Questions & Answers

on Commission Regulation (EC) No 2017/625 (Official Controls Regulation)

DISCLAIMER

This document has no formal legal status. Ultimate responsibility for the interpretation of the law lies with the Court of Justice of the European Union.

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1.	What is the new Official Controls Regulation about?	• The Official Controls Regulation (OCR) provides the framework for Member States (MS) to verify that businesses comply with agri-food chain rules. • The agri-food chain encompasses all those activities that range from plants and animals production to food manufacturing and supply, including activities that take place at farm level, processing and distribution to the consumer. • Agri-food chain rules therefore cover the safety and quality of food and feed, plant health, animal health and welfare. They also cover import controls on animals and goods entering the EU from third countries (i.e. countries outside the EU). • The OCR replaces the current regulation on official controls (Regulation (EC) No882/2004).
2.	What are official controls and who does carry them out?	• Official controls are those activities carried out by the competent authorities (or delegated bodies) in the Member States to verify business compliance with the requirements set out in agri-food chain legislation.
3.	What are competent authorities?	In the context of official controls competent authorities are: • the central authority or authorities of a Member State that are responsible for organising official controls • any other authority which has been given that responsibility • where appropriate, the corresponding authority of a third country. (See Article 3.3).
4.	What new elements does the OCR contain?	• The scope has been extended to cover the agri-food chain; • Increased transparency for official control activities carried out by competent authorities, including on the calculation of fees for official controls; • More specific rules to target fraud, including the obligation for Member States to perform regular and un-announced, risk based controls; • Financial penalties targeting fraudulent behaviour must reflect the economic advantage of the perpetrator, or a percentage of his/her turnover; • EU Reference Centres will be established for animal welfare and the possibility of Centres for the authenticity and integrity of the agri-food chain has been created; • Stronger rules on administrative assistance and cooperation between Member States in cases of cross-border non-compliance;

		• A common framework for import controls with risk adjusted frequencies for all import checks. • Border Control Posts (BCPs) will replace current Border Inspection Posts (BIPs), Designated Points of Entry (DPEs), etc. All BCP will have to fulfil minimum requirements for facilities, equipment, etc. • Use of one Common Health Entry Document (CHED) for consignments from third countries. • An integrated information management system (IMSOC) to link all existing (and future) computer systems, e.g. TRACES[1], RASFF[2] and Europhyt[3] to ensure optimal exchange of information between MS.
5.	How has the scope of the OCR been extended compared to the previous Regulation?	• The new rules extend the scope of the previous Regulation to also cover animal-by product rules and plant health. Plant reproductive material (e.g. seeds) is not covered as the Council and EU Parliament could not agree on this. • Furthermore, the OCR applies when fraudulent and deceptive practices concerning marketing standards for agricultural products are identified during checks performed under marketing standards rules (Regulation (EU) No 1306/2013).
6.	What main benefits will be brought by the new OCR?	The main benefits can be summarised as follows: • A harmonised and coherent regulatory approach to official controls and enforcement actions along the agri-food chain; • Increased transparency and greater accountability required by Member States competent authorities through the publication of information about the organisation and performance of official controls; • More stringent rules on fraud will provide greater consumer protection and benefit compliant businesses; • A common set of rules for controls at EU borders that overcomes the current fragmentation and makes the control system less burdensome for enforcers and businesses; • An integrated computerised system to improve the exchange of information between Member States on official controls; • Greater flexibility in relation to the accreditation of official laboratories (i.e. formal recognition of competence in their field); • Businesses and authorities will benefit from reduced administrative burdens, more efficient processes and strengthened controls.
7.	What are the obligations of the	The OCR sets out a number of general obligations for competent authorities. These include for example: • having a sufficient number of suitably qualified and experienced staff.

[1] https://webgate.ec.europa.eu/sanco/traces/
[2] https://ec.europa.eu/food/safety/rasff_en
[3] https://ec.europa.eu/food/plant/plant_health_biosecurity/europhyt_en

	competent authorities?	• ensuring impartiality, quality and consistency of official controls. • ensuring that staff are free from conflict of interest. • having legal powers to perform controls and suitable facilities and equipment. • carrying out internal audits or have external audits carried out on themselves, etc.
8.	Will staff of the competent authorities be required to undergo the appropriate training?	• Yes. Member States must provide regular training for competent authorities' staff performing official controls. • The Commission can establish rules that identify specific training needs for staff. • Training programmes for competent authorities' staff can be organised and funded by the Commission under the Better Training for Safer Food (BTSF) program.
9.	Can official control activities be delegated?	• The new OCR allows Member States to delegate certain official control tasks to delegated bodies. The delegated bodies must fulfil certain conditions set out in the Regulation. • These conditions include having the necessary expertise, facilities and equipment and employ staff that are suitably qualified, impartial and free from any conflict of interest in respect of the particular task. • In addition, the competent authority must audit or inspect the delegated body and, if the delegated body does not meet any longer the specified conditions, the delegation must be withdrawn.
10.	Can enforcement actions be delegated?	• The responsibility for taking action in the case of established non-compliance cannot be delegated and must be taken by the Competent Authority of the MS.
11.	What are the main principles for performing official controls?	The OCR provides general rules for performing official controls. These rules include for example the obligation for competent authorities to perform controls: • regularly, in accordance with a risk-based approach and with appropriate frequency. • without prior notice, unless prior notice to the business concerned is necessary and duly justified to carry out official controls. • at all stages of production, processing and distribution and use. (See Article 9 and 10)
12.	What is a risk-based approach and what benefits does it bring?	• In planning official controls Member States competent authorities determine how frequent controls on animals and goods need to be carried out along the agri-food chain. • To ensure efficient and effective use of resources controls should focus on those areas and activities where the risk (including risk of non-compliance) is higher. To this end Member States competent authorities must take into account:

		– the risk to human, animal or plant health, animal welfare or the environment (for genetically modified products and plant protection products) associated with animals or goods; – the likelihood that consumers might be misled about the nature, quality or origin of products; – factors such as the operator's past record of compliance and the reliability of own controls must be taken into consideration. (See Article 9 for details).
13.	What are the obligations of the operator?	• Operators, during official controls, are required to assist and cooperate with the staff of the competent authority. • More specifically, to the extent necessary to perform official controls, operators would need to give access for example to their equipment, premises, means of transport, documents, etc.
14.	What measures does the OCR introduce to increase transparency about the outcome of control activities?	• MS have to publish, at least once a year, relevant information about the outcome of the official controls performed, types and number of cases of non-compliance, measures taken, etc. • MS have the option to make publicly available the information about the outcome of official controls regarding individual operators. In this case the operator concerned must be given the opportunity to comment on the information. The operator's comments need to be reflected in the information published. • MS may establish fair and transparent rating scheme systems for operators to inform consumers about the compliance performance of retailers, restaurants, cafes, etc. (See Articles 8 and 11).
15.	What does the OCR do to address fraud along the agri-food chain?	• The OCR requires the Member States competent authorities to carry out regular, unannounced controls directed at identifying possible violations of agri-food chain rules through fraudulent and deceptive practices. • In planning such controls Member States competent authorities must take account of the likelihood that consumers are misled about properties, composition, quality or country of provenance of the food they buy. • Rules on financial penalties for fraudulent and deceptive practices are significantly reinforced. These penalties will need to reflect the economic advantage gained by the operator or a percentage of his/her turnover. • To support Member States in their activities to prevent and detect fraudulent and deceptive practices, EU Reference Centres for the authenticity and integrity of the agri-food chain may be established.
16.	What does the new OCR do to help Member States assist and cooperate with each	• The OCR reinforces and clarifies the rules on administrative assistance and cooperation between Member States in cases of cross-border breaches of agri-food chain rules, so that non-compliance can be addressed in a more efficient manner (Article 102 to 108).

	other?	• The exchange of information between Member States will be supported by an integrated computerised system. • If cross-border non-compliance affects more than one Member States which cannot be solved between the MS concerned, the Commission will coordinate the measures and actions between those Member States (see article 108).
17.	What is the Integrated Management System for Official Controls (IMSOC) and how will it operate?	• The Integrated Management System for Official Controls (IMSOC) will be a new computerised system that will integrate all the existing (and future) information exchange systems, such as TRACES, RASFF and Europhyt. The aim is to make the most effective use of resources.
18.	How does the Regulation affect import controls?	• The Official Control Regulation introduces a common set of rules for controls carried out at EU borders on animals and goods coming from third countries. • Border Control Posts (BCP) will replace what are currently known as Border Inspection Posts (BIP) and Designated Points of Entry (DEP). • Controls (such as documentary, identity and physical checks) will be risk-based and carried out with appropriate frequency (see Article 44). • A list of animals and goods that must be systematically checked at the BCP is provided by the OCR (see Article 47). • Animals and goods to be systematically channelled through the BCP will always undergo documentary checks. Identity and physical checks will be carried out at a frequency depending on the risk posed by the animals or goods.
19.	What documents must be submitted for import purposes?	• The OCR introduces the use of one Common Health Entry Document (CHED) for the prior notification of the arrival of consignments from third countries. The CHED will therefore simplify the current notification system.
20.	Does the OCR apply to exports from the EU?	• Yes. Competent authorities must perform official controls in the same manner, regardless of whether the animals or goods concerned are on the EU market, imported into the EU or to be exported from the EU.
21.	Does the OCR set out requirements for financing of official controls?	• Yes. The OCR requires Member States to ensure that they have adequate financial resources to perform official controls. • For certain controls, the OCR establishes mandatory fees. They are: – Official controls carried out in slaughterhouses, cutting plants, on milk production, on the production and placing on the

		market of fishery and aquaculture products; – official controls on certain animals and goods systematically checked at BCPs; – goods coming from third countries for which a temporary increase of controls at borders has been established; – animals and goods subject to emergency measures to enter the Union; – official controls performed to issue the approval of feed premises; – official controls not originally planned, but necessary after detection of non-compliance. • MS may collect further fees for other official controls or activities.
22.	What types of costs need to be taken into account when calculating the amount of fees for official controls?	• Fees for official controls must take into account the type of costs outlined in the OCR. • These include for example salaries of staff, the cost of facilities and equipment, the cost of tools, etc. (See Article 81).
23.	Will stakeholders be consulted over the calculations fees?	• Yes. Member States must consult relevant stakeholder on the general methods used to calculate fees. (See Article 85.3).
24.	Will the Commission propose implementing legislation on fees?	• No. Requirements for financing of official controls are laid out in the OCR. The Regulation does not provide empowerments for the Commission to adopt implementing legislation on fees.
25.	What are the official laboratories and how will they perform?	• Official laboratories are the laboratories designated by the competent authorities to undertake analysis, tests or diagnosis of samples that have been taken for official control purposes. • The OCR sets out the requirements to be met to designate official laboratories like for example accurate description of the tasks that the laboratory can carry out, the laboratory has the necessary equipment and expertise, accreditation to ISO standards, etc. (See Article 37). • The OCR provides for certain permanent (Article 40) and temporary derogations (Article 42) from mandatory accreditation to avoid disproportionate regulatory burdens.

		• Plant health laboratories have been given a 5-year transitional period in order to comply with mandatory accreditation requirements (see article 167(2)).
26.	What are the changes for EU Reference Laboratories?	• EU Reference Laboratories (EURL) will continue to play an important role in providing the necessary scientific and technical support to national reference laboratories • The Commission designates EURL after a public selection. Such designation will last for at least five years or be regularly reviewed. • The designation of present EURLs will need to be confirmed under the OCR rules once the period of their designation ends.
27.	Will the OCR establish new EU Reference Laboratories?	• The OCR provides procedures to establish EU Reference Laboratories in a two-step approach: 1. The decision that a EURL is needed will be taken by a delegated act involving the European Parliament. 2. The actual designation will be implemented by the Commission. • The Commission will review the EURLs mandate and operations regularly.
28.	Will the OCR establish new EU Reference Centres (EURC)?	• Yes. At least one EU Reference Centre has to be established for animal welfare. The OR provides moreover the option to create an EU Reference Centres for the authenticity and integrity of the agri-food chain. • The new EU Reference Centres are expected to provide Member States with up-to-date, reliable technical data and research findings to support the performance of their control tasks.
29.	Will official controls be performed on sales done over the internet (i.e. e-commerce)?	• Food law applies to products sold via the Internet in the same way as to conventional sales (i.e. via markets, brick-and-mortar stores, catalogues etc.). Hence controls of e-commerce of food must be performed in accordance with the OCR rules. • In case of non-compliance the Member States must take appropriate action, e.g. order closure of the Internet site (see Article 138).
30.	How can products offered on sale online be officially sampled?	• To obtain random samples for official control Member States competent authorities can order products offered online without identifying themselves (i.e. 'mystery shopping'). After receipt of these products, the competent authority must reveal its identity (See Article 36).

31.	Can operators obtain a second expert opinion on test results?	• Operators, whose animals and goods are sampled for analysis, tests or diagnoses in the context of official controls, have the right to request a second expert opinion at their own expense. To this end, sufficient quantities of official samples should be taken where feasible (See Article 35).
32.	Will the Commission check that the national control systems in Member States are effective?	• The OCR enables the Commission to carry out controls and audits in Member States to assess the application of the agri-food chain and of the OCR rules, and the functioning of national control systems (See Article 116). • Where the control system of a Member State is seriously disrupted the Commission can adopt a number of measures (e.g. prohibition to place on the markets the animals or goods affected by the disruption). (See Article 141)
33.	Will the Commission perform controls in third countries?	• Yes. The OCR enables the Commission to verify that legislation and control systems in third countries comply with or are equivalent to the EU standards.
34.	When do the new rules from the OCR apply? Is there a transition period for MS?	• The new OCR will enter into force after 20 days from the publication in the Official Journal: 27/04/2017. • Most provisions like those – concerning the scope, definitions, competent authorities' obligations, financing of official controls, administrative assistance, etc. will apply from 14th December 2019.
35.	How will the OCR's empowerments for delegated and implementing acts be implemented?	• The Commission will prioritise work on those acts which must be adopted by the application date of the OCR.
36.	Will Member States and other stakeholders be consulted on delegated and implementing acts?	• Yes, the Commission will consult Member States and stakeholders in line with Better Regulation Guidelines (see at http://ec.europa.eu/smart-regulation/guidelines/ug_chap7_en.htm)