific rules to perform OCs** on sectors, like products of animal origin intended for human consumption, residues of relevant substances in food and feed, animal by-products, animal welfare, plant health, PDO, PGI and TSG products, etc., whose **requirements are laid down in specific legal acts** (e.g. Reg. EC 852/2004 and 853/2004, Reg. EC 1069/2011, Reg. 2016/2031, etc.)



# Additional requirements for official controls and other official activities in certain areas

Notably, the role of **official veterinarians** is updated: it's possible that certain meat inspections are performed either by an official veterinarian or by an official auxiliary **under his supervision** – or, if there are "sufficient guarantees" [risk-based], **under his responsibility**.



[Criteria and conditions are specified in Delegated Regulation (EU) 2019/624 and further specified in Implementing Regulation (EU) 2019/627]



# Delegation of tasks (art. 28 -33)

In respect of Reg. 882/2004, Reg. 2017/625 better qualifies “**control bodies**” as:

- “**delegated body**” – a **legal person** to which the CAs have delegated certain OC tasks or certain tasks related to other official activities

**Or**

- “**natural persons**” –to which certain official control tasks have been delegated in accordance with the regulation

Only **delegated bodies** are requested to work and to be **accredited** in accordance with standard **EN ISO/IEC 17020**



# Sampling, analyses, tests and diagnoses in the framework of OCs

Reg. 2017/625 clarifies the application of general criteria for **analytical, testing and diagnosing tests methods** already provided for in Reg. 882/2004 (art. 34). CAs may designate as an **official laboratory** or **National Reference Laboratory**, a laboratory located **in another** Member State or in a third **country** that is a Contracting Party to the Agreement on the European Economic Area subject to conditions (art. 37.2 and 100.1)



# Audits of official laboratories

**New**

- The CAs shall organise **audits of the official laboratories** (OL) they have designated, unless they find such audits to be redundant considering the accreditation assessment



# Audits of official laboratories

**New**



The CAs shall immediately **withdraw the designation** of an OL, either completely or for certain tasks, **where it fails to take** appropriate and timely **remedial action** when it is observed that:

- it **no longer complies** with the conditions on the basis of which it has been designated;
- it **does not comply** with the OLs obligations
- it **is underperforming** at inter-laboratory comparative tests

# Second expert opinion

- The operators' right to apply for a **second expert opinion** is strengthened. The way to grant the right for this second opinion is detailed (art 35)





# Sampling of animals and goods offered for sale by means of distance communication (art. 36)



- **Samples** of animals and goods **ordered on-line by CAs** without identifying themselves may be used for the purposes of an OC.
- CAs must, once they are in possession of the samples, **ensure that the operators** are informed and able to exercise the **right to a second expert opinion**.

# European Union reference laboratories and centres

European Union Reference laboratories have been **already designated** in accordance with **Reg (EC) 882/2004**.



Reg. 2017/625 lays down EU Reference Laboratories **designation process** [following a public selection process and being limited in time and with a minimum period of five years or reviewed regularly] – art. 93

# In addition to EU reference laboratories

Reg. 2017/625 provides for the designation of **European Union Reference Centres** for

animal welfare  
(art. 95 and 96)



To support the activities  
of the Commission and  
of the MSs in the field of  
**animal welfare**

the authenticity and integrity  
of the agri-food chain  
(art. 97 and 98)



To support the activities of the  
Commission and of the MSs to prevent,  
detect and combat violations  
perpetrated through fraudulent or  
deceptive practices (**FRAUD**)

# By means of the Implementing Regulation (EU) 2018/329 of 5 March 2018

The Commission designated a first European Union Reference Centre **for Animal Welfare Requirements (pigs)**

In October 2019, another center have been designated for **poultry and other small farmed animals**



# Obligation of the Commission (art 99.3)

EU reference laboratories  
and EU reference centres  
shall be **subject to  
Commission controls** to  
verify compliance with the  
requirements



# Financing OCs and other official activities (art. 78-85)



OCs financing **general criteria are confirmed:**

- adequate financial resources shall be made available to perform OCs and other official activities
- **Mandatory fees or charges:** MS shall collect fees or charges to **cover the costs**
  - following the detection of a case of **non-compliance** by the same operator, during an OC and to assess the extent and the impact of the NC
  - Of OCs carried out **on request of the operator** itself
  - In case of temporary **increased import controls**
- **Other fees or charges (non mandatory)**
- **Method for calculating fees or charges**

# Fees and charges transparency (art. 85)

## Information on

methods and data used to establish fees

the amount charged to each category of operators/official control

OCs costs composition

the identity of the authorities or bodies responsible for the collection of the fees or charges

Shall be made available to  
the public



# Transparency and fees and charges (art. 85)

MSs shall be transparent and make available to the public the information on:

- the **method** and data used **to establish fees or charges**
- **the amount** of the fees or charges, applied to each category of operators and for each category of official controls or other official activities and
- the **components of the costs** born by CAs to perform OCs (how they were determined),



# Fees and charges transparency (art. 85)

CAs shall regularly **make available** to the public the above-mentioned information and **the costs sustained by the relevant CA** to perform OCS for which a fee or charge is due

**Relevant stakeholders** shall be consulted on the general methods of calculation of fees



# Administrative Assistance and Cooperation (AAC) – art. 102 - 108

A **deadline for answering** following a request is defined, both in case of assistance on request and assistance without request

**Assistance on request:** MS must indicate, within **ten working days**, the estimated time necessary to provide an informed response. (art 104)



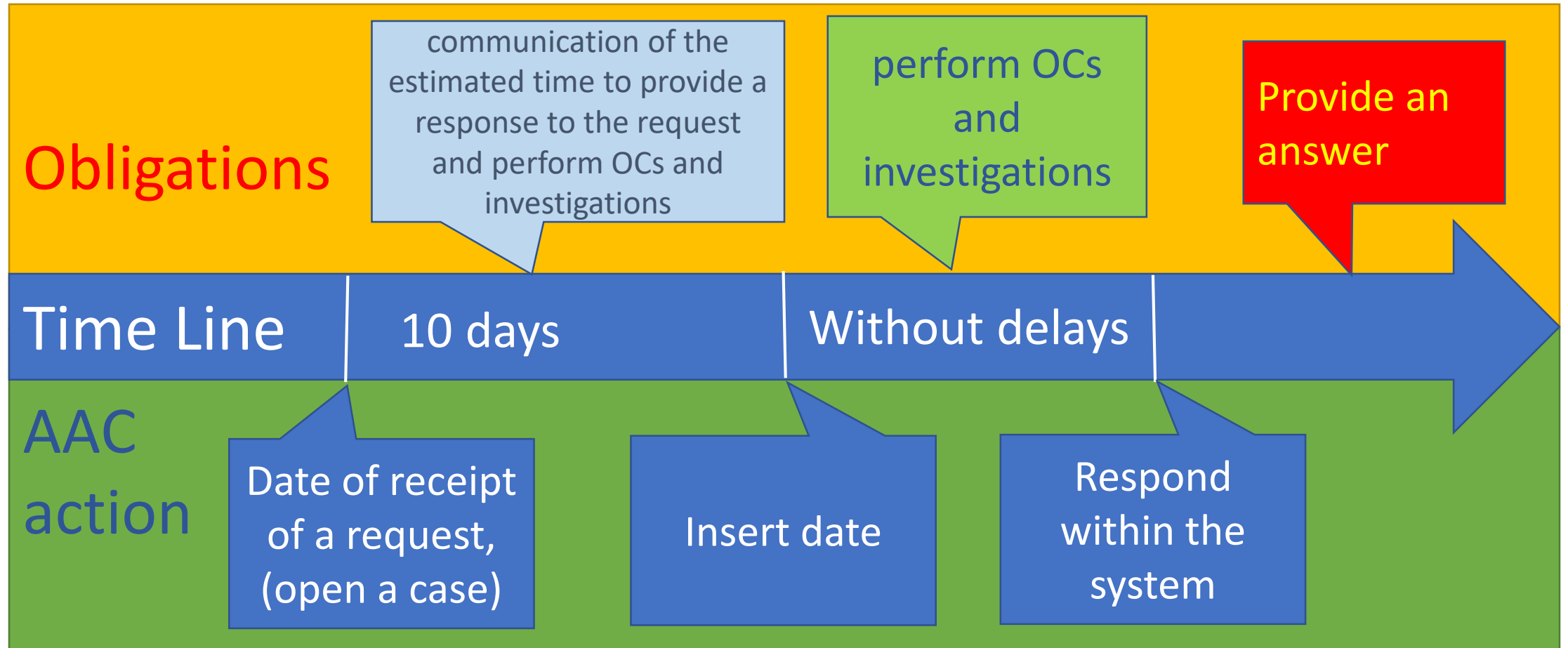
# Administrative Assistance and Cooperation (AAC) – art. 102 - 108



When the CAs in a MS become aware of a case of NC that could have implications for another MS, it shall notify such information to the CAs of that other MS **without undue delay** (Assistance without request) (art 105)

CAs in the notified MS, where requested, must indicate within **ten working days** what investigations they intend to carry out or why no investigation is necessary and other relevant information.

# New procedure for Administrative Assistance



# What is IMSOC?

Keywords

CONSOLIDATION-EFFICIENCY-EVOLUTION

**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/adns/europhyt/irasff/aac)

**NO/YES**

It will connect them and extend functionalities (some systems will be absorbed as functionalities overlap)

**What is its purpose?**

**Toward a better collective controls efficiency**

# IMSOC scope and functionalities

IMSOC shall allow the computerised **handling and exchange** (in real time) **of information**, data and documents

- **necessary for** the performance of OCs,
- **resulting from** the performance of OCs or
- **the recording of** the performance of OCs or
- **the outcome of OCs**





# Multi-annual national control plans (MANCP) (art. 109 – 113)

MSs must:

- ensure that **OCs** are **performed** by the CAs **on the basis of a MANCP**, *“the preparation and implementation of which are coordinated across their territory”*.
- designate **a single body** tasked with **coordinating** the preparation of the MANCP and ensuring its coherence.
- make the MANCP **available to the public**, *“with the exception of those parts of the plan the disclosure of which could undermine the effectiveness of OCs”*.



# Annual reports (art. 113 – 114) - deadlines

By the **end of August** of each year, **MSs** shall submit to the Commission a report summarising the official activities carried out the previous year in the framework of the MANCP

By **31 January** every year, **the Commission** shall make **available to the public** an annual report on the operation of official controls in the Member States and may contain recommendations on possible improvements to the OC systems in the MS.



# Commission controls in MSs (art. 116)



The **Commission experts** may **accompany** the staff of the CAs performing OCs and **experts from the MSs may assist** the Commission experts. National experts accompanying Commission experts shall be given the **same rights** of access as the Commission experts

# The commission controls and transparency (art. 117 – 119)

By the end of each year, the Commission shall **communicate** to the MSs the **annual control program** or any update to the multiannual control program for the following year

The Commission shall issue a **report on the findings** of the controls performed, including possible recommendations addressing the shortcomings identified by its experts during the performed controls and **considering the comments of the concerned MS**

The **final report** shall be made publicly **available** along with the comments of the MS

# Enforcement actions

Action to be perform **in case of suspicion** of NC (e.g. OCs intensification, seizure of animals and goods and of any unauthorized substances or products) are outlined.



The CAs shall perform an **investigation** in order to **confirm or to eliminate** that suspicion (art. 137)

The Commission is empowered to adopt delegated acts laying down rules for the **performance of the OCs in case of suspicion** of NC in certain areas (art. 19, 20)



# Important! – First eliminate or contain risks

The right of appeal (art. 7) and second opinion (art. 35) shall not affect the obligation of competent authorities to take prompt action to eliminate or contain the risks to human, animal or plant health, to animal welfare or, as regards GMOs and plant protection products, also to the environment



# Where the non-compliance is established

the CAs shall take any action necessary to **determine**:



- the **origin** and
- **extent** of the non-compliance and
- to establish the operator's **responsibilities**



Furthermore, the AC shall take appropriate measures to **ensure that the operator** concerned **remedies the non-compliance** and prevents further occurrences of such non-compliance



## Among others, CA



May order:

- the alteration of labels or **corrective information** to be provided **to consumers**,
- the operator to **increase the frequency of own controls**,
- **increased** or systematic **official controls**,
- the **cessation of Internet sites** it operates or employs,
- the **slaughter or killing of animals under certain conditions**.

# Sanctions and Fraud (art.139)

MSs shall ensure that **financial penalties** for violations of Reg. 2017/625 and of the rules to which the regulation applies, perpetrated **through fraudulent or deceptive practices**, reflect, in accordance with national law, **at least** either the **economic advantage** for the operator or, as appropriate, a percentage of the operator's turnover.



# Reporting of infringements and protection for persons reporting an infringement

MSs shall ensure that CAs have effective mechanisms to enable reporting of actual or potential infringements of Reg. 625 including:

- procedures for the receipt of reports of infringements and their follow-up
- appropriate protection for persons reporting an infringement and their personal data in accordance with EU and national law



# A cathedral yet to be finished

The Commission is empowered to adopt **delegated and implementing acts** to ensure the complete the legal frame



# Conclusion

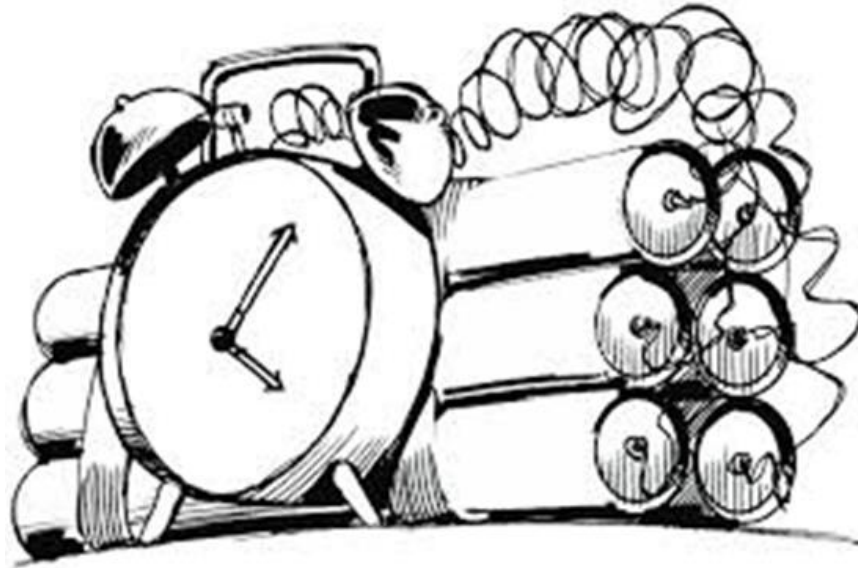
- Reg. (EU) 2017/625 confirms the general principles of Reg. 882/2004, expands the scope of OCs to include any activity connected to the agri-food chain (plants + animal by-products included in the scope) increases the quality of official controls, modernises the legislation and strengthens the legal basis against food fraud
- Reg (EU) 2017/625 does not lay down new requirements for the operators in addition those in the relevant legislation

# Conclusion

- The need to effectively **contrast (food) frauds** is stressed
- **Activities** performed **by CAs** shall be carried out **transparently** and shall be **publicised**
- **Integration and cooperation** among CAS operating at any level is improved. Existing **IT systems shall be integrated**
- To complete the structure of the future OCs system, a series of **implementing and delegated acts** shall be (have been) adopted by the Commission

# Conclusion

- Main **date of application** of the new system is **December 14<sup>th</sup> 2019** (very close!)







Thank you for your  
attention