European Commission

Commission Notice on the Implementation of Regulation (EU) 2017/625 of the European Parliament and of the Council

(Official Controls Regulation)

This Commission Notice is intended to assist national authorities in the application of Regulation (EU) 2017/625. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

Further information on the Health and Food Safety Directorate-General is available on the internet at:
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Health and Food Safety Directorate-General

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Contents

ABBREVIATIONS

BCP	Border control post: As defined in point 38 of Article 3 of Regulation (EU) 2017/625
CA	Competent Authority: As defined in point 3 of Article 3 of Regulation (EU) 2017/625 of the European Parliament and of the Council[1].
CHED	Common health entry document: As referred to in Article 56 of Regulation (EU) 2017/625.
CN	Combined Nomenclature
COI	Certificate of Inspection: As referred to in Articles 4 and 5 of Commission Delegated Regulation (EU) 2021/2306[2]
EU CSW-CERTEX	The electronic European Union Customs Single Window Certificates Exchange System: As defined in Article 4 of Regulation (EU) 2022/2399[3]
EURC	European Union reference centre
EURL	European Union reference laboratory
HACCP	Hazard analysis and critical control points: As referred to in Article 5 of Regulation (EC) No 852/2004[4].
IMSOC	Information Management System for Official Controls: Article 131 of Regulation (EU) 2017/625.

1 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) (OJ L 95, 7.4.2017, p. 1).

2 Commission Delegated Regulation (EU) 2021/2306 of 21 October 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with rules on the official controls in respect of consignments of organic products and in-conversion products intended for import into the Union and on the certificate of inspection (OJ L 461, 27.12.2021, p. 13).

3 Regulation (EU) 2022/2399 of the European Parliament and of the Council of 23 November 2022 establishing the European Union Single Window Environment for Customs and amending Regulation (EU) No 952/2013 (OJ L 317, 9.12.2022, p. 1).

4 Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

iRASFF	The electronic system implementing the RASFF System: As defined in Article 2(7) of Commission Implementing Regulation (EU) 2019/1715[5] (IMSOC Regulation).
NRL	National reference laboratory
OC	Official control(s)
OCR	Official Controls Regulation: Regulation (EU) 2017/625
OIE	Office international des epizooties – World Organisation for Animal Health
OOA	Other official activity
OV	Official Veterinarian: As defined in point 32 of Article 3 of Regulation (EU) 2017/625.
RASFF	Rapid Alert System for Food and Feed: As defined in Article 2(9) of Commission Implementing Regulation (EU) 2019/1715
TRACES TRACES-NT	TRACES (Trade Control Expert System) New Technology: The computerised system referred to in Article 133(4) of Regulation (EU) 2017/625 for the purposes of exchanging data, information and documents.

5 Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation) (OJ L 261, 14.10.2019, p. 37).

INTRODUCTION

Agri-food chain legislation aims to prevent risks and to promote certain aspects of quality of production of animals and goods, both for commodities entering the European Union and those already on the market. Member States have to put in place control systems, which verify operators' compliance with the requirements set out in agri-food chain 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 (Official Controls Regulation – OCR) represents a harmonised framework for the performance of such official controls and activities along the entire agri-food chain.

Since the date of application of the OCR, Member States have asked the Commission at numerous occasions to provide clarifications and advice on the practical application of certain OCR provisions, as well as provisions laid down in implementing or delegated acts adopted on the basis of the OCR. The purpose of this Notice is to compile the Commission's views with regard to the most requested provisions in order to contribute to a harmonised understanding and application of these provisions by Member States' competent authorities and stakeholders.

A first set of clarifications has been published in 'Commission Notice 2022/C 467/02 on the implementation of Regulation (EU) 2017/625 (Official Controls Regulation)' of 8 December 2022. Since then, the Commission has continued discussions with Member States and stakeholders in relation to other OCR provisions. The current document is a revision of the first Commission Notice that adds new elements of clarification, while the elements of the earlier Notice remain unchanged.

This Notice is without prejudice to the exclusive competence of the Court of Justice of the European Union to authoritatively interpret Union law.

1. TITLE I – SUBJECT-MATTER, SCOPE AND DEFINITIONS

1.1. Official Controls and Other Official Activities (Article 2 of the OCR)

Article 2 of the OCR defines and makes a distinction between 'official controls' or 'other official activities' carried out by competent authorities designated in accordance with Article 4 of the OCR:

Article 2 of the OCR

Official controls and other official activities

For the purposes of this Regulation, 'official controls' means activities performed by the competent authorities, or by the delegated bodies or the natural persons to which certain official control tasks have been delegated in accordance with this Regulation, in order to verify:

compliance by the operators with this Regulation and with the rules referred to in Article 1(2); and

that animals or goods meet the requirements laid down in the rules referred to in Article 1(2), including for the issuance of an official certificate or official attestation.

For the purposes of this Regulation, 'other official activities' means activities, other than official controls, which are performed by the competent authorities, or by the delegated bodies or the natural persons to which certain other official activities have been delegated in accordance with this Regulation, and with the rules referred to in Article 1(2), 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.

Further clarifications on 'other official activities' are provided in recital 25 of the OCR:

> *Recital 25 of the OCR*
>
> *Union agri-food chain legislation entrusts additionally the competent authorities of the Member States with specialised tasks to be carried out for the protection of animal health, plant health and animal welfare and for the protection of the environment in relation to GMOs and plant protection products. Those tasks are the public interest activities which the competent authorities of the Member States are required to carry out for the purpose of eliminating, containing or reducing any hazard which may arise for human, animal or plant health, animal welfare or also for the environment. Those other official activities, which include the granting of authorisations or approvals, the epidemiological surveillance and monitoring, eradication and containment of diseases or pests, as well as the issuance of official certificates or attestations, are governed by the same sectoral rules which are enforced through the official controls and therefore by this Regulation.*

This distinction is important, because different rules and conditions apply, depending on whether an activity is an 'official control' or an 'other official activity'. In particular, Article 1(5) of the OCR specifies which provisions of the OCR also apply to other official activities and, as a corollary, which provisions only apply to official controls. For example, while operators are entitled to a second expert opinion with regard to the sampling, analysis, test or diagnosis carried out on their animals or goods in the context of official controls (Article 35 of the OCR), this right does not extend to the sampling, analysis, test or diagnosis of animals or goods in the context of other official activities. The distinction between official controls and other official activities is also relevant in relation to the calculation of mandatory fees and charges in accordance with Article 79 of the OCR because that provision only applies to official controls and not to other official activities (see also 2.5. CHAPTER VI – Financing of official controls and of other official activities (Articles 78 to 85 of the OCR) below).

As stated in Article 2 of the OCR, both 'official controls' and 'other official activities' are carried out by a 'competent authority', 'delegated body'[6] or a natural person to which certain official control tasks or other official activities have been delegated in accordance with the OCR. Article 2(1) of the OCR defines that 'official controls' are performed for the purpose of verifying compliance by operators or by animals or goods[7] with the OCR and/or the rules referred to in Article 1(2) thereof. This definition implies three characteristics that an activity must fulfil at the same time in order to be regarded as an 'official control' in the meaning of the OCR:

6 The definitions of 'competent authority' and 'delegated body' can be found in Article 3(3) and (5) of the OCR, respectively.

7 The definitions of 'animals', according to Article 3(9) of the OCR, is the one included in point (1) of Article 4 of Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1). The definition of 'goods' can be found in Article 3(11) of the OCR.

Its purpose is

(i) the verification of compliance,

(ii) by operators or by animals or goods,

(iii) with the OCR and/or the rules referred to in Article 1(2) thereof.

For example, with regard to point (i) above, while the verification of compliance with the rules referred to in Article 1(2) of the OCR for the purpose of issuing an official certificate or official attestation is an 'official control', the issuance of a certificate (on the basis of an official control performed prior to the issuance) is not itself carried out 'in order to verify compliance' and is therefore an 'other official activity'.

With regard to point (ii) above, for example, the verification of compliance of the competent authority with OCR rules would not be considered an 'official control', because the 'competent authority' in the meaning of Article 3(3) of the OCR is not an 'operator' in the meaning of Article 3(29) of that Regulation. By analogy, verifications of compliance of official laboratories or delegated bodies with obligations established in the OCR would be considered 'other official activities'. However, it is not excluded that the rules referred to in Article 1(2) of the OCR establish obligations for those entities and, in that case, those entities could qualify as 'operators', and verifications of compliance with such rules could therefore qualify as 'official controls'.

With regard to point (iii) above, for example, checks of compliance with rules other than the OCR and the agri-food chain legislation referred to in Article 1(2) of the OCR would be considered neither 'official controls' nor 'other official activities' within the meaning of the Article 2 of the OCR.

In general, all the steps necessary to complete an activity should be considered part of that activity. This includes documentation steps, such as writing official control reports or recording the outcome of an activity in electronic systems (e.g., finalizing and signing a CHED). By contrast, for example, the issuance of an official certificate is a separate activity that results in the production of a document with legal effect, which is based on the outcomes of a finalised and documented official control but is itself not part of the official control. Some other examples of 'other official activities', in line with the views expressed by the Member States during the drafting of the OCR and during the discussions in the Council, are:

- management of lists of registered/ approved operators;
- guidance/advice to operators on Union agri-food chain legislation and its implementation;
- surveys on the presence of pests of plants;

- surveillance for the detection of animal diseases;
- epidemiological investigations of food-borne outbreaks;
- notification of animal diseases or pests of plants;
- eradication and containment of animal diseases or pests of plants;

Where an established non-compliance gives rise to the suspicion of further non-compliances (Article 137(2) of the OCR), or elicits investigations aimed at determining the extent or origin of the non-compliance or the responsibility of the operator (Article 138(1)(a) of the OCR), such activities are itself aimed at verifying compliance and should therefore be considered 'official controls'.

Some activities may be either official controls or other official activities, depending on their purpose. For example, the verification of the presence of a disease in the context of an eradication programme qualifies as an 'other official activity' in accordance with Article 2(2) of the OCR, while the verification of the presence of the same disease can be an 'official control', if it is performed in order to verify compliance with the rules referred to in Article 1(2) of the OCR. In particular, some of the methods and techniques for official controls mentioned in Article 14 of the OCR are equally used during surveillance and epidemiological investigations (e.g., examination of documents and traceability records, interviews, sampling, analysis, diagnosis and tests, etc.). For those activities, if necessary, a differentiation between the two contexts can be made based on the characteristics described above.

Some practical examples of 'official controls' and 'other official activities' are included in Table 1 below.

Table 1: Examples of official controls (OC) and other official activities (OOA)

#	Activity	OC	OOA	Comment / reasoning
1.	Checking the list of prior notifications of consignments entering the Union for the planning of border controls		OOA	Preparation prior to performance of official controls
2.	Establishing an eradication program		OOA	Eradication and containment of diseases or pests (cf. recital 25 of the OCR)
3.	Making use of the results of surveillance conducted by operators		OOA	Data analysis informing/assisting preparation of official controls, not itself verification of compliance
4.	Drafting of written procedures for the performance of official controls		OOA	Preparation/assistance prior to official controls
5.	Checking records of transit consignments	OC		Verification of compliance (with Article 19(e) of Commission Delegated Regulation (EU) 2019/2124[8])
6.	Taking samples of consignments entering the Union according to TRACES-NT	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR
7.	Carrying out checks on animals and goods entering the Union.	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR
8.	Checking whether a CHED has been correctly filled in by the operator	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR

8 Commission Delegated Regulation (EU) 2019/2124 of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for official controls of consignments of animals and goods in transit, transhipment and onward transportation through the Union, and amending Commission Regulations (EC) No 798/2008, (EC) No 1251/2008, (EC) No 119/2009, (EU) No 206/2010, (EU) No 605/2010, (EU) No 142/2011, (EU) No 28/2012, Commission Implementing Regulation (EU) 2016/759 and Commission Decision 2007/777/EC (OJ L 321, 12.12.2019, p. 73).

#	Activity	OC	OOA	Comment / reasoning
9.	Sampling and analysis of a consignment at a Border Control Post	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR
10.	Sampling and analysis of a consignment at the place of destination after cross-border trade	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR
11.	Check if the movement restrictions have been complied with by an operator	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR
12.	Sampling and analysis of a consignment in a quarantine establishment, as required by Union rules	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR
13.	Sampling and analysis for an emerging disease		OOA	Epidemiological surveillance; cf. OCR recital 25
14.	Sampling of wild animals to survey for a listed disease		OOA	Surveillance programme to verify presence of disease; cf. OCR recital 25
15.	Checking if an operator complies with specific requirements prescribed by an eradication programme for a listed disease	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR
16.	Assistance to an operator on biosecurity measures to prevent the spread of listed diseases, provided by the competent authorities, or by the delegated bodies or the natural persons to which certain other official activities have been delegated in accordance with the OCR and with the rules referred to in Article 1(2) of the OCR		OOA	Assistance, not verification of compliance with the rules referred to in Article 1(2) of the OCR

#	Activity	OC	OOA	Comment / reasoning
17.	Checking production data to verify if the operator notifies abnormal mortalities, significant decreased production rates with undetermined cause or suspicions of certain listed diseases etc. as required by Union rules	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR
18.	Sampling and analysis to maintain status of a Member State, zone or establishment as free from a listed disease/pest		OOA	Surveillance programme to verify presence of disease
19.	Carrying out risk-based surveys to check for the presence of pests		OOA	cf. Article 2(2) and recital 25 of the OCR
20.	Assessing compliance of organic food and feed products prior to placing on the market	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR
21.	Verification of compliance with Maximum Residue Levels	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR
22.	Epidemiological investigation to determine the extent of the spread of a disease		OOA	cf. Article 2(2) and recital 25 of the OCR
23.	Regular or risk-based controls in an approved establishment to check if the operator continues to comply with the approval requirements	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR
24.	Actions (e.g., inspection, documentary scrutiny etc.) in relation to an establishment which applied for approval as required by Union rules (e.g., an assembly centre, an aquaculture establishment, a germinal product establishment)	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR

#	Activity	OC	OOA	Comment / reasoning
25.	Auditing of slaughterhouses/cutting plants for good hygiene practices and procedures based on the HACCP principles	OC		Verification of compliance with rules referred to in Article 1(2) of the OCR
26.	Verifying (including sampling and analysis) if the necessary investigations into abnormal mortalities or significantly decreased production are duly done by a private veterinarian in accordance with Article 18(1)(c) of Regulation (EU) 2016/429[9]	OC		Verification of compliance of operators and private veterinarians with the rules referred to in Article 1(2) of the OCR
27.	Verifying compliance with the rules referred to in Article 1(2) of the OCR of animals and goods entering the Union	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR
28.	Taking a decision and signing the CHED	OC		Part of finalization of official control
29.	Inserting the results of checks on animals and goods entering the Union in TRACES-NT	OC		Part of finalization of official control
30.	Issuing a permit for the entry into the Union of animals, including permits on the basis of entry rules that are not fully harmonised at Union level		OOA	Activity based on the outcomes of official controls (in analogy to the issuance of an official certificate or attestation (Article 2(2) of the OCR). Article 1(2) of the OCR refers to rules established both at Union and at national level.

9 Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

#	Activity	OC	OOA	Comment / reasoning
31.	Sampling and analysis done to check the compliance of an animal/consignment with requirements to be certified for cross-border trade	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR
32.	Checks performed by competent authorities or delegated bodies/persons on lots of plants or plant products for the presence of Union quarantine pests or regulated non-quarantine pests for the purpose of issuing a phytosanitary certificate	OC		Verification of compliance with the rules referred to in Article 1(2)(g) of the OCR
33.	Checks performed by competent authorities or delegated bodies/persons on lots of plants or plant products for the presence of Union quarantine pests or regulated non-quarantine pests for the purpose of issuing a plant passport	OC		Verification of compliance with the rules referred to in Article 1(2)(g) of the OCR
34.	Checks performed by competent authorities or delegated bodies/persons on lots of plants or plant products for the presence of Union quarantine pests or regulated non-quarantine pests	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR
35.	Issuance of a phytosanitary certificate or plant passport		OOA	Activity based on the outcome of an official control
36.	Survey activities intended for detecting the presence of plant pests.		OOA	Activity not directly aimed at verification of compliance with the rules referred to in Article 1(2) of the OCR
37.	Sampling and analyses performed in the context of surveys for the presence of Union quarantine pests		OOA	Epidemiological surveillance and monitoring; cf. OCR recital 25

#	Activity	OC	OOA	Comment / reasoning
38.	Ordering the disposal of animal by-products after an outbreak to contain the spread of animal diseases		OOA	Containing the spread of animal diseases (cf. Article 2(2) of the OCR)
39.	Ordering movement restrictions as part of an eradication programme or due to a certain established status (infected, free etc.)		OOA	Eradicating animal diseases (cf. Article 2(2) of the OCR)
40.	Ordering movement restrictions due to an epidemic outbreak		OOA	Containing the spread of animal diseases (cf. Article 2(2) of the OCR)
41.	Culling of animals in the context of an eradication programme		OOA	Eradicating animal diseases (cf. Article 2(2) of the OCR)
42.	Notification of the presence of a listed disease (via ADNS, to OIE, to trading countries etc.)		OOA	Activity following official control (or following other official activity)
43.	Informing the public about certain risks (e.g., an epidemic disease, nature thereof, measures taken etc.)		OOA	Informing, not verifying compliance
44.	Issuing approval of an establishment		OOA	Activity following verification of compliance (Article 148 of the OCR); cf. recital 25
45.	Checks in an EU establishment to verify compliance with export requirements that are laid down in the rules referred to in Article 1(2) of the OCR	OC		Verification of compliance with rules referred to in Article 1(2) of the OCR
46.	Investigatory actions to determine the extent of a non-compliance	OC		Article 138(1) of the OCR; verification of compliance with the rules referred to in Article 1(2) of the OCR;

#	Activity	OC	OOA	Comment / reasoning
47.	Verification of compliance with the rules referred to in Article 1(2) of the OCR for the purpose of issuing an official certificate or official attestation	OC		Verification of compliance with the rules referred to in Article 1(2) of the OCR (cf. Article 2(1)(b) of the OCR)
48.	Issuance of an official certificate or an official attestation on the basis of the outcomes of official controls		OOA	Activity aimed at verification of compliance with the rules referred to in Article 1(2) of the OCR
49.	Preparing inspection/audit/laboratory report (outcome of official control)	OC		Non-targeted monitoring activity not aimed at verifying compliance with the rules referred to in Article 1(2) of the OCR
50.	Monitoring of contaminants in food or feed[10] performed in order to verify compliance with a regulatory level established by Union or national rules, or to verify compliance of an operator with mitigation measures established by Union or national rules	OC		
51.	Monitoring of contaminants in food or feed for which no regulatory level has been established, performed in order to verify the presence of contaminants in food or feed or with the objective to collect data in accordance with Article 33 of Regulation (EC) No 178/2002 of the European Parliament and of the Council[11]		OOA	

10 Including contaminants as defined in Council Regulation (EEC) 315/93 and undesirable substances as defined in Directive 2002/32/EC of the European Parliament and of the Council.

11 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

1.2. The official veterinarian (Article 3 of the OCR)

Article 3 of the OCR

Definitions

For the purposes of this Regulation, the following definitions apply: [..]

(32) "official veterinarian" means a veterinarian appointed by a competent authority, either as staff or otherwise, and appropriately qualified to perform official controls and other official activities in accordance with this Regulation and the relevant rules referred to in Article 1(2);

(49) "official auxiliary" means a representative of the competent authorities trained in accordance with the requirements established under Article 18 and employed to perform certain official control tasks or certain tasks related to other official activities; [..]

As mentioned in recital 44 of the OCR, the performance of certain official controls requires the use of the specific skills of official veterinarians to ensure a sound outcome, without this requirement limiting their work solely to those types of official controls.

It follows from the definition of Article 3(32) of the OCR, that official veterinarians can be staff of the competent authorities, or otherwise. To the latter category could belong a veterinarian from the private sector, therefore the appointment of an official veterinarian is not necessarily linked to an employment contract as staff of the competent authority.

Article 5(2) of the OCR specifies that the competent authorities appoint official veterinarians in writing and that this appointment includes a description of the specific official controls and other official activities and related tasks that they are going to perform. Rules on the delegation of tasks laid down in Articles 28 to31 of the OCR are unrelated to this appointment, as the notion of delegation is not appropriate in this case where the legislation specifically attributes certain control tasks to the official veterinarian.

The OCR stipulates the role of official veterinarians in two separate Chapters of Title II:

(a) Regarding the production of products of animal origin intended for human consumption, in Articles 17 and 18 (Chapter II) on official controls, the OCR establishes among others, a framework on the types of cooperation between the official veterinarian and the official auxiliary during the performance of certain official control tasks and on the terms for the contribution of slaughterhouse staff to the official control tasks.

(b) Regarding consignments referred to in Article 47(1) which are subject to official controls at the border control posts upon entry into the Union, Articles 49 and 55 (Chapter V) differentiate animals and

goods as regards the role of the official veterinarian. More specifically, the OCR distinguishes animals and goods as to whether the official veterinarians must carry out the physical checks and make the relevant decisions on consignments' compliance with rules referred to in Article 1(2), in person, or whether trained staff can substitute them. This distinction is illustrated in Figure 1.

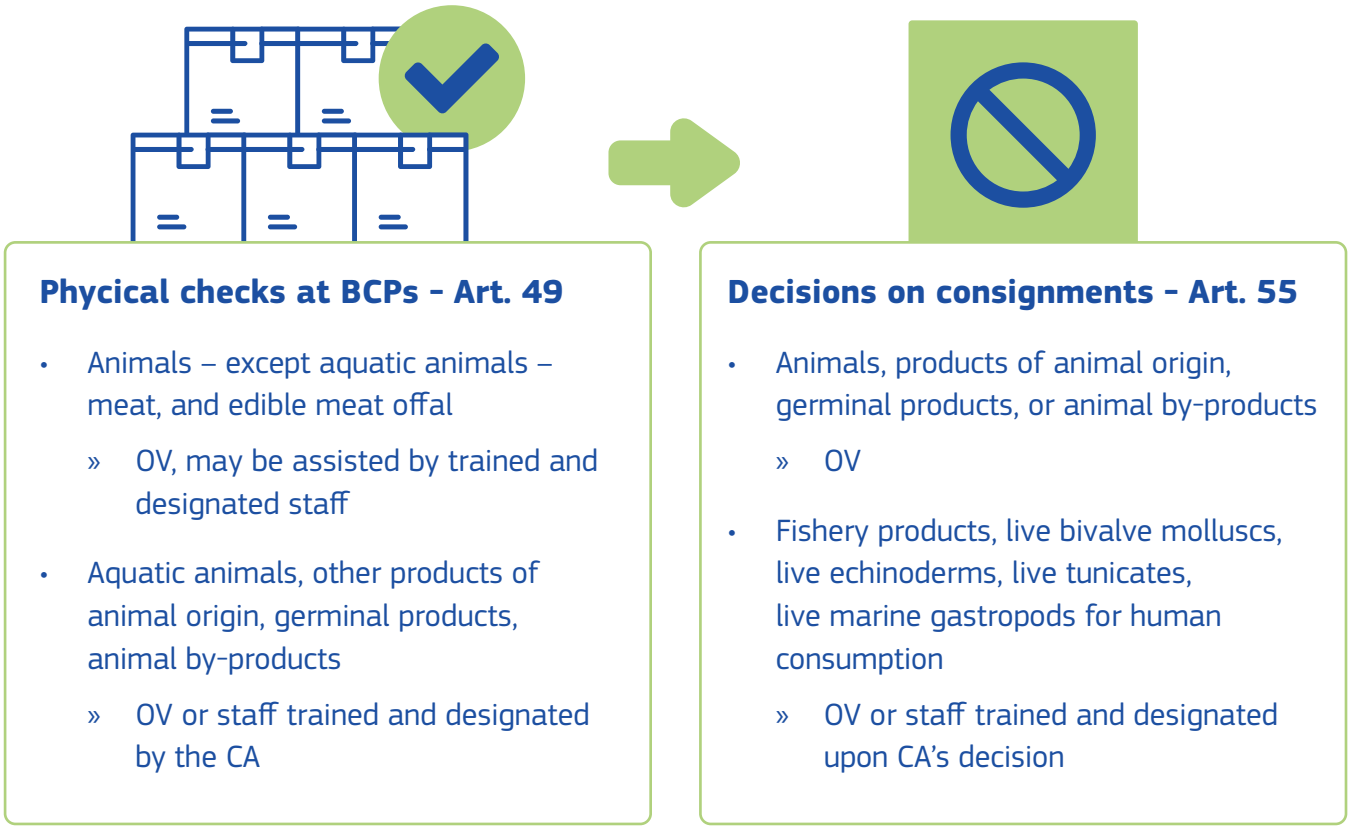


Figure 1: Role of the official veterinarian and of specifically trained and designated staff on physical checks and decisions made on animals and goods entering the Union, under Articles 49 and 55 of the OCR.

It results from Article 5(2) of the OCR, that the requirements applied to the staff of the competent authorities are also imposed to all appointed official veterinarians. At this point, OCR underlines the importance of freedom from any conflict of interest for official veterinarians. To ensure this absence of conflict of interest, competent authorities are required to have procedures or arrangements in place according to Article 5(1)(c) of the OCR.

Article 5(1), (4) and (5) of the OCR apply to all official veterinarians. The same stands for requirements of Article 8 of the OCR on confidentiality and requirements of Article 91(3) on impartiality and freedom of conflict of interest, which in this case, refers to the supervision of the issuance of the official attestation by the official veterinarian.

The obligation of the competent authorities to perform official controls based on documented

procedures, as provided for in Article 12 of the OCR, also applies to official veterinarians. Operators are to assist and cooperate with official veterinarians when they perform official controls or tasks related to other official activities, according to the provisions of Article 15(6) of the OCR.

As regards training, the official veterinarians are subject to general training requirements of Article 5(4) of the OCR, training for the issuance of official attestations referred to in Article 91(3) of the OCR and training provided by the European reference centres for animal welfare referred to in Article 96(e) of the OCR.

In relation to products of animal origin intended for human consumption, Articles 13 and 14 of and Annex II to Commission Delegated Regulation (EU) 2019/624[12] list the training requirements for the official veterinarian, official auxiliary, slaughterhouse staff and staff designated by competent authorities to perform official controls in cutting plants.

Staff assisting the official veterinarian in performing physical checks or performing physical checks at the BCPs for animals and products laid down in Article 49(2) of the OCR, is subject to the specific training requirements laid down in Commission Delegated Regulation (EU) 2019/1081[13].

12 Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

13 Commission Delegated Regulation (EU) 2019/1081 of 8 March 2019 establishing rules on specific training requirements for staff for performing certain physical checks at border control posts (OJ L 171, 26.6.2019, p. 1).

2 TITLE II – OFFICIAL CONTROLS AND OTHER OFFICIAL ACTIVITIES IN MEMBER STATES

2.1 CHAPTER II – Official controls

2.1.1 Official controls of e-commerce

Member States have the general obligation to establish a system of risk-based official controls (Article 9 of the OCR). To the extent necessary to ascertain compliance with the rules referred to in Article 1(2) of the OCR, competent authorities have to perform official controls on "animals and goods at any stage of production, processing, distribution and use"; "substances, materials or other objects which may influence the characteristics or health of animals and goods and their compliance with applicable requirements, at any stage of production, processing, distribution and use"; and "operators as regards activities, including the keeping of animals, equipment, means of transport, premises and other places under their control and their surroundings and on related documentation" (Article 10(1) of the OCR). The official controls may therefore concern animals and goods offered for sale by means of distance communication and operators as regards activities undertaken by means of distance communication.

"Means of distance communication" (referred to in Article 15(5) and Article 36 of the OCR) may be understood as including the internet, but also other mechanisms of distance ordering, such as by mail or phone from a catalogue. However, e-commerce activities, in particular online sales of agri-food products, are the most relevant in terms of volume and exposure to citizens to be considered for the purposes of official controls.

E-commerce activities in the agri-food sector may include:

- business-to-consumer and business-to-business sales;
- online product presentation and information;
- operations using both stationary and online channels as well as online-only channels;
- different modes of purchase for online goods (e.g., payment online or upon delivery/pick-up);

- activities involving digital service providers, including online marketplaces and platforms;
- online-specific business models, such as 'virtual restaurants' (i.e., food preparation facilities operating solely for delivery or takeaway orders placed on websites, apps or platforms);
- cross-border sales, including imports from operators located in third countries directly to EU citizens.

In general, competent authorities are to perform regular, risk-based controls on operators and on animals or goods at any stage of production, processing, distribution and use in accordance with Articles 9 and 10 of the OCR. This requirement applies in the same way to e-commerce activities as to conventional activities.

2.1.1.1 Registration of e-commerce operators

Article 10(2) of the OCR requires competent authorities to keep up-to-date lists of operators (see also section 2.1.2). For this purpose, Article 15(5) of the OCR requires operators to provide competent authorities with updated information regarding their name and legal form as well as the activities carried out, "*including activities undertaken by means of distance communication, and the places under their control*". It should contain specific information about all the channels of distance communication used by the operator, including whether the operator makes use of intermediary services such as social networks and online market places, and should enable competent authorities to perform official controls on operators' "*activities, including the keeping of animals, equipment, means of transport, premises and other places under their control and their surroundings and on related documentation*" in accordance with Article 10(1)(c) of the OCR.

Operators established in one Member State may operate websites that target customers in another Member State (e.g., by using the language of the other Member State and/or offering delivery options).

Online search strategies used by Member States to identify websites or goods sold online usually also reveal operators established outside their jurisdiction. Member States may use the mechanisms of administrative assistance and cooperation (Articles 102 to 108 of the OCR) to inform each other of cross-border activities of operators.

Operators in third countries may be subject to specific requirements for registration or authorisation laid down in the rules referred to in Article 1(2) of the OCR, depending on their activities and the categories of goods exported to the EU.

2.1.1.2 Sampling and analysis of animals and goods sold online

Competent authorities may perform samplings and analyses to verify compliance during risk-based controls of animals and goods in accordance with Article 14(h) of the OCR. This may concern animals and goods offered online. Samples may be taken during the inspection of premises of operators offering products online. Another effective way of sampling (in particular in cross-border situations) is to order goods online and to take samples of those goods upon delivery. For this purpose, and in order to be able to perform official controls without prior notice in accordance with Article 9(4) of the OCR, competent authorities may have to conceal their identity during the ordering process. Article 36 of the OCR provides the legal basis for competent authorities to use

animals and goods ordered online (or by other means of distance communication) without identifying themselves as samples for the purposes of official controls. Competent authorities, once they are in possession of the samples, are to inform operators that goods have been ordered for the purposes of official sampling and/or analysis (Article 36(2)(a) of the OCR). Operators whose animals and goods are subject to sampling and analysis have the right to a second expert opinion (see more details in Chapter 2.3.2 on Article 35 of the OCR).

TRACES network contact points of the Member States may be required to keep up-to-date lists of certain operators as reference data in the TRACES system in accordance with Article 45 of Commission Implementing Regulation (EU) 2019/1715 (IMSOC Regulation). Such lists may also be used for the purpose of Article 10 of the OCR.

2.1.1.3 Action in the event of non-compliance and risk

The responsibility to enforce Union agri-food chain legislation lies with Member States (recital 15 of the OCR), whose competent authorities take action in accordance with Articles 137 and 138 of the OCR. Where non-compliances of animals and goods offered or sold online are found or suspected that have relevance for other Member States, or the responsible operator is located in another Member State, the mechanisms for administrative assistance and cooperation laid down in Articles 102 to 108 of the OCR and implemented in the IT system iRASFF as a component of the Information Management System for Official Controls (IMSOC) are to be used, in order to allow for efficient and consistent enforcement action across all Member States.

Where non-compliant goods offered or sold online are found to present a health risk within the meaning of Article 50 of Regulation (EC) No 178/2002, the RASFF procedure implemented in the iRASFF system should be used accordingly.

The Commission will inform third countries that do not have access to the iRASFF or TRACES systems about products that are subject to RASFF notifications (alert, information or border rejection notification) originating in or distributed to those third countries; in the case of non-compliance notifications and food fraud notifications, the Commission may inform concerned third countries that do not have access to iRASFF or TRACES (Article 27 of Implementing Regulation (EU) 2019/1715).

Further information on the practical use of iRASFF to notify products offered online can be found in the RASFF Standard Operating Procedures[14].

2.1.1.4 Digital service providers

Regulation (EU) 2022/2065[15] (Digital Services Act - DSA) already applies to online platforms and online search engines designated by the Commission as very large online platforms and very large online search engines.[16] It applies to all intermediary service providers active in the Union from 17 February 2024. The DSA

14 https://food.ec.europa.eu/safety/rasff_en

15 Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market for Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1).

16 See https://ec.europa.eu/commission/presscorner/detail/en/IP_23_2413.

lays down rules regarding the exemption from liability of and diligence obligations imposed upon intermediary service providers.

Article 3(g) of the DSA defines different categories of intermediary services, of which "hosting" is the most relevant from a product safety and compliance point of view. Hosting is a service whereby a service provider stores on its server information provided by the user of the service, i.e., an independent third party. An "online platform" service is a specific sub-category of hosting that includes services where the information stored is, in addition, disseminated to the public at the request of the user of the service, such as online social networks or online platforms allowing consumers to conclude distance contracts with traders.

Intermediary service providers carrying out hosting activities have no general obligation to monitor the use of their services for illegal activity and are conditionally exempted of liability for illegal content provided by third parties using their services. The notion of illegal content in this context also covers the offer of unsafe and/or non-compliant goods.

The liability exemption is not absolute. According to Article 6(1) of the DSA, it only applies under the condition that the service provider:

(a) *does not have actual knowledge of illegal activity or illegal content and, as regards claims for damages, is not aware of facts or circumstances from which the illegal activity or illegal content is apparent; or*

(b) *upon obtaining such knowledge or awareness, acts expeditiously to remove or to disable access to the illegal content.*

Therefore, in order to benefit from the liability exemption laid down in Article 6 of the DSA, hosting service providers must act upon obtaining specific information on illegal activity or content, obtained either as a result of voluntary own-initiative investigations[17] or obtained through notification by external individuals or entities. In accordance with Article 16 of the DSA, hosting service providers must put mechanisms in place that allow any individual or entity to notify them of the presence on their service of specific items of information that the individual or entity considers to be illegal content ("notice and action mechanisms").

Furthermore, providers of online platforms that allow consumers to conclude distance contracts with traders are obliged to implement

17 However, in accordance with Article 7 of Regulation (EU) 2022/2065, the mere fact that service providers perform voluntary own-initiative investigations to detect illegal activity must not make them generally ineligible for the liability exemptions provided for in Article 6 of that Regulation.

"compliance by design". This means that they should ensure that their "*online interface is designed in a way that enables traders to comply with their obligations regarding pre-contractual information, compliance and product safety information under applicable Union law*" (Article 31(1) of the DSA).

In addition, and in any case, Articles 9 and 10 of the DSA require providers of intermediary services to inform without undue delay the relevant authorities of any effect given to any order to act against illegal content or to provide information, adopted by the relevant national judicial or administrative authorities on the basis of the applicable Union law or national law in compliance with Union law. For this purpose, Article 11 of that Regulation requires providers of intermediary services to designate a single point of contact for the communication with Member States' authorities, the Commission and the European Board for Digital Services (Article 61 of the DSA).

2.1.1.5 E-commerce control strategies – best practices

Based on the above and on experiences in the Member States, the following measures should be considered as best practices for e-commerce controls:

(i) Official controls by competent authorities of Member States should be supported by conducting web searches to identify online sellers located in the Member State's territory that are not yet known to competent authorities, with the aim of subjecting them to risk-based controls.

(ii) Web searches should also be used to identify online offers of goods that have been identified during official controls as non-compliant or presenting a risk, or where there is a suspicion of non-compliance, including goods notified in the iRASFF system.

(iii) Control of e-commerce activities should include the control of websites and their compliance with product information requirements. For example, online offers of food are to comply with food information requirements laid down in Regulation (EU) No 1169/2011[18]. According to Article 1 of that Regulation, food information requirements apply to food business operators in all stages of the food chain where their activities concern the provision of food information to consumers, all foods intended for the final consumer, and foods delivered by or supplied to mass caterers. Fair commercial practices must be ensured through the provision of food information, also through advertising, according to Article 7 of Regulation (EU) No 1169/2011.

(iv) E-commerce controls should be performed using suitable hard- and software to allow for web searches and online purchases without revealing the competent authority's identity.

(v) Competent authorities should establish contacts with the contact points of intermediary service providers, as relevant including online social networks, online marketplaces, digital payment service providers and top-level domain name

18 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

registries to, among others, facilitate the timely removal of online offers of non-compliant or counterfeit goods or identifying operators or users of digital services if necessary for enforcement purposes.

(vi) For an efficient performance of official controls, competent authorities should be empowered to request information or take appropriate measures with regard to other relevant operators that are not subject to the OCR(this may be the case for some intermediary service providers or financial institutions, for example), or, depending on national administrative structures, should ensure close cooperation with other national authorities which oversee the activities of those other operators.

(vii) In conformity with their constitutional requirements, Member States may consider establishing central e-commerce control units for the above-mentioned tasks, for reasons of efficiency and harmonisation as regards procedures, equipment, and external contacts.

2.1.2. Listing of operators (Article 10(2) and (3) of the OCR)

Article 10(2) of the OCR requires competent authorities to keep up-to-date lists of operators. This provision concerns 'operators' within the meaning of Article 3(29) of the OCR.

Article 10(2) and (3) of the OCR

2. Without prejudice to the rules concerning existing lists or registers established on the basis of the rules referred to in Article 1(2), the competent authorities shall draw up and keep up-to-date a list of operators. Where such a list or register already exists for other purposes, it may also be used for the purposes of this Regulation.

3. The Commission shall adopt delegated acts in accordance with Article 144 to amend this Regulation concerning the setting out of categories of operators to be exempted from the list of operators referred to in paragraph 2 of this Article where their inclusion in such a list would constitute a disproportionate administrative burden for them compared to the risk related to their activities.

Article 3(29) of the OCR:

'operator' means any natural or legal person subject to one or more of the obligations provided for in the rules referred to in Article 1(2);

The definition of operators in Article 3(29) of the OCR includes natural persons, if those are subject to one or more of the obligations provided for in the rules referred to in Article 1(2). For example, Article 1 of Regulation (EC) No 178/2002 excludes '*domestic preparation, handling or storage of food for private domestic consumption*' from the scope of that Regulation. Therefore, in relation to Regulation (EC) No 178/2002, domestic consumers would not be considered operators within the meaning of Article 3(29) of the OCR and do not need to be included in the lists referred to in Article 10(2) of the OCR.`

The requirements for listing and registration of operators in Article 10(2) and (3) of the OCR apply to all the areas referred to in Article 1(2) of the OCR. Where sector-specific rules establish rules for the inclusion or exclusion of certain categories of operators, taking into account the needs in terms of risk management specific to that sector, registers drawn up on the basis of those rules may be used for the purpose of the OCR in accordance with Article 10(2), second sentence, of the OCR.

For example, in the plant health area, Article 65 of Regulation (EU) 2016/2031[19] requires the competent authorities to keep and update a register containing several categories of professional operators who operate in the territory of the Member State concerned. Thus, under these sector-specific rules, only the registration of professional operators is required. Moreover, Article 65 of Regulation (EU) 2016/2031 lays down certain exemptions from this requirement to draw up a register and empowers the Commission to add further categories of professional operators to be exempted, where registration would constitute an administrative burden for operators disproportionate to the low pest risk related to their professional activities. In line with Article 10(2), second sentence of the OCR, in the area of plant health, the registers of professional operators established pursuant to Article 65 of Regulation (EU) 2016/2031 may also be used for the purposes of the OCR. Similarly, in the organic area, the lists of operators and groups of operators kept in accordance with Article 34(6) of Regulation (EU) 2018/848[20] may be used for the purposes of the OCR.

2.1.3. Methods and techniques for official controls: inspections and audits (Article 14 of the OCR)

2.1.3.1. Inspections

Article 14 of the OCR lists methods and techniques of official controls that are to be used, as appropriate, by competent authorities to verify compliance of operators and animals or goods with the rules referred to in Article 1(2). Two important techniques listed in that article are '*inspections*' and '*audits*'.

In the context of official controls within the scope of the OCR, the purpose of an inspection is to verify the (current) compliance of an

19 Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

20 Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1).

object of inspection with specific requirements laid down in the rules referred to in Article 1(2) of the OCR.

The term '*inspection*' is not defined in the OCR and can be understood, by its dictionary meaning, to refer to a close examination of an object, or certain aspects thereof (e.g., equipment, facilities, places, animals, goods, materials, data, activities, processes). An inspection involves mostly direct observations that can be made at a specific moment by the person carrying out the examination. Inspections are often performed with the help of checklists of the specific requirements to be complied with. This understanding of the term is analogous to the definition of "*inspection*" in the international standard ISO/IEC 17000 'Conformity assessment – Vocabulary and general principles'.

Elements to be examined, as appropriate, by '*inspection*' as part of official controls are listed in Article 14(b) of the OCR:

Article 14 of the OCR:

Official control methods and techniques shall include the following as appropriate:

[..]

(b) an inspection of:

(i) equipment, means of transport, premises and other places under their control and their surroundings;

(ii) animals and goods, including semi-finished goods, raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals;

(iii) cleaning and maintenance products and processes;

(iv) traceability, labelling, presentation, advertising and relevant packaging materials including materials intended to come into contact with food;

It is possible that inspections overlap with or additionally involve other methods listed in Article 14 of the OCR. For example, an inspection of the '*traceability*' of an animal or good (Article 14(b)(iv) of the OCR) typically involves the examination of traceability records, as referred to in Article 14(e) of the OCR.

2.1.3.2. Audits

The term '*audit*' is defined in Article 3(30) of the OCR:

> *Article 3(30) of the OCR*
>
> *'audit' means a systematic and independent examination to determine whether activities and the related results of such activities comply with planned arrangements and whether these arrangements are applied effectively and are suitable to achieve the objectives;*

This definition has three elements:

(i) compliance with planned arrangements;

(ii) effective application of those arrangements;

(iii) suitability of those arrangements to achieve objectives.

Therefore, an audit, as compared to an inspection, goes beyond the verification of compliance with specific requirements; it also examines whether predefined outcomes (objectives) can be achieved.

This definition of an audit is comparable to the definition of audits in international standards such as ISO/IEC 17000 'Conformity assessment – Vocabulary and general principles' and ISO 19011 'Guidelines for auditing management systems'.

An audit is typically applied when the subject of controls is an activity such as a procedure or a management system, which needs to be assessed with regard to its suitability to systematically achieve compliant outcomes. An audit therefore requires a broader and systematic assessment of different stages of a process.

When used as a technique during official controls, auditing may involve several or all of the other methods and techniques listed in Article 14 of the OCR, such as the examination of documents or other records, interviews with staff, etc.

Furthermore, some of the elements listed in Article 14 of the OCR may involve auditing as a method, for example:

- an examination of the controls that operators have put in place and of the results obtained (Article 14(a) of the OCR);

- an assessment of procedures on good manufacturing practices, good hygiene practices, good farming practices, and of procedures based on the principles of hazard analysis critical control points (HACCP) (Article 14(d) of the OCR).

Although official controls are in general to be performed without prior notice (Article 9(4) of the OCR), audits can often only be performed with prior notice, because of the necessary preparation of the auditor and the audited entity (cf. recital 33 of the OCR).

Apart from the use of auditing in official controls, auditing as a technique is also relevant for the performance of:

- Internal or external audits on competent authorities (Article 6 of the OCR)[21];
- Audits organised by the competent authorities of delegated bodies and persons (Article 33(a) of the OCR), official laboratories (Article 39 of the OCR) and of national reference laboratories (Article 100(2) of the OCR);
- Accreditation assessments by national accreditation bodies, for example, of delegated bodies (Article 29(b)(iv) of the OCR) or official laboratories (Article 37(4)(e) and (5) of the OCR);
- Commission controls in Member States (Article 116 of the OCR).

2.1.4. Official controls for the production of products of animal origin for human consumption

Article 17 of the OCR lays down specific definitions applicable in the controls on the production of products of animal origin. The definitions 'under the responsibility of the official veterinarian' and 'under the supervision of the official veterinarian' specify the type of cooperation between the official veterinarian and the official auxiliary during veterinary controls, as foreseen in the OCR.

In both cases, the official veterinarian assigns an action to the official auxiliary, the difference being that in the case of the supervision, the official veterinarian is present on the premises during the time of the performance of the action by the official auxiliary.

Furthermore, Article 17 defines the activities that fall into the scope of 'ante-mortem inspection' and 'post-mortem inspection'.

Article 18 of the OCR lays down specific requirements for official controls on the production of products of animal origin. In paragraph 2, it presents the framework for the verification of compliance with Union legislation for the production of products of animal origin intended for human consumption and specifies the official controls and the role of the official veterinarian and of the official auxiliary that perform these controls, as illustrated in Figure 2.

21 For further guidance on audits in accordance with Article 6 of the OCR see: *Commission Notice on a guidance document on the implementation of the provisions for the conduct of audits under Article 6 of Regulation (EU) 2017/625 of the European Parliament and of the Council* (OJ C 66, 26.2.2021, p. 22)

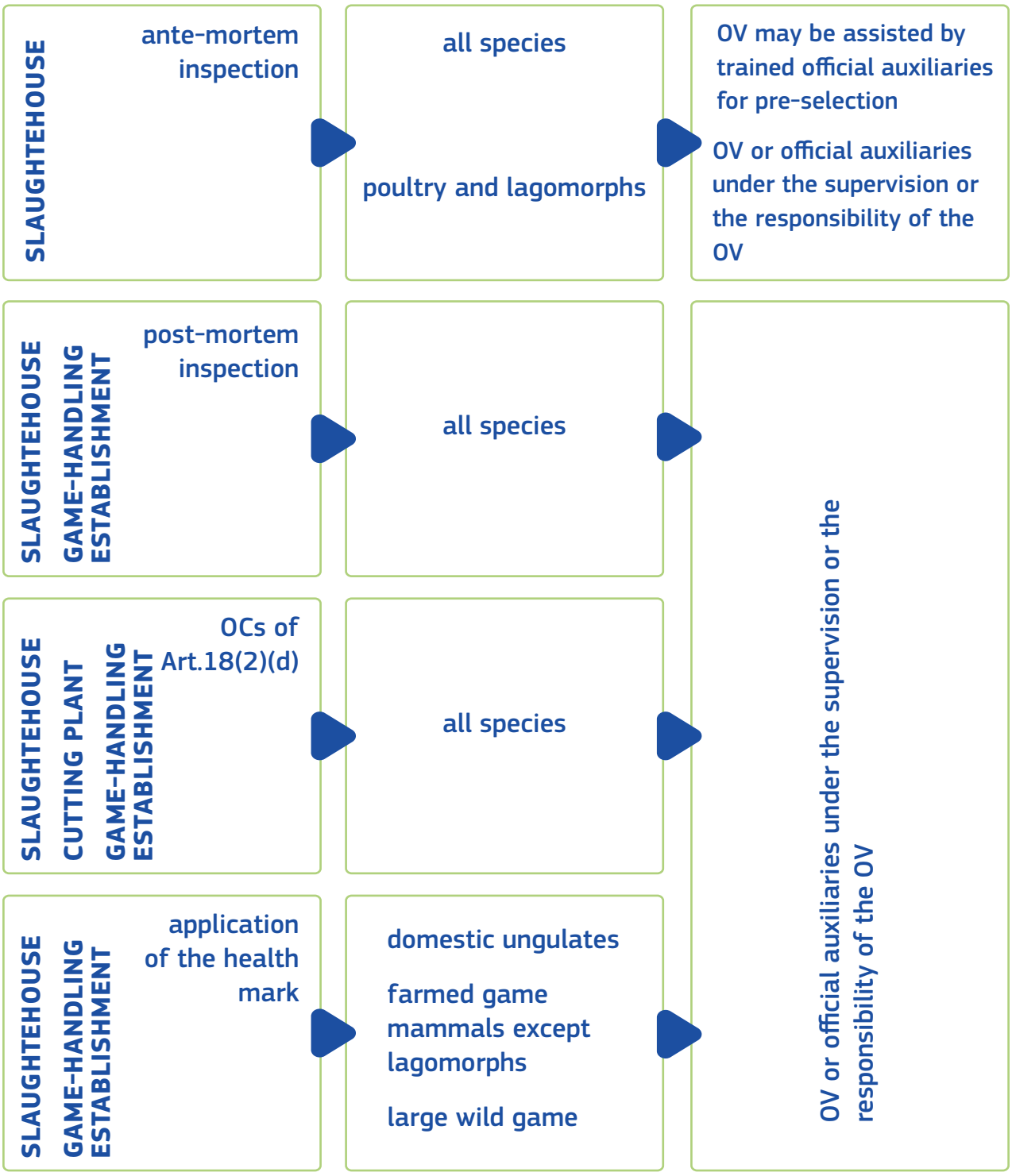


Figure 2: Staff performing the official controls for the production of products of animal origin for human consumption, under Article 17 and 18(2), and (4), 18(7) (a), (b), (e) of the OCR[22].

22 The definitions of Annex I of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55) apply for the establishments "Slaughterhouse", "Game-handling establishment" and "Cutting plant".

It should be underlined that, as it results from Article 18(5) of the OCR, when actions are assigned to the official auxiliaries, the responsibility on relevant decisions remains with the official veterinarians, irrespective of their presence at the premises.

In addition, Article 18(3) of the OCR, provides for the possibility of the slaughterhouse staff to:

(a) assist in the performance of tasks relating to the official controls referred to in Article 18(2) in slaughterhouses of poultry or lagomorphs,

(b) carry out sampling and testing in slaughterhouses of other species.

As a prerequisite for the participation of the slaughterhouse staff to the official controls, a risk-based analysis of the competent authority must demonstrate that the same level of protection of human health, animal health and welfare is ensured during the performance of these official controls in the slaughterhouse. Moreover, the above possibility exists provided the competent authority ensures that this staff is appropriately trained, acts independently from the production staff of the slaughterhouse and carries out the tasks in the presence and under the instructions of the official veterinarian or auxiliary. Under the same conditions, slaughterhouse staff can also apply the health mark.

Paragraphs 7 and 8 of Article 18 of the OCR form the legal base for the adoption of delegated acts supplementing the OCR and implementing acts providing practical arrangements for the performance of official controls.

The assignment of tasks to the official auxiliary, either under the supervision or the responsibility of the official veterinarian, or to staff designated by the competent authorities, is subject to certain criteria and conditions that are set out in the relevant delegated acts.

More specifically, Delegated Regulation (EU) 2019/624 stipulates the roles of the official veterinarian and the official auxiliary concerning specific control tasks and provides for derogations from the rules of the OCR. Official control tasks reserved exclusively for the official veterinarian by Delegated Regulation (EU) 2019/624, are shown in Figure 3.

Provisions of Articles 3, 6, 7 and 9 of Delegated Regulation (EU) 2019/624 complement the roles of the official veterinarian and auxiliary concerning ante-mortem and post-mortem inspection and other official controls.

Furthermore, this Regulation introduces the definition of the staff designated by the competent authorities to conduct specific tasks at cutting plants.

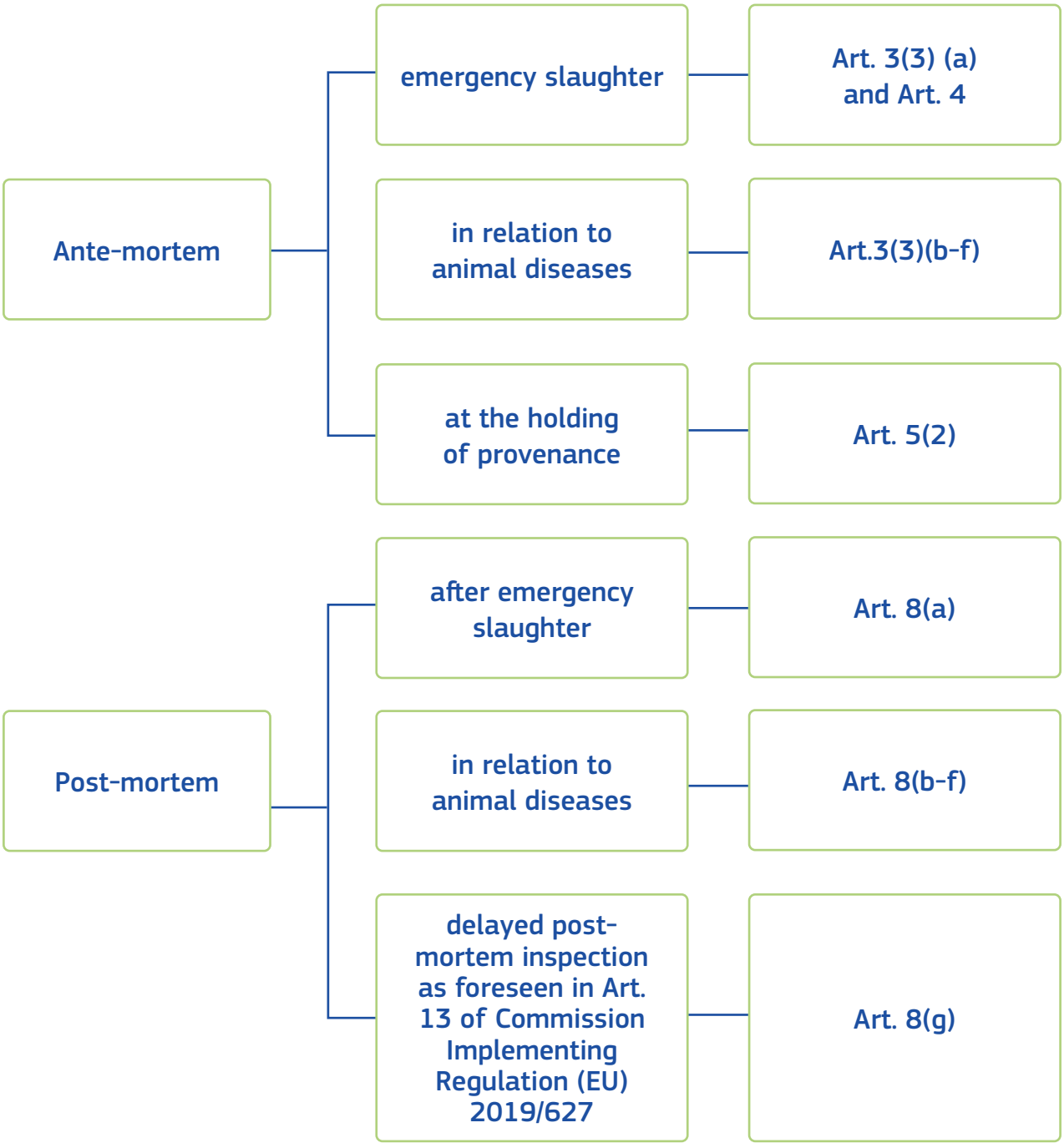


Figure 3: Ante-mortem and post-mortem inspections exclusively carried out by the official veterinarian, as provided for in Delegated Regulation (EU) 2019/624.

Article 2 of Commission Delegated Regulation (EU) 2019/624

Definitions

The following definitions shall apply for the purpose of this Regulation: [..]

(5) "staff designated by the competent authorities" means a person other than the official auxiliary and the official veterinarian, who is qualified in accordance with this Regulation to act in such a capacity in cutting plants and to whom the competent authorities assign the performance of specific actions;[..]"

According to Article 10 of Delegated Regulation (EU) 2019/624, as a derogation to the provisions of the OCR, in cutting plants, other staff designated by the competent authorities can perform the official controls referred to in Article 18(2)(d) of the OCR including auditing activities. These staff are subject to specific training requirements and to regular checks of their performance.

Commission Implementing Regulation (EU) 2019/627[23] lays down detailed rules on the performance of official controls on products of animal origin. It contains directions for the tasks of staff participating in these official controls. In the following tables, the tasks in the performance of official controls of products of animal origin have been summarised with reference to the relevant provisions of the OCR, Delegated Regulation (EU) 2019/624 and Implementing Regulation (EU) 2019/627, allowing for a conclusion to be drawn as to the staff permitted to perform each task.

STAFF PERFORMING OFFICIAL CONTROL TASKS FOR THE PRODUCTION OF PRODUCTS OF ANIMAL ORIGIN

23 Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

Table 2: Tasks performed by the official veterinarian

No		Tasks	OCR	Reg. (EU) 2019/624	Reg. (EU) 2019/627
1	Ante-mortem [definition in Art. 17 (c) OCR]	Ante-mortem inspection of domestic ungulates outside the slaughterhouse in case of emergency slaughter according to Article 4 of Commission Delegated Regulation (EU) 2019/624	Art. 18(7)(c)	Art. 4	-
2		Ante-mortem inspection and checks at the holding of provenance for all species according to Article 5(2)(a), (b) and (c) of Commission Delegated Regulation (EU) 2019/624	Art. 18(7)(d)	Art. 5(2)	-
3		Clinical inspection of isolated animals for more thorough ante-mortem inspection. Ante-mortem inspection of animals suspected of having a disease or condition that may adversely affect human or animal health	Art. 18(2)(a)	Art. 3(3) (b)-(f)	Art. 11(5)

No		Tasks	OCR	Reg. (EU) 2019/624	Reg. (EU) 2019/627
4	Post-mortem inspection [definition in Art. 17 (d) OCR]	In the case of the emergency slaughter of the domestic ungulates outside the slaughterhouse in accordance with Chapter VI of Section I of Annex III to Regulation (EC) 853/2004 Examination of the animal health certificate of Chapter 5 of Annex IV of Commission Implementing Regulation (EU) 2020/2235[24]	Art. 18(2)(c), Art. 18(7)(f)	Art. 8(a)	- Art. 10(3)
5		Inspection of Animals suspected of having a disease or condition that may adversely affect human health	Art. 18(2)(c)	Art. 8(b)	-
6		Inspection of Bovine animals from herds that have not been declared officially free of tuberculosis		Art. 8(c)	-
7		Inspection of Bovine, ovine and caprine animals from herds that have not been declared officially free of brucellosis		Art. 8(d)	-
8		Inspection in the case of an outbreak of animal diseases for which animal health rules are laid down in Union legislation, for animals susceptible to the particular disease in question that come from all areas covered by: • EU emergency measures [certain Cat A: Highly pathogenic avian influenza (HPAI), sheep pox etc.]; • national measures linked to any Cat A disease eradication measures; • additional EU special (additional) disease control measures [certain Cat A: African swine fever (ASF), infection with lumpy skin disease virus (LSD) etc.]; • compulsory approved eradication programmes for Cat B diseases and listed in Annex I-II of Commission Implementing Regulation (EU) 2021/620[25] [Brucellosis and Mycobacterium tuberculosis complex (MTBC)]		Art. 8(e)	-

24 Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).

25 Commission Implementing Regulation (EU) 2021/620 of 15 April 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of the disease-free and non-vaccination status of certain Member States or zones or compartments thereof as regards certain listed diseases and the approval of eradication programmes for those listed diseases (OJ L 131, 16.4.2021, p. 78)

No		Tasks	OCR	Reg. (EU) 2019/624	Reg. (EU) 2019/627
9	Post-mortem inspection	Inspection when stricter controls are necessary to take account of emerging diseases or particular diseases listed by the World Organisation for Animal Health		Art. 8(f)	-
10		Post-mortem inspection delayed by no more than 24 hours from slaughter or arrival at the game handling establishment, in low-capacity slaughterhouses or low-capacity game handling establishments in accordance with Article 13 of Commission Implementing Regulation (EU) 2019/627		Art. 8(g)	Art. 13
11		Performance of the additional post-mortem inspection procedures referred to in Articles 18(3), 19(2), 20(2), 21(2), 22(2) and 23(2) of Commission Implementing Regulation (EU) 2019/627 using incision and palpation of the carcase and offal where there is a possible risk in relation to cases referred to in Article 8 of Commission Delegated Regulation (EU) 2019/624		Art. 8	Art. 24
12	Declaration of meat unfit for human consumption	Non-compliance with requirements for fresh meat	Art.18(5)	-	Art.45
13		Meat infected with cysticerci or trichinae		-	Art. 30, 31
14		Meat of solipeds in which glanders have been diagnosed		-	Art. 32(3)
15		Where animals have reacted positively or inconclusively to tuberculin or there are other grounds for suspecting infection		-	Art. 33
16		Where animals have reacted positively or inconclusively to a brucellosis test or there are other grounds for suspecting infection		-	Art. 34

No		Tasks	OCR	Reg. (EU) 2019/624	Reg. (EU) 2019/627
17	Other	Verification of compliance of performance of the official auxiliary carrying out ante-mortem tasks under the supervision or responsibility of the official veterinarian	-	Art. 3(1)(c) and (2)(c)	-
18		Verification of compliance of performance of food business operators carrying out slaughter and bleeding of farmed game at the holding of provenance	-	Art. 6(4)(b)	-
19		Assessment of the operator's system for the detection and separation of birds with abnormalities, contamination, or defects	-	-	Art. 25(2)(a)
20		Ensuring that additional laboratory testing for the needs of Article 18(2) of the OCR takes place	Art. 18(5)	-	Art. 37(2)
21		Evaluation of the results of official controls carried out in accordance with Article 7 to 38 of Commission Implementing Regulation (EU) 2019/627	Art. 18(5)	-	Art. 39(1)
22		Communication of control results where inspections reveal the presence of any disease or condition that might affect human or animal health or compromise animal welfare		-	Art. 39(2)
23		Verification of compliance with the health requirements for raw milk and colostrum production as laid down in Part I of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004	-	-	Art. 49(1), (3)

Table 3: Tasks performed by the official veterinarian or by the official auxiliary under the supervision of the OV

No		Tasks	OCR	Reg. (EU) 2019/624	Reg. (EU) 2019/627
1	Ante-mortem [definition in Art. 17 (c) OCR]	Ante-mortem inspection at the slaughterhouse on species other than poultry and lagomorphs (including verification of compliance with rules on animal welfare[26]), regarding food chain information, animal's identity check and preselection of animals with abnormalities under the conditions defined in Article 3(1) of Commission Delegated Regulation (EU) 2019/624 except for cases referred to in Article 3(3) of that Delegated Regulation	Art. 18(2)(a) Art. 18(7)(a)	Art. 3(1)	Art. 10(1), Art. 11, Art. 38, Art. 40
2		Ante-mortem inspection of poultry and lagomorphs including verification of compliance with rules on animal welfare.	Art. 18(2)(b)	-	Art. 38

26 Union rules and in particular Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1) and Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1), as well as national rules on animal welfare.

No		Tasks	OCR	Reg. (EU) 2019/624	Reg. (EU) 2019/627
	Post-mortem [definition in Art. 17 (d) OCR][27]	Examination of certificates of animals slaughtered at the holding of provenance	Art. 18(2)(c)	-	Art. 10(2)
4 3		Examination of: (i) declarations (of the trained person) accompanying large wild game issued in accordance with point 4 (a) of Chapter II of Section IV of Annex III to Regulation (EC) 853/2004; (ii) the official certificate of Chapter 2 of Annex II of Commission Implementing Regulation (EU) 2020/2235 for the movement between Member States of unskinned large wild game intended for human consumption.		-	Art. 10(4), Art. 28
5		Post-mortem inspection of carcases and accompanying offal, including specific practical arrangements, laboratory testing and verification of compliance with rules on animal welfare		-	Articles 12,14 (unless not authorised by other specific Articles), 15, 17, 18 (1) & (2), 19(1), 20(1), 21(1), 22(1), 23(1), 25, 26, 27, 28 (1), (2), (3), & (4), 29 (removal from the carcase of specified risk material), 30, 31, 32, 33, 34, 35, 36, 37, 38

27 Establishment not fulfilling the conditions of Article 7 of Delegated Regulation (EU) 2019/624.

No		Tasks	OCR	Reg. (EU) 2019/624	Reg. (EU) 2019/627
6		Performance of the additional post-mortem inspection procedures referred to in Articles 18(3), 19(2), 20(2), 21(2), 22(2) and 23(2) of Commission Implementing Regulation (EU) 2019/627 using incision and palpation of the carcase and offal where there is a possible risk. Additional post-mortem inspection under the supervision of the official veterinarian is not possible in cases referred to in Article 8 of the Delegated Regulation (see Table 2 row 11)		-	Art. 24
7	Other	Official controls in relation to TSEs according to Regulation (EC) No 999/2001[28], as regards the handling and disposal of specified risk material according to Regulation (EC) No 1069/2009[29] on animal by products	Art. 18(2)(d) (iv), (v)	-	Art. 29
8		Sampling for analysis and any additional sampling	Art. 18(2)(d) (ii), (iii) and (iv)	-	Art. 35, Art. 36, Art. 37

28 Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

29 Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

Table 4:Tasks performed by the official veterinarian or by the official auxiliary under the supervision or the responsibility of the OV

No		Tasks	OCR	Reg. (EU) 2019/624	Reg. (EU) 2019/627
1	Ante-mortem definition in Art. 17 (c) OCR]	Ante-mortem inspection at the slaughterhouse on all species (including verification of compliance with rules on animal welfare) in case an ante-mortem inspection has already been performed by the official veterinarian at the holding of provenance, under the conditions defined in Article 3(2) of Commission Delegated Regulation (EU) 2019/624 with the exception of cases referred to in Article 3(3) of that Delegated Regulation Examination of model animal health certificate of live animals transported to the slaughterhouse in the case of ante-mortem inspection has taken place at the holding of provenance [Chapter 1 of Annex IV of Commission Implementing Regulation (EU) 2020/2235]	18(2)(a), (b)	3(2) 5(2)(f)	11(6) 10(2) 38
2		Additional checks on animal identification and animal welfare rules at the slaughterhouse following ante-mortem inspection at the holding of provenance according to Article 5(3) and Article 3 of Commission Delegated Regulation (EU) 2019/624		3(2), 5(3)	-
3	Post-mortem [definition in Art. 17 (d) OCR]	Post-mortem inspection of tasks of Table 3 in low-capacity establishments fulfilling the conditions of Article 7 of Commission Delegated Regulation (EU) 2019/624	18(2)(c), 18(7)(e)	7	-
4		Post-mortem inspection of viscera, genital organs and udder as specified in Article 12(1)(c) of Commission Delegated Regulation (EU) 2019/624, of *Rangifer tarandus tarandus* (reindeer) from areas of Sweden and Finland laid down in Annex I of that Delegated Regulation[30]		12(1)(c)	-

30 *Official veterinary, official auxiliary under supervision or responsibility or appropriately trained slaughterhouse staff (certain tasks).*

No		Tasks	OCR	Reg. (EU) 2019/624	Reg. (EU) 2019/627
5	Other	Collection of information on sampling and the results of sampling for *Salmonella* by food business operators of slaughterhouses as provided for in Article 35(1)(b) of Commission Implementing Regulation (EU) 2019/627	18(2)(d)(iii),18(7)(e)	9	35
6		Collection of information for sampling and the results of sampling for *Campylobacter* by food business operators of slaughterhouses as provided for in Article 36(1)(b) of Commission Implementing Regulation (EU) 2019/627			36
7		Collection of information of official controls as regards good hygiene practices and procedures based on HACCP principles in slaughterhouses and game handling establishments			39
8		Adoption of appropriate measures in cases of non-compliances with animal welfare rules on the protection of animals during transport laid down in Council Regulation (EC) No 1/2005	18(2)(d)(vi)	-	44[31]
9		Verification of operator's corrective and preventive actions in cases of non-compliances with rules on the protection of animals at the time of slaughter or killing laid down in Articles 3 to 9 and Articles 14 to 17 and 19 of Regulation (EC) No 1099/2009		-	
10		Enforcement actions in cases of non-compliances with animal welfare rules on the protection of animals at the time of killing laid down in Regulation (EC) No 1099/2009		-	
11		Communication of identified problems in relation to animal welfare to the competent authorities, where appropriate		-	
12		Application of health mark on domestic ungulates, farmed game mammals other than lagomorphs and large wild game[32]	18(4)	-	48

31 The measure may be taken by an official auxiliary only in urgent cases pending the arrival of the official veterinarian (Art. 44(5) of Implementing Regulation (EU) 2019/627).

32 Slaughterhouse staff may also apply the health mark (Article 18(4) of the OCR), in compliance with the conditions laid down in Article 18(3) of the OCR.

2.2. CHAPTER III – Delegation of certain tasks of the competent authorities (Articles 28 to 33 of the OCR)

Chapter III of Title II of the OCR lays down, on the one hand, conditions for delegating certain *official control* tasks (Articles 28 to 30 of the OCR) and, on the other hand, conditions for delegating tasks related to *other official activities* (Article 31 of the OCR). Article 32 of the OCR lays down rules concerning obligations of the delegated bodies and natural persons. Article 33 of the OCR establishes the obligations of the delegating competent authorities.

Additional rules on the delegation of official control tasks and tasks related to other official activities may be laid down in specific EU rules. For example, in the area of organic production, additional rules on the delegation of official control tasks and tasks related to other official activities to 'control bodies' are laid down in Article 40 of Regulation (EU) 2018/848 on organic production and labelling of organic products.

2.2.1. Conditions for delegating certain official control tasks

Articles 29 and 30 of the OCR lay down conditions for delegating certain official control tasks to delegated bodies and natural persons, respectively.

Competent authorities should grant the delegation of official controls tasks based on on-site controls of the candidate delegated bodies or natural persons. In the case of delegated bodies, the official controls should be performed independently of their accreditation in accordance with Article 29(b)(iv) of the OCR.

Competent authorities that have delegated certain official control tasks to delegated bodies or natural persons must organise audits or inspections of such bodies or persons, as necessary. They must withdraw the delegation fully or partly without delay in the case of non-compliance (Article 33(b) of the OCR).

Therefore, the conditions for delegating certain official control tasks laid down in Articles 29 and 30 of the OCR, and the mechanisms of verification and follow-up measures of non-compliance laid down in Article 33 of the OCR must be understood as a continuous process of monitoring of compliance.

While organising audits and inspections, the competent authorities must consider the outcome of the relevant accreditation audits carried out by the National Accreditation bodies, defined in Article 2(11) of Regulation (EC) No 765/2008[33] (Article 33(a) of the OCR). In respect of those different types of controls, duplication should be avoided (Article 33(a) of the OCR). Consequently, communication with National Accreditation bodies and coordination regarding the timing of the controls, is necessary.

Rules adopted in Member States that allow a provisional delegation of tasks to delegated bodies not yet accredited in accordance with Article 29(b)(iv) of the OCR, could be considered

33 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

compatible with the OCR subject to conditions. This is the case if:

(i) such provisional delegation is not excluded by the rules referred to in Article 1(2) of the OCR establishing specific provisions on the delegation of tasks;

(ii) on-site controls show that all other conditions for the delegation established in Article 29 of the OCR are fulfilled[34];

(iii) the provisional delegation is granted for a limited period of time, having regard to the length of the accreditation procedure, the risks in the concerned area and the protection of consumers interests;

(iv) the body applying for delegation proves that it has already applied for the accreditation.

During such provisional delegation, the competent authority must fully or partially withdraw the delegation without delay in the cases referred to in Article 33(b) of the OCR.

For delegated bodies, accreditation in accordance with Article 29, point (b)(iv) of the OCR is of particular importance to ensuring that the impartiality, quality and consistency of official controls are preserved (cf. recital 46 of the OCR).

Competent authorities should consider the relevance of a standard to the delegated tasks to determine its suitability for use by and accreditation of the delegated body according to Article 29(b)(iv) of the OCR. National Accreditation bodies will subsequently assess whether the delegated body operates in accordance with the requirements of the defined standard, in the context of accreditation.

Member States should ensure consistency across competent authorities when identifying the relevant standard for the delegation of a given control task.

EN ISO/IEC 17020 'Requirements for the operation of various types of bodies performing inspection', is one of the relevant standards that has to be used for the operation and accreditation of delegated bodies, according to the OCR. This is the reference standard for inspection tasks unless another standard is referred to in sectoral legislation under the OCR, or another standard corresponds better to the nature of the delegated tasks (for example: certifications of products, management systems, etc.).

Other standards that can be relevant to the delegated tasks, are:

- EN ISO/IEC 17065 'Conformity assessment — Requirements for bodies certifying products, processes and services';
- EN ISO/IEC 17021-1: 'Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements';
- ISO 22003-1 'Food safety — Part 1: Requirements for bodies providing audit and certification of food safety management systems'.

34 The actual operation of the delegated body in accordance with the relevant standards referred to in Article29(b)(iv) is to be verified during the accreditation process referred to in that provision.

The designation of official laboratories to carry out laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities falls under the rules of Articles 34 to 42 (Chapter IV) of the OCR. In this case, EN ISO/IEC 17025 is mandatory for the operation and accreditation of the designated official laboratory (Article 37(4) of the OCR).

Accreditation of a delegated body in accordance with more than one standard for the same activity is not advisable. It should be noted that EN ISO/IEC 17065 provides the possibility to include in the applicable requirements for the delegated body, all relevant requirements of the other accreditation standards. In this respect, it can be used as an 'umbrella' standard.

Further rules on the identification of the relevant standards can be laid down in:

- Union legislation on areas referred to in Article 1(2) of the OCR:
  - » in the area of organic products, Article 40(3) of Regulation (EU) 2018/848, provides that the relevant standard for the delegation of certain official control tasks to verify compliance with that Regulation is the most recently notified version of the standard for 'Conformity assessment – Requirements for bodies certifying products, processes and services', the reference of which has been published in the *Official Journal of the European Union*, i.e. of standard EN ISO/IEC 17065;
  - » in the area of geographical indications for wine, spirit drinks and agricultural products, as well as traditional specialities guaranteed and optional quality terms for agricultural products, Articles 41 (1) and 73(1) of Regulation (EU) 2024/1143[35], provide that the delegated bodies and the product certification bodies shall comply with and be accredited in accordance with Standard EN ISO/IEC 17065 'Conformity assessment — Requirements for bodies certifying products, processes and services' or Standard EN ISO/IEC 17020 'Conformity assessment — Requirements for the operation of various types of bodies performing inspection'.
- national legislation of Member States.

35 Regulation (EU) 2024/1143 of the European Parliament and of the Council of 11 April 2024 on geographical indications for wine, spirit drinks and agricultural products, as well as traditional specialities guaranteed and optional quality terms for agricultural products, amending Regulations (EU) No 1308/2013, (EU) 2019/787 and (EU) 2019/1753 and repealing Regulation (EU) No 1151/2012 (OJ L, 2024/1143, 23.4.2024, p....)

2.3. CHAPTER IV – Sampling, Analyses, tests and diagnoses (Articles 34 to 42 of the OCR)

2.3.1. Methods used for sampling, analysis, tests and diagnosis (Article 34 of the OCR)

Article 34 of the OCR lays down requirements for methods used in the context of both official controls and other official activities. In particular, a hierarchy of criteria is established which is to be applied when choosing among available methods in the absence of applicable Union rules ('method cascade').

The hierarchical relationship between the options listed in paragraphs (1) to (3) of Article 34 of the OCR is indicated by the use of phrases such as '*in the absence of*' and '*if no such [..] exists*'. Within the hierarchy, some options are established as equal alternatives, as indicated by the use of the conjunction '*or*'.

Article 34(1) of the OCR establishes that methods used for sampling or for laboratory analyses, tests and diagnoses in the context of official controls or other official activities shall comply with Union rules, if such rules exist. These rules may either establish specific methods or lay down performance criteria to be applied for the methods used. Sector-specific Union laws may also lay down different method preferences that deviate from the basic hierarchy established in Article 34 of the OCR, which would then take precedence (*lex specialis*) over the general hierarchy established in Article 34 of the OCR. For example, while Article 34(2)(a) of the OCR presents methods that comply with 'relevant internationally recognised rules or protocols' as an equal option to methods recommended by European Reference Laboratories (EURLs), Article 6(1) of Commission Delegated Regulation (EU) 2020/689[36] gives priority to methods recommended by EURLs over methods recommended by the World Organisation for Animal Health (OIE) in the context of disease surveillance. The requirement laid down in Article 34(1) of the OCR applies to methods of laboratory analysis, test or diagnosis, as well as to methods used for sampling, irrespective of whether those methods are used by competent authorities (or delegated bodies or persons), or by official laboratories.

Article 34(2) of the OCR lays down a hierarchy of methods to be used by official laboratories in the absence of Union rules as referred to in paragraph 1. The methods referred to in paragraph 2 therefore include methods of laboratory analysis, test or diagnosis as well as methods used for sampling or sample preparation, where such methods are used by official laboratories in the context of official controls and other official activities (including, for example, cases where aggregated sample material is divided into samples for analysis in the laboratory).

Article 34(2)(a) of the OCR lays down that in the absence of Union rules as referred to

36 Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (OJ L 174, 3.6.2020, p. 211).

in paragraph 1, methods recommended by relevant internationally recognised rules or protocols (e.g., CEN, OIE), or methods developed or recommended by EU reference laboratories and validated in accordance with internationally accepted scientific protocols shall be used by official laboratories. These two options in Article 34(2)(a) of the OCR are stipulated as equal alternatives that can both be applied in the absence of Union rules.

Article 34(2)(b) of the OCR lists methods that may only be applied when no Union rules as referred to in paragraph 1 and no international protocols or EURL methods as referred to in point (a) of paragraph 2 exist. Within the options listed under Article 34(2)(b) of the OCR, priority shall be given to methods prescribed by national rules over methods recommended by national reference laboratories. However, other validated methods can be applied as an equal alternative to both of the aforementioned options.

Article 34(3) of the OCR refers only to methods of laboratory analysis, test or diagnosis and not to methods of sampling. It allows the use of non-validated methods only when none of the methods referred to in paragraphs 1 and 2 exist and if laboratory analyses, tests or diagnoses are urgently needed. With regard to the first of these conditions, it should be noted that the availability of a method in a given laboratory or Member State is not a relevant criterion in the context of Article 34(3) of the OCR, given the possibility for competent authorities to designate official and reference laboratories in other Member States or EEA countries. Under the conditions established in Article 34(3) of the OCR, non-validated methods may be used by national reference laboratories, and by official laboratories only in the absence of a national reference laboratory.

Article 34(4) of the OCR establishes the baseline requirement for methods of laboratory analysis in the context of official controls and other official activities that methods should be characterised wherever possible using the criteria set out in Annex III of the OCR.

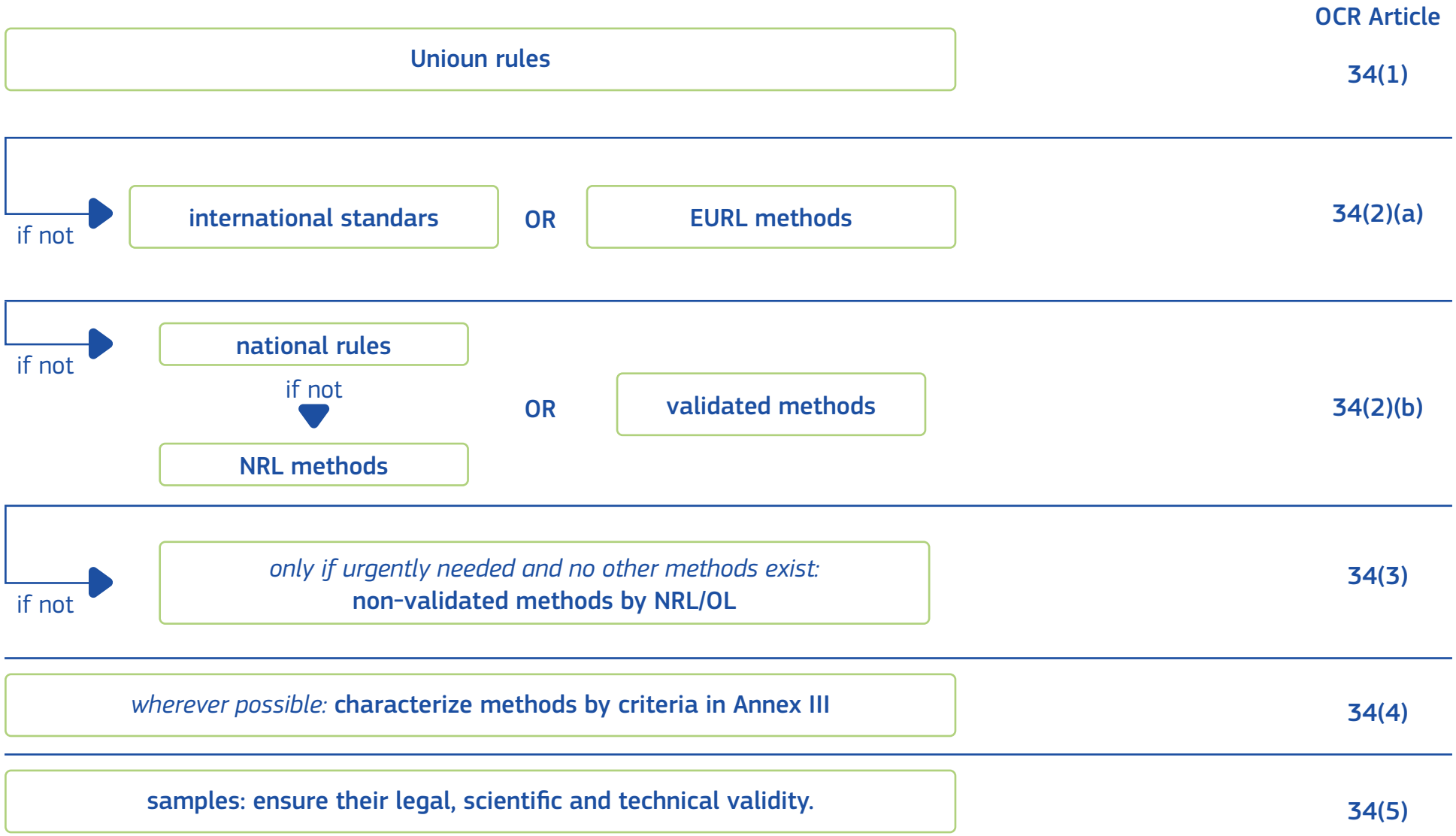
Article 34(5) of the OCR requires that samples are taken, handled and labelled in such a way as to ensure their legal, scientific and technical validity. This requirement applies to the processing of samples both during sampling itself, whether performed by competent authorities (or delegated bodies or persons) or by official laboratories, during transfer of the samples to the laboratory and during the performance of laboratory analyses, tests or diagnoses performed by official laboratories or national reference laboratories.

Figure 4 provides an overview of the paragraphs of Article 34 of the OCR as regards their applicability to sampling methods and/or methods of laboratory analysis, test or diagnosis.

Figure 4: Applicability of Article 34(1) to (5) of the OCR to i) methods of sampling used by competent authorities (or delegated bodies or natural persons to which certain tasks have been delegated), ii) methods of sampling used by official laboratories and iii) methods of laboratory analyses, tests and diagnoses used by official laboratories. (CA = competent authority (or delegated body or natural person to which certain tasks have been delegated); OL = official laboratory).

Article 34: Methods used for sampling, analyses, tests and diagnoses	paragraph applies to:		
1. Methods used for **sampling and for laboratory analyses, tests and diagnoses** during official controls and other official activities shall comply with Union rules establishing those methods or the performance criteria for those methods.	sampling (by CA)	sampling (by OL)	lab. analyses, tests and diagnoses (by OL)
2. In the absence of the Union rules as referred to in paragraph 1, and in the context of official controls and other official activities, **official laboratories** shall use one of the following methods according to the suitability for their specific analytical, testing and diagnostic needs: (a) available methods complying with relevant internationally recognised rules or protocols including those that the European Committee for Standardisation (CEN) has accepted; or relevant methods developed or recommended by the European Union reference laboratories and validated in accordance with internationally accepted scientific protocols; (b) in the absence of the suitable rules or protocols, as referred to in point (a), methods which comply with relevant rules established at national level, or, if no such rules exist, relevant methods developed or recommended by national reference laboratories and validated in accordance with internationally accepted scientific protocols; or relevant methods developed and validated with inter or intra-laboratory methods validation studies in accordance with internationally accepted scientific protocols.		sampling (by OL)	lab. analyses, tests and diagnoses (by OL)
3. Where **laboratory analyses, tests or diagnoses** are urgently needed and none of the methods referred to in paragraphs 1 and 2 of this Article exists, the relevant national reference laboratory or, if no such national reference laboratory exists, any other laboratory designated in accordance with Article 37(1) may use methods other than those referred to in paragraphs 1 and 2 of this Article until the validation of an appropriate method in accordance with internationally accepted scientific protocols.			lab. analyses, tests and diagnoses (by NRL/OL)
4. Wherever possible, **methods used for laboratory analyses** shall be characterised by the relevant criteria set out in Annex III.			lab. analyses, tests and diagnoses (by OL)
5. **Samples shall be taken, handled and labelled** in such a way as to ensure their legal, scientific and technical validity.	sampling (by CA)	sampling (by OL)	lab. analyses, tests and diagnoses (by OL)

Figure 5: 'Cascade' for methods of laboratory analysis, test and diagnosis in the context of official controls and other official activities as described in Article 34 of the OCR. Note that not all of the elements in the hierarchy apply to sampling methods (see Figure 4).



2.3.2. Second Expert Opinion (Article 35 of the OCR)

Article 35(1) of the OCR lays down the right of the operator to a second expert opinion at the operator's own expense:

> *Article 35 of the OCR*
>
> *Second expert opinion*
>
> *1. The competent authorities shall ensure that operators, whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls, have the right to a second expert opinion, at the operator's own expense.*
>
> *[..]*

This right applies to the sampling, analysis, test or diagnosis carried out in the context of official controls, not in the context of other official activities. The second expert opinion safeguards the legitimate rights of the operators, in particular their right of appeal against measures taken as laid down in Article 7 of the OCR, by contributing to a sound factual basis. Therefore, the operators that are the addressees of the measures taken by the competent authority are entitled to this right.

The right to a second expert opinion does not affect the obligation of the competent authorities to take immediate action to eliminate or contain risks to human, animal and plant health, or to animal welfare or, as regards GMOs and plant protection products, also to the environment (Article 35(4) of the OCR).

Competent authorities may not subject the right to a second expert opinion to the payment of a fee. However, as clearly stated in Article 35(1) of the OCR, the costs of a second expert opinion shall be borne by the operator.

The right to a second expert opinion consists of three elements, which entitle the operator to:

(i) request a documentary review of the initial sampling, analysis, test or diagnosis by a recognized and appropriately qualified expert (Article 35(1) of the OCR);

> *Article 35 of the OCR*
>
> *1. [..]*
>
> *The right to a second expert opinion shall entitle the operator to request a documentary review of the sampling, analysis, test or diagnosis by another recognised and appropriately qualified expert.*

(ii) request that the competent authority takes sufficient sample quantity for the purpose of a second analysis carried out as part of the second expert opinion (recital 48 and Article 35(2) of the OCR, subject to the conditions mentioned therein); this element of the second expert opinion does not apply when assessing the presence of quarantine pests in plants, plant products or other objects for the purpose of verifying compliance with the rules referred to in point (g) of Article 1(2) of the OCR (Article 35(2) second sentence).

Recital 48 of the OCR

[..] Such a right should allow the operator to request a documentary review by another expert of the initial sampling, analysis, test or diagnosis, as well as a second analysis, test or diagnosis of the parts of the sampling material taken initially unless any such second analysis, test or diagnosis is technically impossible or irrelevant. Such would be the case, in particular, where the prevalence of the hazard is particularly low in the animal or good or its distribution particularly sparse or irregular for the purpose of assessing the presence of quarantine organisms or, as the case may be, for performing a microbiological analysis.

Article 35 of the OCR

[..]

2. Where relevant, appropriate and technically feasible, having regard in particular to the prevalence and distribution of the hazard in the animals or goods, to the perishability of the samples or the goods and to the amount of available substrate, the competent authorities shall:

(a) when taking the sample, and if so requested by the operator, ensure that a sufficient quantity is taken to allow for a second expert opinion and for the review referred to in paragraph 3, should this prove necessary; or

(b) where it is not possible to take a sufficient quantity as referred to in point (a), inform the operator thereof.

This paragraph shall not apply when assessing the presence of quarantine pests in plants, plant products or other objects for the purpose of verifying compliance with the rules referred to in point (g) of Article 1(2).

(iii) request that the competent authority takes sufficient sample quantity for the purpose of another analysis by another official laboratory performed upon request of the operator in case of a dispute based on the initial analysis and the second expert opinion, if this right is provided for in national law (Article 35(3) of the OCR, subject to the conditions mentioned in Article 35(2) of the OCR).

Article 35 of the OCR

[..]

3. Member States may decide that, where there is a dispute between the competent authorities and the operators that is based on the second expert opinion referred to in paragraph 1, the operators may request, at

their own expense, the documentary review of the initial analysis, test or diagnosis and, where appropriate, another analysis, test or diagnosis by another official laboratory.

Where sector specific legislation establishes rules for the sampling or analysis in a specific area, such rules take precedence over the basic principles laid down in Article 35 of the OCR. In particular, sector specific rules may make the extraction of sufficient quantity for additional samples obligatory or require specific procedures to be followed to obtain final samples. For example, several Union legal acts[37][38][39] establish specific procedures to ensure that sufficient quantity is taken to obtain representative samples for 'enforcement, defence and referee purposes'. Where sector specific rules were adopted on the basis of Regulation (EC) No 882/2004[40], the relevant provisions continue to apply, unless repealed or replaced by new legislation adopted under the OCR.

Where the procedures are not further specified in Union legislation, it is at the level of Member States to implement rules concerning the following:

- qualification criteria for the *recognised and appropriately qualified expert* in performing the documentary review as referred to in Article 35(1) of the OCR;
- the handling and storage of additional sample quantity taken for the purpose of an additional analysis as part of the second expert opinion;
- the use of the results of the initial analysis, of the second expert opinion and, if applicable, of a second official analysis, by the competent authorities and by the operators. The rules laid down in the OCR aim to ensure among others that operators have a sound factual basis for their decisions to exercise their right of appeal (Article 7 of the OCR). The appeal procedure itself however is not regulated by the OCR, but by way of national rules;
- any time limit with regard to the exercise of the right to a documentary review, e.g., taking into account time limits foreseen for relevant means of redress at national level, including for the right of appeal.

2.3.2.1. Conditions for sampling for a second expert opinion and for another analysis by another official laboratory

Additional sample quantity for the purpose of a second expert opinion and/or to be retained for the review (another analysis by another official laboratory) referred to in Article 35(3) of the OCR must be taken at the time of initial extraction of sample material. The competent

37 Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs (OJ L 88, 29.3.2007, p. 29).

38 Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (OJ L 70, 9.3.2006, p. 12).

39 Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

40 Regulation (EC) No 882/2004 of the European Parliament and of the Council (OJ L 165, 30.4.2004, p. 1) has been repealed by Regulation (EU) 2017/625 on 14 December 2019.

authority should ensure that each sample is equally representative of the sampled lot.

The sampling of sufficient sample quantity to allow for a second analysis as part of the second expert opinion and for the review referred to in Article 35(3) of the OCR is subject to the condition that such sampling is 'relevant, appropriate and technically feasible'.

Article 35(2) and recital 48 of the OCR describe some exemplary cases where the taking of sufficient sample quantity may not be 'relevant, appropriate or technically feasible'. Factors to be considered may vary depending on the type of animal or good, matrix, target agent, sampling conditions and the type of analysis to be performed. The following, non-exhaustive list of examples may be taken into account, without prejudice to sector-specific rules:

The sampling of sufficient sample quantity for the purposes of a second expert opinion and/or the review referred to in Article 35(3) of the OCR may not be

'*relevant*', where

- the right to a second official analysis is not implemented in national law;
- another analysis by another official laboratory in accordance with Article 35(3) of the OCR cannot be performed because no other official laboratory in the EU or EEA has the expertise or equipment to perform the analysis in question, if this circumstance is known to the competent authority prior to sampling; this decision should be justified on the basis of an investigation using, for example, the mechanisms of administrative assistance and cooperation provided for in Articles 102 to 108 of the OCR and/or available tools provided for by the Commission[41];

'*appropriate*', where

- the sampled material represents a risk if made available to the operator, e.g., disease material or potential bioterrorism agents; the taking of sufficient sample quantity for another analysis by another official laboratory in accordance with Article 35(3) of the OCR may nevertheless be appropriate in such cases, if the sample is transported, stored and handled under the control of the competent authority and official laboratories;
- the prevalence of the hazard in the animal or good may be particularly low or its distribution may be particularly sparse or irregular, so that the detection of the hazardous agent in additional material may not be possible with sufficient reliability;

'*technically feasible*', where

- there is an insufficient amount of sample quantity available for sampling;
- sufficient quantity that is equally representative of the sampled lot

41 https://ec.europa.eu/eusurvey/runner/contactform/DGSANTE_official_labs_R2017_625

cannot be obtained from goods that are ordered from operators by the competent authorities by means of distance communication without identifying themselves in accordance with Article 36. To the extent possible, competent authorities should attempt to preserve the operator's right to a second expert opinion by ordering sufficient units, but should inform the operator in accordance with Article 35(2)(b) of the OCR in case they fail to retrieve sufficient representative quantity.;

- the perishability, degradability or activity of the biological, chemical or physical agent to be analyzed prevents that (or limits the timeframe within which) samples can be stored and handled in compliance with Article 34(5) of the OCR.

In general, whenever the sampling of sufficient quantity in accordance with Article 35(2) of the OCR is deemed not "*relevant, appropriate or technically feasible*", the competent authority shall inform the operator thereof in accordance with Article 35(2)(b).

2.3.2.2. Another analysis by another official laboratory

Article 35(3) gives Member States the prerogative to implement the right to a documentary review of the initial analysis and to another official analysis (second official analysis) test or diagnosis by another official laboratory. The implementation of this right requires the adoption of national legislation (adopted after the entry into force of the OCR) specifically providing for the right to another official analysis.

The official laboratory carrying out another analysis in accordance with Article 35(3) of the OCR takes over the function of a 'referee' in cases where there is a dispute between the competent authority and the operator based on the initial analysis and the second expert opinion. Where no other official laboratory in the territory where the competent authority operates has the expertise or equipment to perform another analysis, competent authorities should, wherever possible, employ the mechanisms of cross-border designation provided for in Article 37(2) of the OCR.

If Member States decide to provide for the right to another analysis, test or diagnosis in accordance with Article 35(3) of the OCR, operators bear the costs of such analyses, tests or diagnoses.

2.3.3. Official laboratories (Articles 37 to 42 of the OCR)

2.3.3.1. Designation

Competent authorities are required to designate official laboratories to carry out the analyses, tests and diagnoses on samples taken during both official controls and other official activities. This designation shall be in writing, shall contain the elements referred to in Article 37(3) of the OCR and should provide documentary evidence to prove that the requirements in Article 37(4) and (5) of the OCR have been assessed and met.

Article 37(1) of the OCR does not preclude the designation of private laboratories as official laboratories, if they meet the requirements of Article 37(4) and (5) of the OCR. However, if a private laboratory maintains business relationships with operators subject to official controls in addition to their role as official laboratory, mechanisms should be in place to ensure impartiality with regard to the laboratory's tasks as official laboratory, in accordance with Article 37(4)(c) of the OCR. Unless official laboratories are designated with

a derogation from mandatory accreditation (see chapter 2.3.3.2. on accreditation), the mechanisms to ensure impartiality established in EN ISO/IEC 17025 are applicable.

A laboratory may take the function of both official laboratory and reference laboratory or reference centre, provided that it fulfils the requirements and obligations and is designated for each of its functions in accordance with the relevant provisions of the OCR (Articles 37-42 and Articles 92-101 of the OCR). The designation shall, among others, include a detailed description of "*the arrangements necessary to ensure efficient and effective coordination and collaboration between the laboratory and the competent authorities*" (Article 37(3)(c) of the OCR). Such arrangements may cover, for example:

- procedures for regular planning and resource allocation, to ensure that competent authorities have access to laboratory capacities in accordance with Article 37(4)(a), (b) and (d) of the OCR and in line with their multi-annual national control plans;
- procedures for regular reporting, including timely exchange of data on samples and laboratory results, in particular where these results point to non-compliances or risks to human, animal or plant health, or, as regards GMOs and plant protection products, also to the environment (Article 38(1) of the OCR);
- the collaboration of official laboratories with national and/or EU reference laboratories, in particular ensuring that the competent authority is informed about the outcomes of inter-laboratory comparative tests or proficiency tests in accordance with Article 38(2) of the OCR, enabling it to fulfil its obligations arising from Article 39(2) of the OCR;
- the performance of audits in accordance with Article 39(1) of the OCR, including mechanisms to ensure that the competent authority is informed about the outcomes of accreditation assessments, enabling it to fulfil its obligations arising from Article 39(2) of the OCR.

2.3.3.2. Accreditation

Official laboratories are obliged to operate in accordance with EN ISO/IEC 17025 and to be accredited under this standard. According to Article 37(5) of the OCR, the scope of their accreditation shall include all the methods of laboratory analysis, test or diagnosis required to be used by the laboratory when it operates as an official laboratory.

In this context, the term "method" can be understood as a measurement procedure that is applied to a specific matrix or group of matrices, and to a specific analyte or group of analytes, or a combination thereof, depending on the method in question, in line with EN ISO/IEC 17025. The OCR foresees derogations from this obligation, by giving Member States the prerogative of designating an official laboratory that does not fulfil the obligation

of accreditation under certain conditions, and grants some flexibility with respect to the scope of the accreditation:

1. The scope of the accreditation of an official laboratory may
   a. comprise groups of methods (Article 37(5)(b) of the OCR)
   b. may be defined in a flexible manner[42] (Article 37(5)(c) of the OCR)
2. Permanent derogations from mandatory accreditation are established for official laboratories that only carry out detection of *Trichinella*[43] in meat and laboratories that only carry out analyses, tests or diagnoses in the context of other official activities (under the conditions described in Article 40(1)(a) and Article 40(1)(b) of the OCR, respectively);
3. Permanent derogations from the obligation that the scope of accreditation shall cover all methods used by the official laboratory are established in Commission Delegated Regulation (EU) 2021/1353[44] for the areas of plant health, food contact materials, food additives, food enzymes, flavourings and feed additives based on the empowerment in Article 41 of the OCR;
4. A temporary derogation from mandatory accreditation (1 + 1 year) is allowed for official laboratories in the following cases, referred to in Article 42(1) of the OCR, and subject to the conditions referred to in Article 42(2) to (4) of the OCR:
   a. where the use of the method is newly required by Union rules (counting from the date of entry into force of such rules)
   b. when changes to a method in use require a new or extended accreditation (if not covered by a flexible accreditation scope)

42 'Flexible accreditation scope': Scope of accreditation expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the conformity assessment body as confirmed by the accreditation body (ISO/IEC 17011:2017).

43 Guidelines on minimum recommendations for official laboratory appointed for the detection of Trichinella in meat: https://ec.europa.eu/food/system/files/2021-10/biosafety_fh_legis_guidance_min-recom-trichinella-meat_en.pdf

44 Commission Delegated Regulation (EU) 2021/1353 of 17 May 2021 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to the cases and conditions under which competent authorities may designate official laboratories which do not fulfil the conditions in relation to all the methods they use for official controls or other official activities (OJ L 291, 13.8.2021, p. 20).

c. when the need for the use of the method results from an emergency situation or an emerging risk.

Based on the empowerment in Article 41 of the OCR, Commission Delegated Regulation (EU) 2021/1353 lays down rules under which competent authorities may designate official laboratories that do not fulfill the requirement laid down in Article 37(4)(e) of the OCR in relation to all the methods they use for official controls.

The areas covered under Delegated Regulation (EU) 2021/1353, for which derogations under Article 41 of the OCR may be applied, are contact materials, food additives, food enzymes, flavourings, feed additives and plant health.

Articles 2 and 3 of Delegated Regulation (EU) 2021/1353 lay down the following conditions for an official laboratory in the areas covered under that Regulation to be designated for a method outside the scope of its accreditation:

(i) The laboratory must have a quality assurance system in place to ensure that reliable results are obtained from the use of methods of laboratory analysis, test or diagnosis outside the scope of their accreditation.

Having a quality assurance system in place is a requirement to obtain accreditation in accordance with standard EN ISO/IEC 17025 as required by Article 37(4)(e) of the OCR. However, for the purposes of Delegated Regulation (EU) 2021/1353, the quality assurance system must *also* be applied to the methods used *outside* the scope of accreditation.

(ii) The non-accredited method used by the laboratory is characterised by the criteria relevant to the respective area set out in Annex III to the OCR.

This requirement is similar to the basic requirement for method characterisation in Article 34(4) of the OCR. However, for the specific purpose of Delegated Regulation (EU) 2021/1353, this requirement must be fulfilled (and not only '*whenever possible*', as required in Article 34(4) of the OCR).

(iii) For the area of plant health, Article 3 of Delegated Regulation (EU) 2021/1353 requires that in addition, the official laboratory is already accredited (in accordance with standard EN ISO/IEC 17025) for a method that belongs to one of the categories listed in the Annex to that Regulation; the laboratory may then be designated under the condition that it uses that same method outside the scope of accreditation on a pest from the same organism group as the pest for which the accredited method is used. The following groups are to be considered '*organism groups*', in line with recital 8 of Delegated Regulation (EU) 2021/1353:

» nematodes;

» bacteria;

» fungi and oomycetes;

» viruses, viroids and phytoplasmas;

» insects and mites.

Where competent authorities designate a laboratory both as an official laboratory in accordance with Article 37(1) of the OCR and as a national reference laboratory in accordance with Article 100(1) of the OCR, the

derogation provided for in Article 41 of OCR can be applied for the designation as an official laboratory. For that laboratory's function as a reference laboratory, the derogation provided for in Article 41 of the OCR does not apply.

However, in the area of plant health, official laboratories designated on the basis of a derogation provided for in Article 41 of the OCR can subsequently be designated as national (or EU) reference laboratory regardless of whether it fulfills the accreditation requirements laid down in Article 37(4)(e) of the OCR (or Article 93(3)(a) of the OCR for EURLs, respectively)[45].

2.3.3.3. Cross-border designation

Competent authorities may designate as an official laboratory an official laboratory located in another Member State or EEA country (under the conditions laid down in Article 37(2) of the OCR). This provision gives Member States some flexibility, for example, when no laboratory that fulfils the requirements of Article 37(4) and (5) of the OCR is available in the territory in which the competent authority operates. The rules and requirements set out in Articles 34-42 of the OCR also apply to official laboratories designated in another Member State or EEA country. For example, laboratories designated by two or more competent authorities must be able to fulfil the requirement to have sufficient laboratory capacity (Article 37(4)(a), (b) and (d) of the OCR) with respect to its commitments toward all designating competent authorities.

In addition to the arrangements between each designating competent authority and its designated laboratories, competent authorities that have designated the same laboratory as official laboratory should communicate and coordinate between themselves in order to arrange for:

- the performance of audits (Article 37(2) in conjunction with Article 39(1) of the OCR): audits can either be carried out by both/all competent authorities separately or can be delegated to the competent authority of the Member State where the laboratory is located;
- the exchange of information on the scope of accreditation of the laboratory and the outcomes of accreditation assessments, particularly in cases where the hosting Member State relies on accreditation assessments;
- the exchange of information for the case of withdrawal of designation as official laboratory according to Article 39(2) of the OCR, in particular the withdrawal by the competent authority in the Member State where the laboratory is located, given that this designation is a prerequisite for designation by another Member State according to Article 37(2)(b) of the OCR.

In order to facilitate collaboration between Member States for the purpose of cross-border designation, and for the evaluation of cases described in Article 37(6) of the OCR, the Commission offers a central platform for Member States to share among each other contact information of designated national laboratories in their territories. In addition to the information shared via the platform, Member States may consider offering additional, more detailed information with regard to their designated laboratories' activities (such as available methods, accreditation status) on their competent authorities' or laboratories' websites.

45 Article 100(2), second sentence of the OCR and Article 93(4) of the OCR for NRLs and EURLs, respectively.

2.3.3.4. Sub-contracting

All laboratories that perform analyses, tests and diagnoses on official samples must be designated as official laboratories, unless no official laboratory designated in the Union or an EEA country has the expertise, equipment, infrastructure and staff necessary to perform new or particularly uncommon laboratory analyses, tests or diagnoses (Article 37(6) of the OCR). Therefore, other than in cases pursuant to Article 37(6) of the OCR, official laboratories may only subcontract tasks to another official laboratory. For laboratories accredited in accordance with EN ISO/IEC 17025, the relevant provisions regarding externally provided products and services of that standard shall be followed in such cases.

The designating competent authority should always be informed prior to sub-contracting any activity to another official laboratory. If the sub-contracted laboratory is located in the same Member State, but is designated by a different competent authority, coordination and communication between the designating competent authorities is necessary to ensure that the sub-contracted laboratory fulfils the designation requirements laid down in Article 37(4) and (5) of the OCR for the time of the sub-contract and for the sub-contracted activity. For this purpose, competent authorities located in the same MS may draw on existing forms of administrative cooperation.

In the case of subcontracting tasks to an official laboratory in another Member State or EEA country, Article 37(2) of the OCR requires the competent authority in the first Member State to designate the laboratory located in the other Member State or EEA country. This rule ensures that the designating competent authority in the first Member State has oversight over each designated laboratory with regard to its tasks, performance and fulfilment of requirements at all times, and that effective coordination can take place in accordance with Article 37(2)(a) of the OCR.

Article 37(6) of the OCR stipulates an exception to the designation requirement, by allowing competent authorities to task laboratories not designated as official laboratories or diagnostic centres with new or particularly uncommon laboratory analyses, tests or diagnoses. However, this is only allowed, if no other official laboratory in a Member State or EEA country has the expertise, equipment, infrastructure and staff necessary to perform such analyses. Competent authorities should justify their decision to apply this provision by showing that investigations have revealed that no other suitable official laboratory could be identified. Investigations could involve the mechanisms for administrative assistance and cooperation provided for in Articles 102-108 of the OCR and/or the database of laboratories developed by the Directorate-General for Health and Food Safety of the Commission[46]. The procedure to 'request a laboratory or diagnostic centre [..] to carry out those analyses, tests and diagnoses' does not require a formal designation in accordance with Article 37(1) of the OCR but can be based on a contractual agreement with the respective laboratory.

2.3.3.5. Audits

It is the responsibility of the designating competent authority to verify that the official laboratory continues to fulfil the designation requirements laid down in Article 37(4) and (5) of the OCR and the obligations in Article 38 of the OCR. Accreditation audits are the main instrument to ensure high performance of official laboratories. Therefore, competent authorities may fulfil their obligation to organise regular audits by relying on

46 https://ec.europa.eu/eusurvey/runner/contactform/DGSANTE_official_labs_R2017_625

accreditation assessments performed by the national accreditation body, if they consider these audits redundant, i.e. equivalent to audits performed by the competent authority, in accordance with Article 39(1) of the OCR. Competent authorities should ensure that they are informed about the outcomes of accreditation assessments as well as any remedial action taken by the official laboratory, in order to be able to take action in accordance with Article 39(2) of the OCR.

In addition to accreditation assessments, mechanisms should be in place that enable the competent authority to respond to non-compliance of the official laboratory with the requirements laid down in Article 37(4)(a) to (d) of the OCR and its obligations laid down in Article 38 of the OCR. Such mechanisms may include annual reporting, regular reporting, exchange of information with local authorities to which the competent authority has transferred responsibilities in accordance with Article 4(2) of the OCR and which work with the official laboratory on a regular basis, as well as review of outcomes of inter-laboratory comparative tests or proficiency tests organised by NRLs.

When there is indication of non-compliance of the official laboratory with regard to any of the points mentioned in Article 39(2) of the OCR, the competent authority shall take action, for example by organising additional audits in accordance with Article 39(1) of the OCR, by requesting the laboratory to take remedial action and by ultimately withdrawing the designation, if the laboratory fails to take appropriate and timely remedial action.

For guidance on audit arrangements between competent authorities of different Member States see above under 'cross-border designation' and 'sub-contracting'.

2.4. CHAPTER V – Official controls on animals and goods entering the Union

2.4.1. Official control rules for consignments entering the Union

2.4.1.1. Consignments and accompanying documents

Article 3 of the OCR

Definitions

For the purposes of this Regulation, the following definitions apply: [..]

(37) "consignment" means a number of animals or quantity of goods covered by the same official certificate, official attestation or any other document, conveyed by the same means of transport and coming from the same territory or third country, and, except for goods subject to the rules referred to in point (g) of Article 1(2), being of the same type, class or description; [..]

Official certificates, official attestations or documents accompanying a consignment, identify the animals or goods that belong to the same consignment. According to Article 89 of the OCR, official certificates must allow the easy verification of the link with the consignment, lot or individual animal or good that they cover and must allow for the identification of the issuing authority, the person who signed

them and the date of issue. Similarly, it results from Article 91 of the OCR that, where official attestations relate to a consignment or a lot, they must allow the verification of the link with that consignment or lot. Consequently, these documents contribute to the identification of the consignment and accompany it to provide assurance that the rules referred to in Article 1(2) of the OCR are complied with.

Animals and goods of the same consignment must be of the same type, class, or description, except for plants, plant products and other objects, subject to the rules referred to in Article 1(2)(g) of the OCR, which can be heterogeneous as regards the type, class or description. For example, a consignment of plant products can consist of different kinds of fruits and vegetables, covered by the same phytosanitary certificate.

Being of the same type, class or description, where a certificate is required to enter the animals or the goods into the Union, implies the following:

(i) the animals and goods can be covered by the same certificate, as required by EU legislation;

(ii) they can respond to the same description of the consignment in Part I of that certificate and

(iii) they all have to meet the selected statements in Part II of the relevant certificate.

A single consignment can be comprised of different lots. The animals or goods in a consignment are transported in the same means of transport.

Goods of the same consignment should be preserved at the same temperature (ambient, chilled or frozen) during transport.

2.4.1.2. Certification rules for animals, products of animal origin, composite products and germinal products.

A key specificity related to animals, products of animal origin and germinal products, is that the certifying officer authorised to sign the official certificates must be an official veterinarian according to Article 237(2) of Regulation (EU) 2016/429, unless other specific rules apply.

For animals and hatching eggs, the certificates must be issued within 10 days prior to the date of arrival at the BCP, a period which, in the case of sea transport, can be extended to cover the duration of the journey by sea (when supported by a supplementary declaration by the captain of the ship) according to Articles 3, 14 and 101 of Commission Delegated Regulation (EU) 2020/692[47].

47 Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

As regards germinal products, pursuant to Article 182a of the same Delegated Regulation, it is possible to import into the Union old stocks collected and produced under previously applicable EU rules. Specific certificates are available for that purpose[48].

Case of transit or transhipment in third countries

After leaving their third country of origin, consignments can transit through or be transhipped in other third countries before entering the Union territory. However, the transit, unloading, or transhipment in third countries of animals (including change of water for aquatic animals) is only allowed in third countries listed for the entry into the Union of the given commodity according to Articles 14(2) and 167(b) of Commission Delegated Regulation (EU) 2020/692. Some derogations from this rule for terrestrial animals are provided for in Articles 15 and 16 of the same Delegated Regulation.

Where the products of animal origin or the composite products stay in their sealed transport container so that the sanitary status of the consignment does not change, the third country of transit does not need to issue a new certificate,, as the animal health requirements referred to in Article 238(1) of Regulation (EU) 2016/429 and the public health requirements referred to in Article 21(4)(a) of Commission Delegated Regulation (EU) 2022/2292[49] are not compromised.

However, the third country of transit must be listed for the concerned product and issue a new certificate in the following cases, considering that the health guarantees provided by the initial certificate are no longer valid:

- unloading of products in bulk, including palletised packages, and reloading into a transport container destined for the Union;
- unloading for storage in a warehouse of the third country of transit, regardless of its customs status, and re-loading into a means of transport destined for the Union;

48 Articles 20-23 of Commission Implementing Regulation (EU) 2021/403 of 24 March 2021 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates and model animal health/official certificates, for the entry into the Union and movements between Member States of consignments of certain categories of terrestrial animals and germinal products thereof, official certification regarding such certificates and repealing Decision 2010/470/EU (OJ L 113, 31.3.2021, p. 1).

49 Commission Delegated Regulation (EU) 2022/2292 of 6 September 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption (OJ L 304, 24.11.2022, p. 1).

- unloading and any handling or processing in an establishment of the third country of transit, before re-loading into a means of transport destined for the Union.

Case of multiple certification

As a general principle, a consignment of products of animal origin referred to in Article 21(1)(b) of Delegated Regulation (EU) 2022/2292 or composite products referred to in Article 21(1)(f) of the same Regulation is accompanied by only one official certificate. However, in certain circumstances, a consignment may have to be accompanied by several official certificates. This could be the case for foodstuffs (the so-called mixed products) containing different products of animal origin, for example, fishery products and dairy products. In this case:

- the consignment must be accompanied by the relevant certificates required for each type of product of animal origin according to Article 21 of Delegated Regulation (EU) 2022/2292;
- in each certificate, the description of the consignment must specify the species, the type of products, the treatment and the listed establishment(s) related to the only category(ies) of product of animal origin covered by the certificate. However, the HS codes, the number of packages and weights should be related to the final product, meaning that this information should be the same in all of those certificates and refer to the consignment as a whole and not to the product covered by each specific certificate;
- to ensure proper traceability, the certificates should either be identified with the same reference, or each certificate should include a reference to the other certificates;
- at the BCP, only one CHED will be issued, as there is one consignment. The description of the consignment must refer to the information related to the final product.

Similarly, a consignment of products containing or composed of different animal by-products, like compound feed or compound fertilisers, may need more than one official certificate. With such products, relevant certificates must be issued for each type of animal by-product.

2.4.1.3. Certification rules for plants, plant products and other objects

Certain plants, plant products and other objects originating from a third country may enter the Union if accompanied by a phytosanitary certificate, as specified in Article 71 of Regulation (EU) 2016/2031, issued by the competent authorities of the third country.

Whilst a phytosanitary certificate for export must be issued for consignments introduced directly from the third country of origin, pursuant to Article 76 of Regulation (EU) 2016/2031, a phytosanitary certificate for export or re-export must be issued when consignments are introduced from a third country of dispatch, meaning a re-exporting country, i.e., other than the one of their origin.

A phytosanitary certificate for re-export may be issued by the country of dispatch in the case where the commodity in the consignment has not been grown or processed to change its nature in that country and only where an original phytosanitary certificate for export, or its certified copy, is available.

The content of these certificates is set out in Annex V to Regulation (EU) 2016/2031. The phytosanitary certificate for export, or its certified copy, must accompany the phytosanitary certificate for re-export and must be linked to it. For the issuance of the phytosanitary certificate for re-export, the responsible competent authorities must take into account any changes in the pest risk associated with the consignment that may have occurred in the country of dispatch. If the consignment has been repacked, reloaded, stored, split up or combined with other imported consignments, a phytosanitary certificate for re-export may still be issued, provided that it has not been exposed to infestation or contamination by pests regulated by Union legislation.

In certain cases, in order to provide assurance that the consignment complies with the applicable Union requirements, the competent authorities of the third country of dispatch must take appropriate action to issue a new phytosanitary certificate of export.

An additional declaration, where applicable, must be present and correct for the competent authority to accept the consignment, according to Article 76 of Regulation (EU) 2016/2031.

2.4.1.4. Electronic certification

The electronic certification service of TRACES allows the production in and transmission to TRACES of electronic official certificates and documents. It facilitates the performance of official controls as all actors involved in a certain movement have instant access through TRACES to the original electronic certificate or CHED. In addition, the electronic certification service of TRACES is offered to all competent authorities using TRACES (both EU and non-EU) free of charge. Official certificates and CHEDs have to be signed electronically, where sectoral rules require so, as in the case of the issuance of the official certificate referred to in Article 35(1) of Regulation (EU) 2018/848, which must be issued in electronic form in TRACES (Article 1 of Commission Implementing Regulation (EU) 2021/2119[50]).

Only official certificates and CHEDs that comply with the requirements for electronic certification provided for in the IMSOC Regulation can be considered as electronic and waive the requirement for the issuance of the relevant official certificates and documents in paper format.

50 Commission Implementing Regulation (EU) 2021/2119 of 1 December 2021 laying down detailed rules on certain records and declarations required from operators and groups of operators and on the technical means for the issuance of certificates in accordance with Regulation (EU) 2018/848 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2021/1378 as regards the issuance of the certificate for operators, groups of operators and exporters in third countries (OJ L 430, 02/12/2021, p. 24).

2.4.1.5. Animals and goods entering the Union subject to official controls

Article 3 of the OCR

Definitions

For the purposes of this Regulation, the following definitions apply: [..]

(40) "entering the Union" or "entry into the Union" means the action of bringing animals and goods into one of the territories that are listed in Annex I to this Regulation from outside these territories, except in relation to the rules referred to in point (g) of Article 1(2) for which these terms mean the action of bringing goods into the 'Union territory' as defined in the second subparagraph of Article 1(3) of Regulation (EU) 2016/2031;

(44) "transit" means movement from one third country to another third country passing under customs supervision through one of the territories listed in Annex I or from one of the territories listed in Annex I to another territory listed in Annex I after passing through the territory of a third country, except in relation to the rules referred to in point (g) of Article 1(2), for which it means one of the following;

(a) movement from one third country to another third country, as defined in the first subparagraph of Article 1(3) of Regulation (EU) 2016/2031 passing under customs supervision through the 'Union territory' as defined in the second subparagraph of Article 1(3) of that Regulation; or

(b) movement from the 'Union territory' to another part of the 'Union territory', as defined in the second subparagraph of Article 1(3) of Regulation (EU) 2016/2031, passing through the territory of third country as defined in the first subparagraph of Article 1(3) of that Regulation; [..]

The OCR lays down rules for official controls on all consignments of animals and goods entering the Union in Articles 43 to 77 and distinguishes between animals and goods which are subject or not to official controls at BCPs, in order to ascertain compliance with rules referred to in Article 1(2).

Articles 44 to 46 of the OCR provide for official controls on animals and goods which are not subject to mandatory presentation at BCPs. They apply to consignments considered to be of a lower risk and allow for flexibility as to the location of the official controls, which can be carried out at any appropriate place from the point of entry into the Union, including a BCP, to the place of destination (Article 44(3) of the OCR). Those controls are to be performed on a risk basis.

To determine the risk, the competent authorities must consider, *inter alia*, in accordance with Article 44(2) of the OCR the history of compliance of: the establishment of production or origin, the exporter, the operator responsible for the consignment, the country

exporting to the EU, and the guarantees provided by its competent authorities as regards the compliance with rules referred to in Article 1(2) of the OCR.

Articles 47 to 64 of the OCR provide for official controls on animals and goods referred to in Article 47(1) that are required to be presented at the BCP of first arrival in the Union and undergo official controls.

Prior to the physical arrival of the consignment at the BCP, the operator responsible for the consignment must give prior notification of its arrival by completing part I of the CHED. This is an obligatory step for the presentation of the consignment for official controls at the BCP and is provided for in Article 56 of the OCR, except in specific cases such as transhipment within the time limits defined by Commission Delegated Regulation (EU) 2019/2124. This notification must be made no later than one working day before the expected arrival of the consignment to the BCP of first arrival and if there are logistical constraints no later than four hours before the expected arrival, according to Article 1 of Commission Implementing Regulation (EU) 2019/1013[51].

In addition to these requirements, for all categories of organic products and in-conversion products, a prior notification pursuant to Article 3 of Commission Implementing Regulation (EU) 2021/2307[52] must be given through TRACES within the same time limits provided for in Implementing Regulation (EU) 2019/1013. Box 20 of the COI is used for this purpose.

According to Article 5 of the Delegated Regulation (EU) 2021/2306, the control body or control authority must upload in TRACES the commercial and transport documents of the consignment while issuing the relevant COI. In case the consignment is also covered by a CHED, it is recommended that the same commercial and transport documents are attached to it, to facilitate the cooperation between the competent authorities during the parallel checks.

Under the empowerments of Article 47(2) of the OCR, the Commission establishes the lists of some of the animals and goods subject to official controls at border control posts, identified with the corresponding Combined Nomenclature (CN) codes.

51 Commission Implementing Regulation (EU) 2019/1013 of 16 April 2019 on prior notification of consignments of certain categories of animals and goods entering the Union (OJ L 165, 21.6.2019, p. 8).

52 Commission Implementing Regulation (EU) 2021/2307 of 21 October 2021 laying down rules on documents and notifications required for organic and in-conversion products intended for import into the Union (OJ L 461, 27.12.2021, p. 30).

In particular, Commission Implementing Regulation (EU) 2021/632[53] lists the animals, products of animal origin, germinal products, animal by-products and derived products, composite products, and hay and straw, subject to official controls at BCPs. Animals and products that are not included in the Annex to the Implementing Regulation are by default *excluded* from the official controls provided for in Article 47(1) of the OCR. Commission Delegated Regulation (EU) 2021/630[54] exempts from official controls at BCPs certain shelf-stable composite products presenting a low risk for public health and animal health and lays down rules for the performance of official controls on those products.

Further to that, Commission Implementing Regulation (EU) 2019/1793[55] lists certain food and feed of non-animal origin from certain third countries subject to a temporary increase of official controls as well as emergency measures (special conditions for entry and suspension of entry into the Union) governing the entry of such food and feed, in accordance with Article 47(1)(d) and (e) of the OCR.

In the plant health area, Commission Implementing Regulation (EU) 2019/2072[56] establishes in its Annexes XI and XII, the lists of plants, plant products and other objects pursuant to Articles 72(1) and 74(1) of Regulation (EU) 2016/2031, that are subject to official controls at the BCP of first arrival into the Union, in accordance with Article 47(1)(c) of the OCR.

53 Commission Implementing Regulation (EU) 2021/632 of 13 April 2021 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the lists of animals, products of animal origin, germinal products, animal by-products and derived products, composite products, and hay and straw subject to official controls at border control posts, and repealing Commission Implementing Regulation (EU) 2019/2007 and Commission Decision 2007/275/EC (OJ L 132, 19.4.2021, p. 24)

54 Commission Delegated Regulation (EU) 2021/630 of 16 February 2021 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of goods exempted from official controls at border control posts and amending Commission Decision 2007/275/EC (OJ L 132, 19.4.2021, p. 17).

55 Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660 (OJ L 277, 29.10.2019, p. 89).

56 Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1).

Competent authorities are responsible for assessing the identity of animals and goods and deciding if they correspond to the descriptions provided for in the above Regulations and, therefore, whether they fall within their scope or not.

2.4.1.6. Performance of checks

Article 3 of the OCR

Definitions

For the purposes of this Regulation, the following definitions apply: [..]

(41) 'documentary check' means the examination of the official certificates, official attestations and other documents including documents of a commercial nature, which are required to accompany the consignment as provided for by the rules referred to in Article 1(2), by Article 56(1) or by implementing acts adopted in accordance with Articles 77(3), 126(3), 128(1) and 129(1);

(42) 'identity check' means a visual inspection to verify that the content and the labelling of a consignment, including the marks on animals, seals and means of transport, correspond to the information provided in the official certificates, official attestations and other documents accompanying it;

(43) 'physical check' means a check on animals or goods and, as appropriate, checks on packaging, the means of transport, labelling and temperature, the sampling for analysis, testing or diagnosis and any other check necessary to verify compliance with the rules referred to in Article 1(2); [..]

According to Article 15(1) and (3) of the OCR, staff of the competent authorities must be granted access by the operators to equipment, means of transport and premises, information management systems, the animals and goods under their control and the documents, to the extent that this is necessary to perform official controls on consignments. The operators responsible for the consignments must make available all information contained in paper or electronic form concerning the consignment.

There are three different types of checks on animals and goods referred to in Article 47(1) of the OCR or which fall under Article 44 of the OCR and must be performed in this standard order: documentary checks, identity checks, physical checks. They have to be carried out at different frequencies, ranging from the highest frequency for documentary checks to a reduced frequency for identity checks and an equal or lower frequency for physical checks.

For the animals and goods referred to in Article 47(1) of the OCR, documentary checks must be carried out on all consignments by the competent authority responsible of the BCP (Article 54(1) of the OCR). For those falling under the scope of Article 44 of the OCR, official controls shall be carried out at an appropriate place (as defined in Article 44(3)). In accordance with the general rule laid down in Article 9(5) of the OCR, the administrative burden and operational disruption for operators must be kept to the minimum necessary. The resulting operational disruption should therefore be taken into account for the choice of place of official controls of goods falling under Article

44 of the OCR, in order to ensure a smooth functioning of the trade. Documentary checks are performed on the basis of a risk assessment and with appropriate frequency (Articles 44(1) and 45(1) of the OCR).

Consignments of animals and goods referred to in Article 47(1) of the OCR subject to official controls at the BCP, must be accompanied by the original certificates or documents, or electronic equivalents required by the rules referred to in Article 1(2). Pursuant to Article 50 of the OCR, these certificates or documents must be kept by the competent authorities of the BCPs who must provide authenticated or electronic copies to the operators, unless otherwise provided for by the rules referred to in Article 1(2). Under Articles 11, 13 and 15 of Delegated Regulation (EU) 2019/2124 concerning animals staying on the same means of transport for onward travel and transhipped consignments, the accompanying certificates must remain with the consignments for the rest of the journey.

Documentary checks for certain plants, plant products and other objects may be performed at a distance from the BCP, according to Article 7 of Commission Delegated Regulation (EU) 2019/2123[57].

Documentary checks include:

- the inspection of official certificates, official attestations and other documents accompanying the consignments, or their electronic equivalents submitted in TRACES and
- the verification of compliance of these documents with the relevant legal requirements and of the information they provide with the rules referred to in Article 1(2) of the OCR.

For animals and goods referred to in Article 47(1) of the OCR, when performing a documentary check, the competent authorities must examine the certificates, attestations and other documents which are required to accompany the consignment. They must verify that, in accordance with the provisions of Article 56 of the OCR, part I of the CHED, duly and accurately completed, has been submitted by the operator in the IMSOC (TRACES) *prior* to the arrival of the consignment at the BCP and that the information contained corresponds to that included in the official certificates, official attestations, and other documents. Documentary checks also concern the information on the use of animals and goods and their destination.

Following documentary checks, the competent authorities must carry out identity checks on consignments that are presented at the place of official controls, at a certain frequency, as required by Union law such as Commission Implementing Regulation (EU)2019/2129[58] Commission Implementing Regulation (EU) 2019/1793 and Commission Implementing

57 Commission Delegated Regulation (EU) 2019/2123 of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for the cases where and the conditions under which identity checks and physical checks on certain goods may be performed at control points and documentary checks may be performed at distance from border control posts (OJ L 321, 12.12.2019, p. 64).

58 Commission Implementing Regulation (EU) 2019/2129 of 25 November 2019 establishing rules for the uniform application of frequency rates for identity checks and physical checks on certain consignments of animals and goods entering the Union (OJ L 321, 12.12.2019, p. 122).

Regulation (EU) 2022/2389[59]. These checks, defined in point 42 of Article 3 of the OCR, include in particular the verification of the number and characteristics of animals, the content and quantity of goods entering the Union and, where applicable, stamps, identification marks, codes, seals and means of transport, in relation to the respective information contained in the official certificates, official attestations and other documents.

For consignments of certain products of animal origin, germinal products, animal by-products, derived products, hay and straw and composite products, identity checks may be limited to the identification of the means of transport and seal checks when certain conditions are met, as laid down in Article 3(2) of Commission Implementing Regulation (EU) 2019/2130[60].

Finally, physical checks must be performed at a certain frequency as required by Union law (such as the Regulations mentioned above establishing frequencies for identity checks), in order to verify compliance of animals and goods with the applicable rules referred to in Article 1(2) of OCR and the specific requirements defined in the official certificates, official attestations and other documents (Article 4(1) of Commission Implementing Regulation (EU) 2019/2130).

Implementing Regulation (EU) 2019/2130 lays down detailed rules on the operations to be carried out during and after documentary checks, identity checks and physical checks on animals and goods subject to official controls at BCPs.

Article 6 of Regulation (EU) 2021/2306 provides detailed rules for the official controls of organic products and in-conversion products.

2.4.1.7. Use of the CHED

In accordance with Article 56(1) and (4) of the OCR, for each consignment of goods referred to in Article 47(1) of the OCR, the operator responsible for the consignment must complete and submit Part I of the CHED to provide the required information to the competent authorities of the BCP on the identification and the destination of that consignment.

The competent authorities of the BCP must record in the CHED the outcome of the official controls they carried out and the decision made on the consignment (Article 56(3) of the OCR).

59 Commission Implementing Regulation (EU) 2022/2389 of 7 December 2022 establishing rules for the uniform application of frequency rates for identity checks and physical checks on consignments of plants, plant products and other objects entering the Union (OJ L 316, 8.12.2022, p. 42).

60 Commission Implementing Regulation (EU) 2019/2130 of 25 November 2019 establishing detailed rules on the operations to be carried out during and after documentary checks, identity checks and physical checks on animals and goods subject to official controls at border control posts (OJ L 321, 12.12.2019, p. 128).

Finally, the custom authorities must use the finalised CHED to select the appropriate customs procedure and to release the consignment with a validated CHED for free circulation in accordance with Article 57 of the OCR.

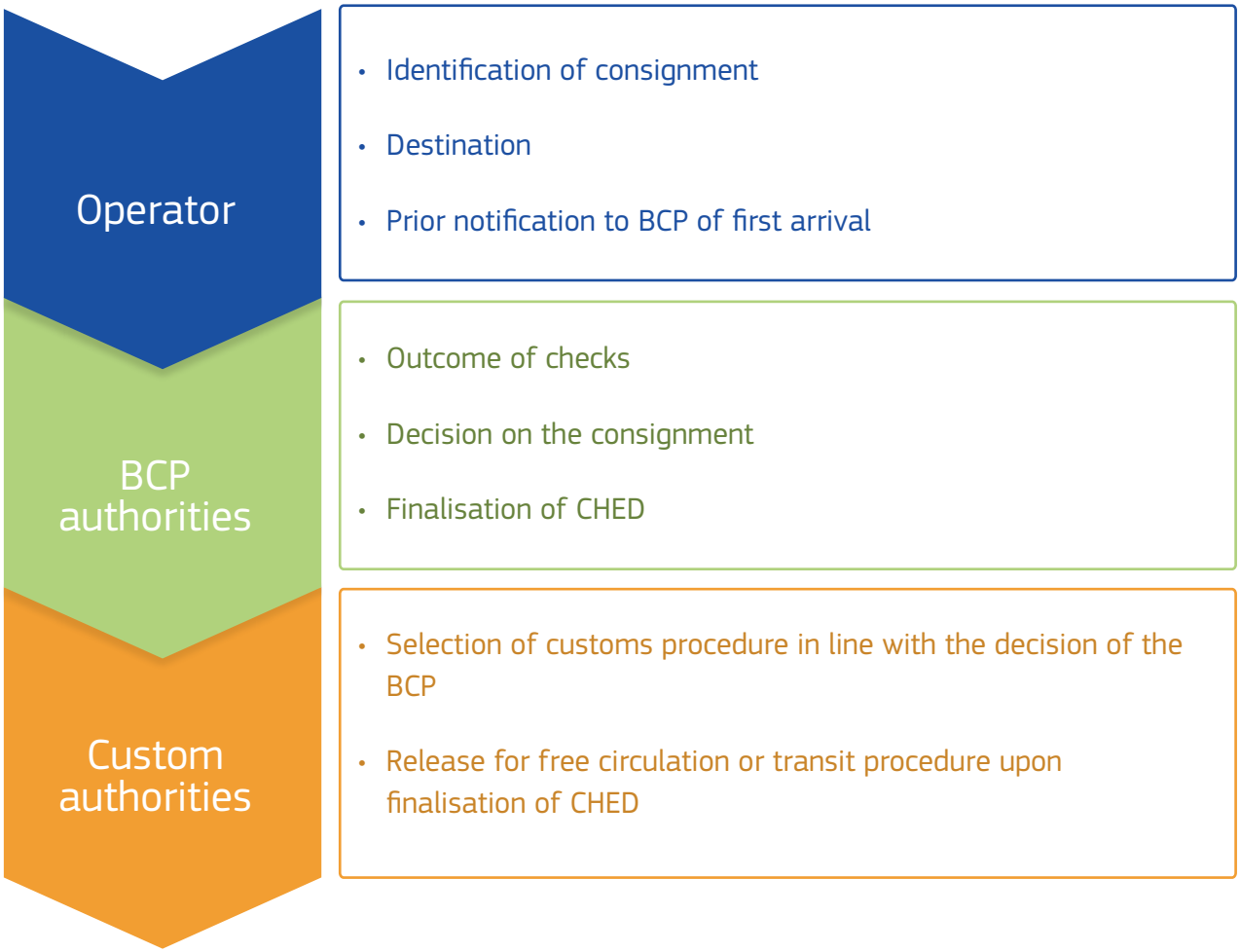


Figure 6: CHED completion and use according to Articles 56 and 57 of the OCR

The finalisation of the CHED is a prerequisite for the possible split of a consignment according to Article 50(3) of the OCR. The authenticated paper or electronic copy of the official certificates or documents of the original consignment must be issued for the responsible operator according to Article 50(2) of the OCR.

A finalised CHED on paper or electronic form *must* accompany the consignment to the place of destination and until it is released for free circulation, according to Article 4 of Commission Delegated Regulation (EU) 2019/1602[61] or until it leaves the Union. According to Article 57(2) of the OCR, customs authorities can only authorise the placing of the consignment under a customs procedure which is compatible with the BCP decision mentioned in the CHED.

Each BCP decision opens different options available to the operator in relation to the customs declaration and the handling of the consignment. For example, if the BCP decision on a consignment is for it to be released for free circulation, the operator can still opt for the consignment to undergo the customs procedures of transit or re-export. However, if the BCP decision on the consignment is for transit, then the operator cannot request a customs release for free circulation.

2.4.1.8. Change of purpose and special treatment of consignments

In cases where the intended use of the consignment changes, after its rejection at the BCP but while it is still under the control of the BCP authority, a replacement CHED must be issued and linked to the initial CHED.

By contrast, when the consignment is rejected and is subsequently directed for special treatment, a CHED replacement is not appropriate.

Instead, the competent authority which supervises the special treatment must decide on the consignment's compliance with Union and national rules. Based on this *documented* decision, customs authorities will decide on the release of the consignment for free circulation and the quantity management will be performed outside the EU CSW-CERTEX

61 Commission Delegated Regulation (EU) 2019/1602 of 23 April 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council concerning the Common Health Entry Document accompanying consignments of animals and goods to their destination (OJ L 250, 30/09/2019, p. 6).

2.4.1.9. CHED-PP linked to a phytosanitary certificate

It results from the definition of the word "*consignment*" in Article 3(37) of the OCR, that for goods subject to plant health rules referred to in Article 1(2)(g) of the OCR, the goods in the consignment do not need to be of the same type, class or description. According to the said provision, a consignment means a quantity of goods which is, among others, "*(…) covered by the same official certificate*".

The combined reading of Article 56 of the OCR and of Article 3(37) of the OCR shows that a CHED-PP, as defined in Article 40 of the IMSOC Regulation, can only be issued in relation to a quantity of plants, plant products or other objects covered by the *same* phytosanitary certificate.

Accordingly, while a phytosanitary certificate can cover products of different type, class and description, a CHED-PP can *only* be linked to *one* phytosanitary certificate for export or to one phytosanitary certificate for re-export. In case a CHED-PP is linked to a phytosanitary certificate for re-export, one or more phytosanitary certificates for export may be attached to the phytosanitary certificate for re-export.

2.4.2. Illegal entry of consignments in the Union

In accordance with Article 66(6) of the OCR in case a consignment of animals and goods referred to in Article 47(1) of the OCR, that must undergo official controls at the BCP, is not presented at the BCP or is not presented in accordance with the rules referred to in the same article, the competent authorities must order the consignment to be retained or recalled and placed under official detention.

At the stage of the customs declaration, a finalised CHED for those consignments must be presented to the customs authorities. Pursuant to Article 57(3) of the OCR, if a CHED is not presented where a customs declaration is made, the customs authorities *must* detain the consignment and immediately notify the competent authorities of the BCP.

2.4.2.1. Notification

When the Member State of entry of the consignment in the Union is different from the Member State of the customs declaration, Articles 14 and 15 of Council Regulation (EC) No 515/97[62] on spontaneous assistance (without prior request) between competent authorities of Member States, apply.

62 Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters (OJ L 82, 22.3.1997, p. 1).

In the OCR, concerning animal and goods referred to in Article 47(1), the obligation to immediately notify the competent authorities of the BCP is laid down in Art. 57(3). However, this notification depends on whether a BCP exists at the point of entry.

When there is a BCP at the point of entry

The custom authorities of the Member State where the declaration is made, must notify:

- the competent authorities of the BCP of the point of entry, for the purpose of possible investigations or further actions. Where several competent authorities are involved in the performance of official controls at the BCP on the same consignment (for example, if the consignment is to be accompanied by both a CHED-PP and a CHED-D and the authorities responsible for the performance of checks recorded in these documents are different) *each* of them must be informed;
- the custom authorities of the Member State of entry that illegal trade has taken place also in breach of Article 57(1) of the OCR, based on their obligation to closely cooperate with other authorities as provided for in Art. 75(1) of the OCR and in the context of the risk management referred to in Article 46 of Regulation (EU) 952/2013[63].

When there is no BCP at the point of entry

Based on their obligations for cooperation under Articles 57(3) and 75(1) of the OCR as well as Articles 46 and 47(2) of Regulation (EU) 952/2013, either the customs authorities of the Member State where the declaration is made, or the competent authorities of that Member State, must notify:

- the central competent authority responsible for BCP official controls of the Member State of entry;
- the customs authorities of the Member State of entry that illegal trade has taken place also in breach of Article 57(1) of the OCR.

For the purposes of this notification, Member States may establish procedures to ensure immediate:

1. communication between the customs authorities and the competent authorities of the Member State where the declaration is made;
2. communication of the information by the competent authorities of the Member State where the declaration is made to the competent authorities of the BCP and/or the central competent authority for the BCP checks of the Member State of entry.

2.4.2.2. Measures

Article 57(3) of the OCR states that competent authorities must take the necessary measures in accordance with Article 66(6) of the OCR, with no further specification. Therefore, it is up to the Member States to decide which competent authorities (as defined in Article 3(3) of the OCR) are responsible for these measures. Depending on the specific situation, it may be either the competent authority of the BCP, or the local competent authority where the customs office is located and the consignment

63 Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (recast) (OJ L 269, 10.10.2013, p. 1).

is detained, or the central competent authority responsible for BCP official controls.

The same article also states that the customs authorities must immediately notify the competent authorities of the BCP. When there is no designated BCP at the presumed point of entry in the EU, pragmatism implies that the customs authorities notify the competent authorities of their Member States.

The measures to be taken on the consignment depend on its location at the time of the detection:

- if the consignment is *still at the point of entry*, the customs should redirect it to the BCP where, as required by Article 65(2) of the OCR, the competent authorities will perform the official controls in accordance with Article 47(1).

  If, according to the results of the official controls, the consignment does not comply with the substantive rules, the competent authorities will refuse its entry into the Union according to Article 66(1) and take the corresponding measures in application of Article 66(3)

- if the consignment has already *left the point of entry* and its customs area, it should be subjected to official controls by the local competent authority, with retention, recall and detention as provided for in Article 66(6) in order to make the decision on the possible measures referred to in Article 66(3). The consignment should not return to the BCP.

Finally, the measures should be communicated to the competent authorities of the Member State of entry in case this is different from the Member State where the consignment is detained.

2.4.2.3. Incorrect CN codes

According to Article 56 of the OCR and Article 40 and Annex II to the IMSOC Regulation, the operator responsible for the consignment must provide the information on the animals and goods in part I of the CHED by indicating (among others) the codes from the Combined Nomenclature ('CN codes'), more specifically in box I.31 of the CHED. In addition, the CN codes mentioned in the CHED must be in line with the CN codes mentioned in the customs declarations, so that the customs services can make the necessary verifications as provided for in Article 57 of the OCR.

Where the CN codes indicated by the operator in the CHED are incorrect, there are practical consequences in the performance of official controls at the BCP. In such cases, the following principles should apply:

- whether there is intention or not, the indication of incorrect CN codes in the CHED remains the operator's responsibility.
- *only* customs authorities are competent to assess if the indicated CN code is correct. Therefore, the BCPs should consult the customs authorities to determine if the CN code is correct.
- where the operator indicates an incorrect CN code which leads to the exclusion of the consignment from official controls at the BCP, the BCP cannot be aware of the existing consignment. Therefore, it is the role of the customs authorities to detect the incorrect CN codes in the customs declarations. In this case, the measures to be taken on the consignment depend on the location at the time of the detection in line with the measures taken in cases of illegal entry of consignments in the Union, explained in the previous section.

- where the operator declares an incorrect CN code which leads to the presentation of the consignment at the BCP, the measures to be taken depend on whether the incorrect CN codes are detected or not by the BCP:
  - » if the BCP detects the incorrect CN codes, the operator should be consulted as a first step, to exclude the case of an erroneous declaration. If there is no consensus or there is still doubt on the correctness of the CN codes, the customs authorities should be consulted for official confirmation. In this case, part I of the CHED can still be corrected by the operator.
  - » if the BCP does not detect the incorrect CN codes, and the mistake is detected by the customs authorities at a later stage, the BCP should be informed in order to replace and cancel the validated CHED. In certain cases, the BCP should also reconsider the possible consequences in terms of import requirements and modify the final decision as necessary.

2.4.3. Handling of non – compliant consignments

2.4.3.1. Non-compliance detected before release for free circulation

Where there is a suspicion that a consignment of animals or goods referred to in Articles 44(1) or 47(1) of the OCR, does not comply with the rules referred to in Article 1(2) of the OCR, that consignment *must* be placed under detention and subjected to official controls to confirm or eliminate that suspicion of non-compliance, according to Article 65(1) and (3) of the OCR.

Upon confirmation of a non-compliance, the competent authorities must refuse the entry of the consignment into the Union (Article 66(1) of the OCR) and take the measures in accordance with Articles 66, 67 and 72 of the OCR as the consignments are not yet released for free circulation.

Similarly, when consignments of the categories of goods referred to in point (a) of Article 1(1) of Delegated Regulation (EU) 2019/2124, presented at the place of final destination after authorisation for onward transportation, prove to be non-compliant based on laboratory results, the competent authorities of the BCP must take the subsequent measures provided for by Article 66(3) to (6) of the OCR in coordination with the competent authorities of the place of final destination, according to Articles 7 and 8 of Delegated Regulation (EU) 2019/2124. TRACES is the system used for the performance of the notifications of Article 66(5) of the OCR.

To impose suitable measures, the competent authorities should first assess on a case-by-case basis, whether the consignments present a risk, considering the definition of risk in Article 3(24) of the OCR.

Article 3 of the OCR

Definitions

For the purposes of this Regulation, the following definitions apply: [..]

(24) 'risk' means a function of the probability of an adverse effect on human, animal or plant health, animal welfare or the environment and of the severity of that effect, consequential to a hazard; [..]

Where the non-compliant consignment presents a risk, Article 67 of the OCR applies, and destruction or special treatment are the two possible measures to be taken.

In other cases, according to the first subparagraph of Article 66(3) of the OCR, while considering the operator's views, the competent authorities have the possibility to order alternative measures, including re-dispatch to a third country, under the conditions of Article 72 of the OCR, or allocation of the consignment for purposes other than those for which it was originally intended.

In certain cases of non-compliance, the competent authority may consider on a case-by-case basis that a consignment can be re-dispatched to a third country under the conditions of Article 72 OCR, when an adverse effect on health or on the environment is not likely to materialise. The following examples of non-compliances comprise a non-exhaustive list of such cases:

(a) unsatisfactory results of food safety criteria set in Commission Regulation (EC) 2073/2005[64];

(b) non-compliance with the microbiological standards set out in Commission Regulation (EU) No 142/2011[65] for feed containing or composed of animal by-products subject to Regulation (EC) No 1069/2009;

(c) the presence of a contaminant in food or the presence of an undesirable substance in feed above a legal limit applicable in the Union;

(d) the presence of a pest, defined in the Union as a Union quarantine pest, a protected zone quarantine pest or a pest subject to the measures of Article 30 of Regulation (EU) 2016/2031 in the Union;

(e) the presence of a genetically modified organism that is not authorised in the Union;

(f) the presence of a pesticide in food or feed above the level set by Regulation (EU) No 396/2005[66] and for which a consumer health risk has been identified in accordance with this Regulation;

64 Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

65 Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

66 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

(g) the presence of a food additive that is not authorised for any food in the Union in accordance with Regulation (EC) No 1333/2008[67];

Article 72 of the OCR lays down certain requirements for the operator responsible for the consignment, to allow the re-dispatch to a third country. More specifically, the operator must:

(i) agree the destination with the competent authorities of the Member State (this is the sole condition for the re-dispatch of plants, plant products and other objects referred to in Article 47(1)(c) of the OCR);

(ii) inform the competent authority of the Member State *in writing*, that it has informed the third country of origin or the third country of destination of the reasons of the refusal of entry into the Union of the consignment;

(iii) obtain the agreement of the competent authorities of the country of destination to accept the consignment in case this country is not the country of origin. This agreement must be notified to the authorities of the Member State, by the authorities of the third country, on the initiative of the latter.

When, there is evidence that only a part of the consignment is non-compliant, the operator may *exceptionally* be authorised to proceed with the measures provided for in Article 66(3) of the OCR, for that part only, in accordance with Article 66(4) of the OCR. In such a case, a risk assessment that allows the competent authority to clearly distinguish the compliant part from the non-compliant part of the consignment must underpin the decision of a partial rejection, to ensure the correct splitting and application of measures. Such a decision is subject to the conditions of Article 66(4) of the OCR, including the non- disruption of the control operations. In addition, according to Annex III to Implementing Regulation (EU) 2019/2130, the decision to refuse entry of and take measures on part of the consignment of plants, plant products and other objects, must be related to lots identified ahead of the physical checks.

Pursuant to Article 69 of the OCR, the operator must execute all measures ordered by the competent authorities within a maximum period of 60 days from the day it was notified of the decision. The competent authorities may specify a shorter period, for example in order to contain particular risks to human, animal or plant health, or extend this period if the results of the second expert opinion referred to in Article 35 of the OCR are pending, on condition that this extension does not adversely affect human, animal and plant health, animal welfare and the environment. In any case, the obligation of the competent authorities to take prompt action for the elimination or containment of risks is not affected by the right of the operator to a second expert opinion as provided for in Article 35(4) of the OCR.

In case the competent authorities detect serious or repetitive infringements or suspect fraudulent or deceptive practices, they must *intensify* official controls on consignments of the same origin or use, as required by Article 65(4) of the OCR. The Commission has established rules on the procedures for the coordinated performance of intensified

67 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

controls for products of animal origin, germinal products, animal-by-products and composite products by competent authorities of the Member States in Commission Implementing Regulation (EU) 2019/1873[68] using the empowerment of Article 65(6) of the OCR.

2.4.3.2. Non-compliance detected after release for free circulation

For consignments of products of animal origin, germinal products, animal by-products, hay and straw and composite products (referred to in Article 47(1)(b) of the OCR) that are subjected to random laboratory testing at the BCPs on the basis of the monitoring plan referred to in Article 4(5) of Implementing Regulation (EU) 2019/2130 and then released for free circulation pending the results of the analyses, Articles 137 and 138 of the OCR apply if these results prove that the concerned goods do not comply with the rules referred to in Article 1(2) of the OCR.

In general, for consignments of food and feed released for free circulation, Article 12 of Regulation (EC) No 178/2002 applies, and they can be re-exported to a third country in one of the following cases:

(i) if they comply with the requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

(ii) if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the Union, except where food is injurious to health or feed is unsafe.

(iii) if they comply with the provisions of a bilateral agreement concluded between the Union or one of its Member States and the third country of destination.

As for any case of a direct or indirect risk to human health deriving from food or feed, iRASFF must be used as means of communication of the results of the official controls and relevant measures to the Commission, other Member States and third countries.

The same principles apply for consignments of food and feed not required to be presented at the BCPs (falling under Article 44 of the OCR), in case the results of the laboratory analyses performed at the place of final destination after a risk-based selection of the consignment, are unsatisfactory in relation to the rules of Article 1(2) of the OCR.

A coordinated performance of intensified official controls (in IMSOC – TRACES), as required by Article 65(4) of the OCR, can also be triggered following the detection of serious or repetitive infringements or suspicion of fraudulent or deceptive practices on consignments which are already released on the market.

2.4.4. Use of commercial storage facilities (Article 64 of the OCR)

As regards animals and goods referred to in Article 47(1) of the OCR, Article 64 of the OCR

68 Commission Implementing Regulation (EU) 2019/1873 of 7 November 2019 on the procedures at border control posts for a coordinated performance by competent authorities of intensified official controls on products of animal origin, germinal products, animal by-products and composite products (OJ L 289, 8.11.2019, p. 50).

lays down minimum requirements for BCPs. More detailed rules on the requirements for BCPs and inspection centres thereof are laid down in Commission Implementing Regulation (EU) 2019/1014[69], based on the empowerment in Article 64(4) of the OCR.

A BCP designated for a given category of goods must meet the minimum requirements for BCPs regarding the facilities required for that category of goods. The required facilities (unloading area/room, inspection area/room and storage area/room according to the temperature regime of the goods and access to toilet facilities) *must* be in place and accessible for official controls. Details on the fitting and equipment of the areas/rooms are also laid down in Implementing Regulation (EU) 2019/1014. In case a BCP comprises several inspection centres, each inspection centre must fulfil the minimum requirements as laid down in Article 8 of Implementing Regulation (EU) 2019/1014.

The competent authorities at the BCP may, in addition, permit, under their control, the use of commercial storage facilities for the goods referred to in Article 47(1) of the OCR, as laid down in Article 3(11), first subparagraph of Implementing Regulation (EU) 2019/1014. The use of commercial storage facilities is *in addition* to the compliance with the requirement for the BCP itself (Article 3(1) of Implementing Regulation (EU) 2019/1014) to have storage facilities for the categories of goods for which it is designated, and *not instead* of those facilities.

Such use may only be permitted provided that the commercial storage facilities:

- are in the close vicinity of the BCP; and
- are under the competence of the same customs authority as the BCP.

Moreover, pursuant to Article 3(12) of Implementing Regulation (EU) 2019/1014, goods stored in commercial storage facilities in accordance with Article 3(11) of that Regulation must be:

- stored under hygienic conditions; and
- properly identified by barcodes or other electronic means, or labelling; and
- where the goods may pose a risk to human, animal and plant health, or in the case of GMOs and plant protection products also to the environment, they must in addition be detained in separate lockable room or areas fenced off from

69 Commission Implementing Regulation (EU) 2019/1014 of 12 June 2019 to lay down detailed rules on minimum requirements for border control posts, including inspection centres, and for the format, categories and abbreviations to use for listing border control posts and control points (OJ L 165, 21.6.2019, p. 10–22).

all other goods stored in the commercial storage facility. That means among others that these goods must be stored separately from other goods and clearly identified as goods detained under supervision of the competent authority.

2.4.4.1. Use of commercial storage facilities for identity and physical checks of products of non-animal origin

Article 3(11) second subparagraph, of Implementing Regulation (EU) 2019/1014 provides the competent authority of BCPs with the possibility to use the commercial storage facilities referred to in Article 3(11) first subparagraph, of that Regulation to perform identity checks and physical checks on products of non-animal origin, provided that these commercial storage facilities comply with the minimum requirements laid down in that Regulation.

The term 'products of non-animal origin' is mentioned in point (d) of Annex II to Implementing Regulation (EU) 2019/1014 and refers to food and feed of non-animal origin as well as to non-human consumption products other than feed (i.e., food contact materials) covered by conditions or measures referred to in Article 47(1)(d), (e) or (f) of the OCR. The flexibility allowed for this category of goods by virtue of Article 3(11) second subparagraph of Implementing Regulation (EU) 2019/1014 is related to the low need for hazard containment for these goods. This flexibility does not apply to 'plants, plant products and other objects', which are specified as a distinct category of goods in point (c) of Annex II to Implementing Regulation (EU) 2019/1014, corresponding to the need for pest control for plants, plant products and other objects subject to Regulation (EU) 2016/2031. Similarly, this flexibility does also not apply to consignments of hay and straw, which belong to the category of goods referred to in point (b) of Annex II to Implementing Regulation (EU) 2019/1014, corresponding to the need for animal disease control for these goods.

Notwithstanding the above, individual inspection centres of a BCP designated for the performance of checks on products of non-animal origin or on plants, plant products and other objects *may* be located in private sector facilities where commercial activities take place, *provided* that those inspection centres fulfil the requirements laid down in Article 8 of Implementing Regulation (EU) 2019/1014. Inspection centres being facilities set up within a border control post, they must, for example, be in the immediate vicinity to the point of entry in accordance with Article 64(1) of the OCR[70]. Furthermore, all the required facilities

70 Exemptions to this requirement are laid down in Article 3 of Commission Delegated Regulation (EU) 2019/1012 of 12 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by derogating from the rules on the designation of control points and from the minimum requirements for border control posts (OJ L 165, 21.6.2019, p. 4).

must be available and accessible for official control purposes when needed (Article 64(3) (b), (c) and (d) of the OCR)[71], and appropriate arrangements must be in place to ensure hygienic conditions and prevention of risks due to cross-contamination (Article 64(3)(h) and (i) of the OCR). It should be noted that official import controls on hay and straw are performed under the rules applicable for products of animal origin (Article 47(1)(b) of the OCR), with additional requirements as regards the layout of facilities and the separation of goods and activities, as laid down in Article 6 of Implementing Regulation (EU) 2019/1014.

2.4.4.2. Procedure for the use of commercial storage facilities for competent authorities at the BCP

It is for the competent authorities of the BCP to decide whether they permit the use of commercial storage facilities, as provided for in Article 3(11) of Implementing Regulation (EU) 2019/1014. There is no requirement to notify the use of commercial storage facilities to the Commission if those facilities are only used as *additional* storage.

However, where competent authorities permit the use of commercial storage facilities for the performance of identity and physical checks on products of non-animal origin, this must be notified to the Commission in accordance with Article 3(14) of Implementing Regulation (EU) 2019/1014 as a change in the infrastructure or operation of that BCP (without a change of the scope of designation of that BCP). In this case, the competent authorities should have a procedure in place to demonstrate that the facilities comply with the minimum requirements laid down in Implementing Regulation (EU) 2019/1014, and to provide all information necessary to the Commission to verify the compliance of such facilities with those requirements.

2.4.4.3. Listing of commercial storage facilities and registration in TRACES-NT

There is no legal requirement to include commercial storage facilities in the list of published BCPs referred to in Article 60 of the OCR and Article 7 of Implementing Regulation (EU) 2019/1014. However, in case commercial storage facilities are used for identity and physical checks (Article 3(11) of Implementing Regulation (EU) 2019/1014), Member States should make this information publicly available and include it in column 7 of the list of published BCPs[72].

In addition, there is no requirement for those commercial storage facilities to be registered in TRACES-NT or to have their own individual unique TRACES identifier. The BCP code may be used instead.

The table below provides an overview of the differences between BCPs/inspection centres, commercial storage facilities and control

71 For example, as governed by opening hours of an inspection centre.

72 Format of the list of published BCP established in Annex I to Implementing Regulation (EU) 2019/1014.

Table 5: Comparison of requirements for BCPs/inspection centres, commercial storage facilities and control points.

	BCP / inspection centres	**Commercial storage facilities** (used for storage of goods in addition to BCP infrastructure)	**Commercial storage facilities** (used for identity and physical checks of products of non-animal origin in addition to BCP infrastructure)	**Control points other than BCPs**
Legal framework	Article 59 of the OCR, Commission Implementing Regulation (EU) 2019/1014, Commission Delegated Regulation (EU) 2019/1012	Article 3(11), first subparagraph of Commission Implementing Regulation (EU) 2019/1014	Article 3(11), second subparagraph of Commission Implementing Regulation (EU) 2019/1014	Article 53(1)(a) and 53(2) of the OCR and Commission Delegated Regulation (EU) 2019/2123
scope	official controls of animals or goods referred to in Article 47(1) of the OCR	storage of goods referred to in Article 47(1) of the OCR	identity and physical checks of products of non-animal origin subject to Article 47(1) of the OCR	identity and physical checks of food and feed of non-animal origin and of plants, plant products and other objects subject to Article 47(1) of the OCR, including organic and in-conversion products, as laid down in Commission Delegated Regulation (EU) 2019/2123
applicable minimum requirements	Article 64 of the OCR and Commission Implementing Regulation (EU) 2019/1014 (applicable minimum requirements depending on the categories of animals and goods included in the scope of designation)	Article 3(11), first subparagraph and (12) of Commission Implementing Regulation (EU) 2019/1014	applicable minimum requirements for BCPs designated for products of non-animal origin as laid down in Article 64 of the OCR and in Commission Implementing Regulation (EU) 2019/1014	Article 64(3) of the OCR and Commission Implementing Regulation (EU) 2019/1014 (applicable minimum requirements depending on the categories of animals and goods included in the scope of designation) (Article 53(1)(a) of the OCR)

	BCP / inspection centres	**Commercial storage facilities** (used for storage of goods in addition to BCP infrastructure)	**Commercial storage facilities** (used for identity and physical checks of products of non-animal origin in addition to BCP infrastructure)	**Control points other than BCPs**
location in relation to the point of entry into the Union	in the immediate vicinity of the point of entry into the Union (Article 64(1) of the OCR); derogations in cases of geographical constraints are laid down in Commission Delegated Regulation (EU) 2019/1012 based on Article 64(2) of the OCR	within the close vicinity of the BCP and under the competence of the same customs authority (Article 3(11), first subparagraph of Commission Implementing Regulation (EU) 2019/1014)	within the close vicinity of the BCP and under the competence of the same customs authority (Article 3(11), first subparagraph of Commission Implementing Regulation (EU) 2019/1014)	at a distance to BCP, under the conditions laid down in Delegated Regulation (EU) 2019/2123; for example, transport to control points must be carried out under customs supervision and requires the issuance of a separate CHED to be finalised by the competent authorities at the control point.
designation / notification procedure	notify the Commission before the designation (Article 59(2) of the OCR); verification of compliance by the Commission with the applicable minimum requirements	no prior notification to the Commission required; recommendation to inform the Commission whether the use of commercial storage facilities is permitted when: • notifying the designation; or • updating information of a BCP or inspection centres thereof; or • in preparation of Commission controls.	notify the Commission prior to the use of commercial storage facilities for checks (Article 59(2) of the OCR and Article 3(14) of Commission Implementing Regulation (EU) 2019/1014); verification by the Commission of compliance with the applicable minimum requirements	No prior notification to the Commission prior to the designation is required (Article 53(2) of the OCR)
include in published list of BCPs	yes (Article 60 of the OCR)	no	yes	yes (Article 53(2) and Article 60(1) of the OCR and Article 7 of Commission Implementing Regulation (EU) 2019/1014)

2.5. CHAPTER VI – Financing of official controls and of other official activities (Articles 78 to 85 of the OCR)

2.5.1. Financing - general rules

In order to reduce the dependency of the official control system on public finances, competent authorities are required to collect fees or charges to cover the costs they incur in relation to certain official controls (mandatory fees and charges). This is the case for example for the recovery of costs incurred by the competent authorities in relation to official controls performed on animals and goods referred to in Article 47(1) of the OCR. In accordance with Article 78 of the OCR, Member States must ensure that adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to perform official controls and other official activities. This also applies in the case of delegation of certain official control tasks and other official activities in accordance with Articles 28 and 31 of the OCR.

Although operators are primarily responsible for ensuring that their activities are carried out in compliance with Union agri-food chain legislation, the system of own controls that they put in place for that purpose is to be complemented by a dedicated system of official controls maintained by each Member State to ensure effective surveillance along the agri-food chain.

2.5.2. Mandatory fees or charges

To that effect, Article 79(1) of the OCR provides that:

> *Article 79(1) of the OCR*
>
> *1. The competent authorities shall collect fees or charges for the official controls performed in relation to the activities referred to in Chapter II of Annex IV and on animals and goods referred to in points (a), (b) and (c) of Article 47(1), at border control posts or at control points referred to in point (a) of Article 53(1), either;*
>
> *(a) at the level of the cost calculated in accordance with Article 82(1); or*
>
> *(b) at the amounts provided for in Annex IV.*

Example: In case of transit consignments of plants at the border, the fees must be charged according to Chapter I of Annex IV part VII (VII. CONSIGNMENTS OF ANIMALS AND GOODS FROM THIRD COUNTRIES TRANSITING OR TRANSHIPPED) and not according to part VIII (VIII. CONSIGNMENTS OF PLANTS, PLANT PRODUCTS AND OTHER PRODUCTS, OBJECTS AND MATERIALS CAPABLE OF HARBOURING OR SPREADING PESTS OF PLANTS).

In addition, Article 79(2) of the OCR provides that the competent authorities shall collect fees or charges to recover the costs they incur in relation to official controls performed on animals and goods, referred to in points (d), (e) and (f) of Article 47(1) of the OCR, to official controls requested by the operator to obtain the approval provided for in Article 10

of Regulation (EC) No 183/2005 and official controls, which were not originally planned, and which have become necessary following the detection of a cases of non-compliance by the same operator and are performed to assess the extent and the impact of the case of non-compliance or to verify that the non-compliance has been remedied.

2.5.3. Other fees or charges (not mandatory)

As stated in Article 80 of the OCR, Member States may collect fees or charges to cover the costs of official controls and other official activities other than those fees or charges referred to in Article 79 of the OCR, unless prohibited by the legislative provisions applicable in the areas governed by the rules referred to in Article 1(2) of the OCR. These fees or charges are not mandatory and Article 81 of the OCR regarding costs and Article 82 of the OCR regarding calculation of fees or charges do not apply to these fees or charges. However, fees collected pursuant to Article 80 of the OCR shall respect the requirements laid out in Articles 83, 84 and 85 of that Regulation.

For example, Article 21, paragraph 2, letter (a) of the OCR states specific rules on official controls performed prior to the loading to check the fitness of the animals for transport. The fees or charges for official controls under Art. 21(2)(a) of the OCR, may be collected pursuant to Article 80 of the OCR, because the controls neither fall within the scope of Article 79 of the OCR nor does the animal transport legislation prohibit the charging of fees and charges, including for fitness checks of animals prior to the loading and transport to third countries. These should cover, but not exceed, the costs incurred.

2.5.4. Level of costs and methods of calculation of mandatory fees or charges

Competent authorities are to collect mandatory fees or charges in relation to official controls referred to in Article 79(1) of the OCR either at the level of the cost calculated in accordance with Article 82(1) of the OCR or at the amounts provided for in Annex IV of the OCR. Charges or fees collected in relation to official controls referred to in Article 79(2) of the OCR, shall also be calculated in accordance with Article 82(1) of the OCR, or collected at the amounts provided for in Annex IV of the OCR, for those animals or goods or activities for which fees are established in that Annex.

Chapter I of Annex IV of the OCR states the fees or charges for the official controls on consignments of animals and goods entering the Union, for example live animals, meat, fishery products, plant, plant products, transiting goods, etc. Chapter II of the same

Annex states the fees or charges for the official controls in slaughterhouses, cutting plants, game-processing plants, milk production and producing and placing on the market fishery products and aquaculture products.

Article 79(1) of the OCR does not allow the competent authorities to use a combination of the two methods mentioned in points (a) and (b) of that Article in relation to consignments referred to in Chapter I of Annex IV to the OCR of animals and goods belonging to the same category[73] (e.g., official controls on consignments of fishery products) and in relation to activities referred to in Chapter II of Annex IV to the OCR belonging to the same category[74] (e.g., official controls in slaughterhouses).

However, Member States may determine fees or charges at the level of the costs calculated in accordance with Article 82(1) of the OCR and at the amounts provided for in Annex IV to that Regulation, provided that the consignments or the activities belong to different categories. For example:

1. a calculation method could be used for official controls on consignments of meat and at the same time a fixed amount of Annex IV Chapter I of OCR could be used for official controls on consignments of meat products, poultry meat, wild game meat, rabbit meat or farmed game meat; or
2. a calculation method could be used for official controls in cutting plans and at the same time a fixed amount of Annex IV Chapter II of OCR could be used for official controls on milk production.

Member States may only do so to the extent that such differentiation complies with the fundamental principles of non-discrimination and equal treatment.

The costs listed in Article 81 of the OCR are only relevant for Article 79(1)(a) and Article 79(2) of the OCR, not for Article 79(1)(b) of the OCR.

Example: In relation to import fees, a Member State is opting for the application of Article 79(1)(b) of the OCR (i.e., fees or charges for the official controls on consignments of animals and goods entering the Union as specified in Chapter I of Annex IV of the OCR). Nevertheless, there are additional costs, such as the transport in case of checks held away from the BCPs and overtime charges of officers carrying out inspections outside official business hours. These costs cannot be added to the fees based on Article 79(1)(b) of the OCR, because the fees in Annex IV of the OCR are fixed fees and additional costs should not be required by Member States.

Article 82(1) of the OCR, states:

> *Article 82(1) of the OCR*
>
> *1. Fees or charges collected in accordance with point(a) of Article 79(1) and with Article 79(2) shall be established in accordance with one of the following methods of calculation or a combination of them:*
>
> *(a) at a flat-rate on the basis of the overall costs of official*

73 There are 8 (eight) categories of animals and goods listed in points I to VIII of Chapter I of Annex IV to the OCR.

74 There are 5 (five) categories of activities listed in points I to V of Chapter II of Annex IV to the OCR.

controls borne by the competent authorities over a given period of time, and applied to all operators irrespective of whether any official control is performed during the reference period in relation to each operator charged; in establishing the level of the fees to be charged for each sector, activity and category of operators, the competent authorities shall take into consideration the impact that the type and the size of the activity concerned, and the relevant risk factors, have on the distribution of the overall costs of those official controls; or

(b) on the basis of the calculation of the actual costs of each individual official control, and applied to the operators subject to such official control.

The letter (a) of this provision allows Member States to calculate the flat-rate for a specific sector, activity or category of operators, on the basis of costs of all official controls in the scope of the OCR. As regards the calculation of the fees to be charged for each sector, activity and category of operators, Article 82(1)(a) of the OCR requires Member States to take into consideration the impact that the type and the size of the activity concerned, and the relevant risk factors, have on the distribution of the overall costs of the official controls.

According to Article 82(3) of the OCR, where fees or charges are calculated at a flat-rate in accordance with Article 82(1)(a) of the OCR, those fees or charges collected by competent authorities *shall not exceed the overall costs incurred for the official controls performed over the period of time referred to therein*. Pursuant to Article 82(4) of the OCR, where fees or charges are calculated in accordance with Article 82(1)(b) of the OCR, *they shall not exceed the actual cost of the official control performed*.

Article 81(a) to (g) of the OCR further clarifies the scope of the said overall costs. These include, in so far as they result from the official controls concerned, 'the salaries of the staff, *including support and administrative staff*, involved in the performance of official controls, their social security, pension and insurance costs (under (a)), as well as the 'cost of *facilities and equipment*, including maintenance and insurance costs and other associated costs' (under (b)), 'the cost of training' — with the exclusion of the *training* necessary to obtain the qualification necessary to be employed by the competent authorities (under (e)) — and 'the cost of *travel*' (under (f)) of such staff.

As regards the scope of the *overall costs of official controls borne by the competent authorities over a given period of time* referred to in Article 82(1)(a) of the OCR, recital 66 of that Regulation clarifies that these can cover *overhead costs* incurred by the competent authorities to perform official controls. That recital further clarifies that *overhead costs could include the costs of the support and organisation necessary for planning and carrying out the official controls.*

In addition, where fees or charges are applied on the basis of the actual cost of individual official controls, operators with a good record of compliance should bear lower overall charges than non-compliant ones, as they should be subject to less frequent official control. When fees or charges are calculated on the basis of overall costs incurred by the

competent authorities over a given period of time and imposed on all operators irrespective of whether they are subject to an official control during the reference period, those fees or charges should be calculated so as to reward operators with a consistent good record of compliance with Union agri-food chain legislation.

In relation specifically to costs related to administrative and support staff, according to settled case law of the Court of Justice of the European Union[75] *only the time required by administrative and support staff for activities inextricably linked to the performance of official controls may be taken into consideration in the calculation of the fees*.

Article 79(3) of the OCR allows Member States to reduce the amount of the fees or charges for activities referred to in Chapter II of Annex IV of the OCR (slaughterhouses, cutting plants, game-processing plants, milk production and producing and placing on the market fishery products and aquaculture products), on an objective and non-discriminatory basis, taking into account:

- the interests of operators with a low throughput;
- the traditional methods are used for production, processing and distribution;
- the needs of operators located in regions subject to specific geographical constraints;
- and the operator's record of compliance with the relevant rules referred to in Article 1(2) of the OCR, as ascertained through official controls.

2.5.5. Transparency

Recital 68 of the OCR:

The financing of official controls through fees or charges collected from operators should be fully transparent, so as to enable citizens and businesses to understand the method and data used to establish fees or charges

Article 85 of the OCR

Transparency

1. Member States shall ensure a high level of transparency on:

(a) the fees or charges provided for in point (a) of Article 79(1),

Article 79(2) and Article 80, namely on:

(i) the method and data used to establish these fees or charges;

(ii) the amount of the fees or charges, applied to each category of operators and for each category of official controls or other official activities;

(iii) the breakdown of the costs, as referred to in Article 81;

(b) the identity of the authorities or bodies responsible for the collection of the fees or charges.

75 CJEU, 19 December 2019, Exportslachterij J. Gosschalk, C-477/18 and C-478/18, para 66

2. *Each competent authority shall make available to the public the information referred to in paragraph 1 of this Article for each reference period and the costs to the competent authority for which a fee or charge is due in accordance with point (a) of Article 79(1), Article 79(2) and Article 80.*

3. *Member States shall consult relevant stakeholders on the general methods used to calculate the fees or charges provided for in point (a) of Article 79(1), Article 79(2) and Article 80.*

It results from Article 85 of the OCR that Member States are to ensure a high level of transparency on the *fees or charges* provided for in point (a) of Article 79(1), Article 79(2) and Article 80 of the OCR *and on the identity of the authorities or bodies* responsible for the collection of the fees or charges.

Member States must provide a link to the web page of the competent authority containing the public information on fees or charges referred to in Article 85(2) of the OCR in their annual reports in accordance with Article 113(1)(e) of the OCR and Commission Implementing Regulation (EU) 2019/723.

2.6. CHAPTER VII – Official certification (Articles 86 – 91 of the OCR)

2.6.1. Official certification

Official certificates and official attestations provide assurance concerning compliance with legal requirements in the areas covered by the OCR. Their definitions are included in Article 3 of the OCR. They are both components of official certification as laid down in Chapter VII of Title II of the OCR. Articles 86 to 91 of the OCR establish a set of rules for a uniform and harmonised framework for official certification in all concerned OCR areas.

Article 3 of the OCR

Definitions

For the purposes of this Regulation, the following definitions apply: [..]

(27) *"official certificate" means a paper or electronic document signed by the certifying officer and providing assurance concerning compliance with one or more requirements laid down in the rules referred to in Article 1(2);*

(28) *"official attestation" means any label, mark or other form of attestation issued by the operators under the supervision, through dedicated official controls, of the competent authorities or by the competent authorities themselves, and providing assurance concerning compliance with one or more requirements*

laid down in this Regulation or in the rules referred to in Article 1(2); [..]

It results from the definitions in Article 3(27) and (28), as well as from the recitals 69 and 70 of the OCR that, while official certificates are documents in paper or electronic form, official attestations for certain animals or goods are labels and marks or other forms of attestations.

The issuance of official certificates and official attestations, when carried out by competent authorities, is considered an official activity, other than official controls, in the context of Article 2(2) of the OCR.

These two forms of certification have common and different characteristics. As regards official certificates, Articles 88(3) and 89 of the OCR provide for the basis of their issuance and properties of their content. Further requirements for official certificates can be included in the rules referred to in Article 1(2) of the OCR or established in the implementing acts based on the empowerments conferred to the Commission in Article 90 of the OCR. For official attestations, Article 91 of the OCR sets out the general principles, while sectoral legislation under the OCR contains specific rules for their issuance.

The OCR requires competent authorities to ensure reliability for both official certificates and official attestations. Consequently, there are comparable provisions in Articles 88(2), 89(1) and 91(2) and (3) that refer to the authenticity and the accuracy of official certification as well as to the obligation of the competent authorities to ensure that:

(i) staff signing official certificates or

(ii) staff performing official controls to supervise the issuance of official attestations or taking part in the issuance of official attestations when issued by competent authorities,

are impartial, free from conflict of interest and are appropriately trained.

The mandatory components of the official certificates are specified in Article 89 of the OCR and illustrated in Figure 7.

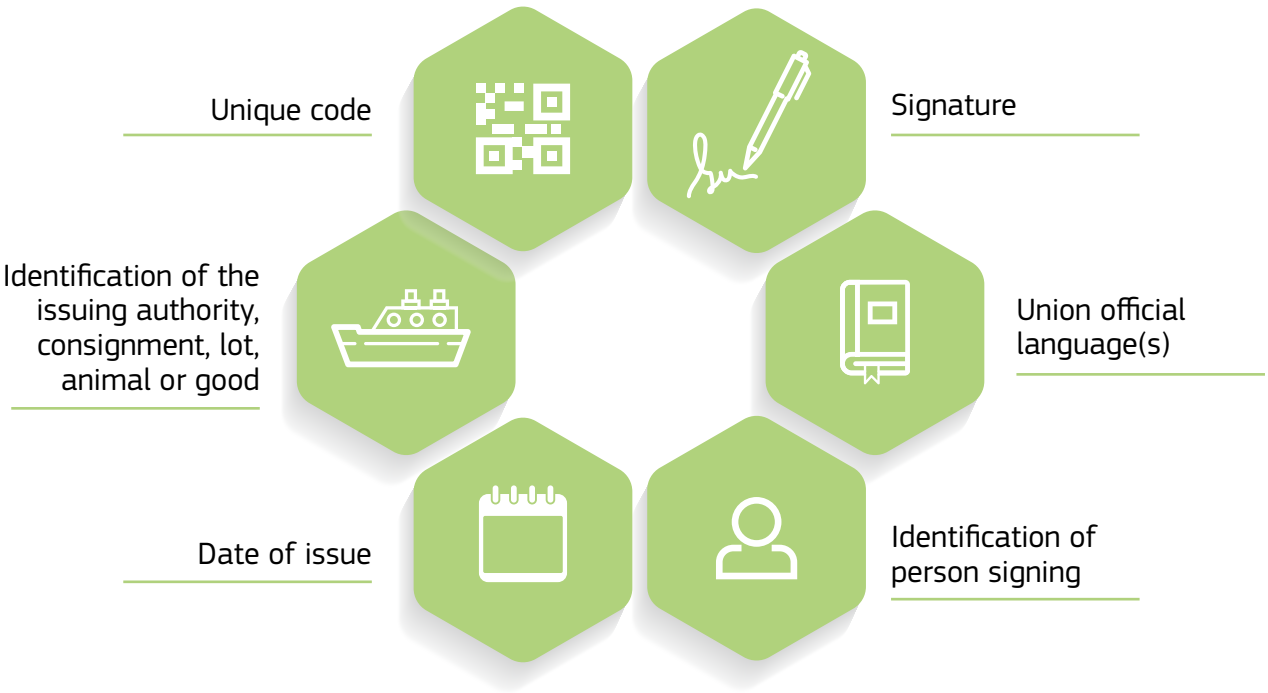


Figure 7: Components of official certificates based on OCR provisions.

Concerning official attestations, the respective requirements are the use of Union official languages and the verification of the link between the official attestation and the consignment or lot, where relevant (Article 91(2) of the OCR).

Figure 8 and Figure 9 reflect the different roles of the competent authorities and staff that contribute to the issuance of official certification, as provided for in Articles 3, 88, 89 and 91 of the OCR.

Figure 8: Roles of the authorities and staff involved in the process of issuing official certificates, based on OCR provisions.

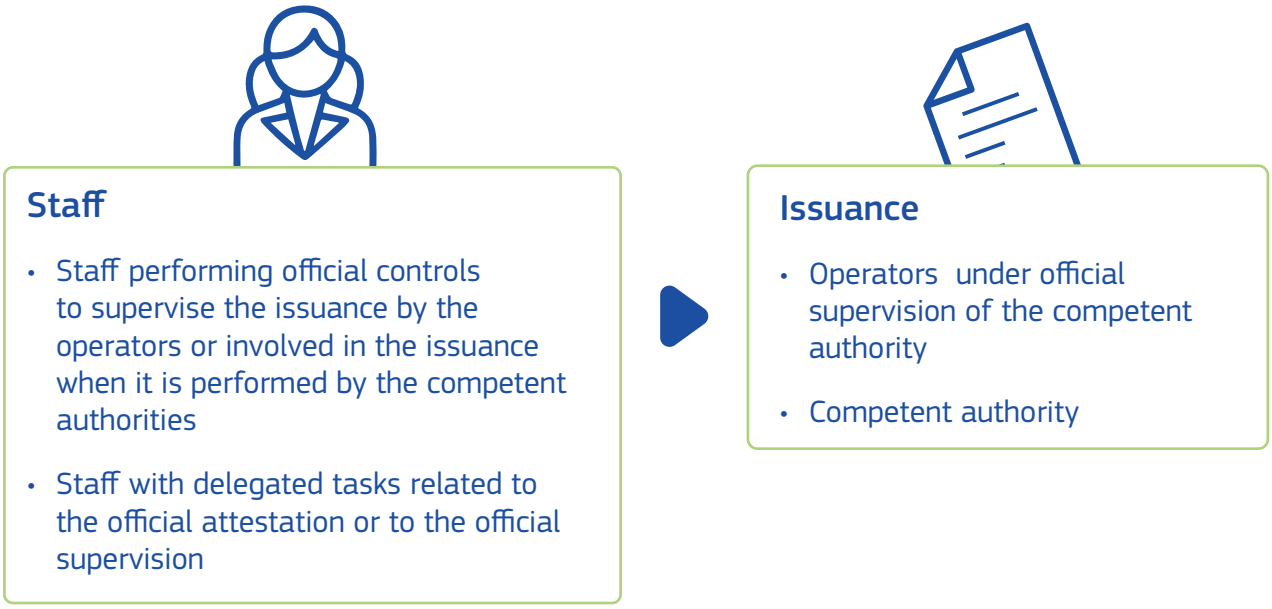


Figure 9: Roles of the authorities and staff involved in the process of issuing official attestations based on OCR provisions.

2.6.2. Official certificate

It results from Article 88(1) of the OCR, that competent authorities are *exclusively* responsible for the issuance of official certificates. Certain tasks related to the issuance of the official certificates can, however, be delegated according to Article 86(2) of the OCR, provided that this delegation complies with Articles 28 to 33 of the OCR.

Official certificates allow for the identification of the animals or goods for which they are issued and indicate the date of their issuance and the person who signed them (Article 89(1) of the OCR), rendering this person responsible for the information included in the certificate. The issuance of an official certificate is based on the verification or confirmation of specific facts and data concerning the animals and goods under certification (Article 88(3) of the OCR), thus guaranteeing the reliability of the information for each single certificate.

Additional elements to ensure the accuracy and the reliability of the official certificates have been included in Article 89(1) of the OCR:

(i) blank or incomplete certificates are not to be signed by certifying officers.

(ii) certificates are to be drawn up in one or more of the official languages understood by the certifying officer and, where relevant, of the Member State of destination.

It is worth noting that Article 89(2) of the OCR, underlines the responsibility of the competent authorities to take appropriate measures to prevent fraudulent practices relevant to the issuance and use of official certificates. The provisions of Article 138(5) of the OCR further enhance this responsibility by stipulating the measures the competent authority is obliged to take in such cases. These measures include administrative measures against individuals, namely the temporary suspension of the

certifying officer or withdrawal of authorisation to sign certificates, as well as actions to prevent the reoccurrence of the offences.

Aiming at providing flexibility to competent authorities, the rules of Article 88(3) of the OCR list three different ways through which the certifying officers gain knowledge of the necessary information before signing the certificates.

More specifically, facts and data can be obtained either directly by the certifying officer, or indirectly through the contribution of another person authorised by and acting under the control of the competent authorities, or of the operator itself, as mentioned in Art. 88(3), provided that the conditions laid down in this provision are complied with. It should be noted however that, as it results from Article 88(4) of the OCR, specific provisions of rules referred to in Article 1(2) of the OCR may require that the certificate is signed by the certifying officer and issued exclusively on the grounds of direct knowledge of facts and data by the certifying officer.

Official certificates may be a prerequisite:

(i) for placing on the market or movement of animals and goods, based on rules referred to in Article 1(2) of the OCR.

Categories of such official certificates include in particular:

a. animal health certificates pursuant to Articles 149, 161, 167 and 216 of the Animal Health Law [Regulation (EU) 2016/429], for the movement of kept terrestrial animals, germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species and germinal products of poultry, products of animal origin and aquatic animals, respectively;

b. official certificates pursuant to Article 21 of Commission Delegated Regulation (EU) 2022/2292;

c. health certificates for animal by products and derived products as required by Article 21 of Regulation (EC) No 1069/2009 and Commission Regulation (EU) No 142/2011;

d. certificates of competence of drivers and attendants on a road vehicle transporting domestic *Equidae* or domestic animals of bovine, ovine, caprine or porcine species or poultry pursuant to Article 6(5) of Regulation (EC) No 1/2005 and certificates of

approval of means of transport by road and of livestock vessels pursuant to Articles 18 and 19 of that Regulation;

e. official certificates pursuant to Article 11 of Commission Implementing Regulation (EU) 2019/1793;

f. phytosanitary certificates for export, re-export, pre-export certificates as provided for in Articles 100, 101 and 102 of Regulation (EU) 2016/2031;

g. certificates pursuant to Article 35 of Regulation (EU) 2018/848 on organic production and labelling of organic products;

h. health certificates for products originating in or consigned from China as required by Article 4 of Commission Implementing Decision 2011/884/EU[76].

(ii) for exporting consignments to third countries by a Member State which is either the country of origin or the country of dispatch, as referred to in Article 87(b) of the OCR.

2.6.3. Official attestation

In contrast to official certificates which are only issued by the competent authorities, it results from Articles 3(28) and 91 of the OCR, that official attestations are primarily issued by operators. For example, under Regulation (EU) 2016/2031, plant passports required for the movement of plants, plant products and other objects within the Union territory, are generally issued by authorised professional operators.

The operators in this case are supervised by the competent authorities through dedicated official controls. According to Article 86(2) of the OCR, competent authorities can delegate certain tasks related to the official supervision, on condition that this delegation complies with Articles 28 to 33 of the OCR. Delegation can also be used for other specific tasks related to the issuance of attestations, if it complies with the rules of these articles.

There is a dual role of the competent authorities regarding official attestations:

(i) either to also issue attestations,

(ii) or, where issued by operators, supervise the operator, and in particular to perform official controls on a regular basis, according to Article 91(4) of the OCR, aiming at verifying the compliance of the operators issuing the attestation with the applicable rules and the facts and data upon which the issuance is based.

Examples of official attestations are the following:

76 2011/884/EU: Commission Implementing Decision of 22 December 2011 on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC (OJ L 343, 23.12.2011, p. 140).

(i) health and identification marks, as provided for in Article 18(4) of the OCR and Article 5 of Regulation (EC) No 853/2004;

(ii) plant passports required for the movement of plants, plant products and other objects within the Union territory, as provided for in Chapter VI Section 2 of Regulation (EU) 2016/2031;

(iii) the marking of wood packaging material provided for in Article 96 of Regulation (EU) 2016/2031 and attestations other than the mark of wood packaging material as provided for in Article 99 of the same act;

(iv) the Organic production logo of the European Union provided for in Article 33 of Regulation (EU) 2018/848 on organic production and labelling of organic products;

(v) the protected designations of origin and protected geographical indications Union symbol pursuant to Article 37 of Regulation (EU) 2024/1143 and the traditional speciality guaranteed Union symbol pursuant to Article 70 of the same Regulation.

2.6.4. Certifying officer

Article 3(26) of the OCR

Definitions

For the purposes of this Regulation, the following definitions apply: [..]

(26) "certifying officer" means:

(a) any official of the competent authorities authorised to sign official certificates by such authorities; or

(b) any other natural person who is authorised by the competent authorities to sign official certificates in accordance with the rules referred to in Article 1(2); [..]

The qualification of certifying officer is reserved exclusively for the signature of official certificates, as defined in Article 88(2) the OCR. It also appears by the definition of the certifying officer that it can be either an official or another natural person authorised by the competent authorities to sign official certificates in accordance with the rules referred to in Art. 1(2) of the OCR. Other natural persons signing the certificates are required to be "designated" and "authorised" by the competent authorities, thus delegation is not required in this context.

Further rules on the qualifications of the certifying officer may be laid down in Union legislation. In Implementing Regulation (EU) 2020/2235 establishing model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, it is either the official veterinarian or the certifying officer the person who signs the certificate.

3 TITLE III – REFERENCE LABORATORIES AND REFERENCE CENTRES

The purpose of EU reference laboratories and national reference laboratories is to promote uniform practices in relation to the development or use of the methods applied by the official laboratories designated by Member States, thus ensuring the reliability and consistency of results of tests, analyses and diagnoses performed in the context of official controls and other official activities.

The purpose of EU Reference Centres is to promote scientific and technical expertise in the areas of animal welfare and authenticity and integrity of the agri-food chain, thus fostering a common scientific understanding in their respective areas of focus as a foundation for official controls and other official activities.

3.1. Designation and scope of mission

3.1.1. EU reference laboratories and EU reference centres (Articles 92 to 99 of the OCR)

The scopes of activities of EURLs and EURCs are primarily determined by the sector specific legislation that governs the respective policy areas of EU agri-food chain law and that establishes the need for harmonized methods and scientific expertise, in accordance with Article 92(1) of the OCR for EURLs, and Articles 95(1) and 97(1) of the OCR for EURC, respectively.

The Commission can take a formal decision to establish an EURL for a specific sector by means of a delegated act (Article 92(4) of the OCR) and will then designate – by means of an implementing act (Article 93(1) of the OCR) – one or several laboratories to take over the functions of EURLs following a public selection procedure (Article 93(2)(a) of the OCR). These establishing and designating decisions may narrow the scope of EURLs to certain areas of expertise (e.g., groups of pathogens, pest species, etc.). Similarly, the formal decision of the Commission to designate one or several EURCs for animal welfare or for the authenticity and integrity of the agri-food chain[77] by means of implementing acts can narrow the scope of an EURC to certain areas of expertise.

The mandatory tasks to be carried out by EURLs and EURCs, as well as the requirements for their

77 As of the date of publication of this Notice, no EURC for authenticity and integrity of the agri-food chain has been designated.

operation (e.g., equipment, staff, accreditation, etc.) are laid down in Articles 93(3) and 94 of the OCR for EURLs, in Articles 95(3) and 96 of the OCR for EURCs for animal welfare and in Articles 97(3) and 98 of the OCR for EURCs for the authenticity and integrity of the agri-food chain. Within this legal framework, there is considerable flexibility to specify the detailed scope of a EURL's or EURC's mission in its annual or multiannual work program.

If additional tasks or requirements are identified for an EURL or EURC after its designation, an assessment should be made whether these additional tasks and requirements fall within the scope of 1) the respective sector specific legislation, 2) the establishing delegated act and/or designating implementing act and 3) the catalogue of tasks and requirements described in Articles 93-98 of the OCR. If the additional tasks or requirements fall within this scope, the Commission may decide to include them in the EURL's or EURC's annual or multiannual work program. If the additional tasks or requirements do not fall within the scope as described above, a formal decision by the Commission by means of a delegated act according to Article 99(2) of the OCR is required. However, this procedure is restricted to situations of new or emerging risks, new or emerging animal diseases or pests of plants or where new legal requirements so warrant.

3.1.2. National reference laboratories (Articles 100 to 101 of the OCR)

Member States shall designate one or more NRL for each EURL. The range of activities of an EURL can be covered by a single corresponding national institution functioning as NRL or be divided over several national institutions. In the latter case, Member States shall ensure close cooperation between laboratories that share an NRL function (Article 100(5) of the OCR). Member States may also decide to designate additional NRLs for policy areas where there is no corresponding EURL (Article 100(1) of the OCR). These additional NRLs shall nevertheless fulfil the requirements, tasks and responsibilities of NRLs as laid down in Articles 100 and 101 of the OCR, except those regarding cooperation with EURLs (e.g., Article 101(1)(a) and 101(1)(d) of the OCR).

A laboratory may take the function of both official laboratory and reference laboratory, provided that it fulfils the requirements and obligations and is designated for each of these functions.

Member States may designate as NRL a laboratory located in another EU or EEA country. This mechanism may be employed, for example, when national laboratories do not have the capacity or expertise to fulfil the requirements for accreditation of NRLs. Furthermore, pursuant to the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community[78], and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland and its Annex 2, section 43, this is the only mechanism by which a NRLs in respect of Northern Ireland may be designated.

78 OJ L 29, 31.1.2020, p. 7–187

3.2. Accreditation

3.2.1. EURLs (Article 93 of the OCR) and NRLs (Article 100 of the OCR)

EURLs and NRLs are obliged to operate in accordance with EN ISO/IEC 17025 and to be accredited under this standard. The scope of their accreditation shall include all methods of laboratory analysis, test or diagnosis required to be used by the laboratory when it operates as an EURL or NRL. The term "method" can be understood as a measurement procedure that is applied to a specific matrix or group of matrices, and to a specific analyte or group of analytes, or a combination thereof, depending on the method in question, in line with EN ISO/IEC 17025.

These rules correspond to the relevant obligations established for the designation of official laboratories in Article 37(4)(e) and Article 37(5) of the OCR (see chapter 2.3.3.2. on accreditation). The OCR foresees derogations from this obligation, by giving Member States the prerogative of designating a NRL that does not fulfil the obligation of accreditation under certain conditions, and grants some flexibility with respect to the scope of the accreditation:

1. The scope of the accreditation of an NRL or EURL may
    a. comprise groups of methods (Article 100(2) in conjunction with Article 37(5)(b) of the OCR for NRLs, Article 93(3)(a)(ii) of the OCR for EURLs)
    b. be defined in a flexible manner (Article 100(2) in conjunction with Article 37(5)(c) of the OCR for NRLs, Article 93(3)(a)(iii) of the OCR for EURLs)
2. A temporary derogation from mandatory accreditation (1 + 1 year) is allowed for NRLs (Article 100(2) in conjunction with Article 42(1), Article 42(2)(a)+(b) and Article 42(3) of the OCR):
    a. where the use of the method is newly required by Union rules, in line with Article 34(1) of the OCR (from the date of entry into force of such rules)
    b. when changes to a method in use require a new or extended accreditation (if not covered by a flexible accreditation scope[79])
    c. when the need for the use of the method results from an emergency situation or an emerging risk.

79 'Flexible accreditation scope': Scope of accreditation expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the conformity assessment body as confirmed by the accreditation body (ISO/IEC 17011:2017)

3. For the field of plant health, there was a transitional period until 29 April 2022 for the accreditation requirement to enter into force (Article 167(2) of the OCR).

NRLs and EURLs do not fall under the scope of the derogations from mandatory accreditation established in Article 41 of the OCR and in Commission Delegated Regulation (EU) 2021/1353. However, for the area of plant health, competent authorities or respectively the Commission may designate official laboratories, designated as such on the basis of a derogation adopted under Article 41 of the OCR, as NRL or EURL irrespective of whether they fulfil the condition of having all their methods accredited (Article 93(4) and Article 100(2) of the OCR, respectively). This possibility would not affect NRLs and EURLs in the area of plant health that have been designated as such prior to the adoption of the delegated act under Article 41 of the OCR.

3.2.2. EURCs (Articles 95 to 98 of the OCR)

Due to their support-focused mission, there is no provision for mandatory accreditation of EURCs. Nevertheless, EURCs shall '*possess a high level of scientific and technical expertise*' in their respective areas of focus and '*ensure that their staff have good knowledge of international standards and practices*' (Article 95(3)(b) and (e), and Article 97(3)(b) and (e) of the OCR, respectively).

3.3. Publishing and notifying obligations

3.3.1. List of NRLs

Member States shall, in accordance with Article 100(4) of the OCR, communicate to the Commission, to other Member States and to the relevant EURLs an updated list of the names and addresses of NRLs and make this list publicly available.

EURLs shall, in accordance with Article 94(3) of the OCR, publish a list of their corresponding NRLs designated by Member States in their respective area of focus.

3.3.2. Lists of EURLs and EURCs

The Commission publishes, in accordance with Article 99(1) of the OCR, an updated list of the names and addresses of designated EURLs (https://ec.europa.eu/food/ref-labs_en) and EURCs (for animal welfare: https://ec.europa.eu/food/animals/welfare/eu-ref-centre_en) on its website.

3.3.3. Data Privacy

When publishing information of NRLs (Member States) or EURLs (European Commission), the EU rules on data protection apply (Regulation (EU) 2016/679 of the European Parliament and of the Council[80] and Regulation (EU) 2018/1725 of the European Parliament and

80 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

of the Council[81] , respectively). Information on natural persons may not be published without their consent. As a best practice, only general contact information (e.g., address, functional mailbox) of a laboratory should be published, as it sufficiently fulfils the publication obligations laid down in Article 94(3), Article 99(1) and Article 100(4) of the OCR.

3.4. Reporting and Commission controls

3.4.1. EURLs and EURCs

In accordance with Article 99(3) of the OCR, EURLs and EURCs shall be subject to Commission controls to verify compliance with the requirements of Articles 93(3) and 94 of the OCR for EURLs, and Articles 95(3) and 97(3) of the OCR for EURCs.

It is current practice of the Commission to perform, as part of its controls: a documentary review of reports on the basis of EURLs' and EURCs' annual or multi-annual work programmes;

- a documentary review of annual financial reports.

In addition, the Commission may decide to perform on-site controls on a case-by-case basis, to verify the laboratories' compliance with the designation criteria and to verify, whether submitted annual or multi-annual programmes have been adequately implemented and reported,

- for elements that cannot easily be verified through documentary review
- if reports or other sources of information raise concerns or indicate non-compliance.

3.4.2. NRLs

NRLs are not subject to the Commission controls described in Article 99(3) of the OCR. However, NRL activities may be included in the Commission controls to verify the functioning of Member States' control systems as described in Articles 116-119 of that Regulation.

3.4.2.1. NRLs: Inter-laboratory comparative tests and proficiency tests

EURLs will monitor the performance of NRLs on a regular basis through inter-laboratory comparative tests or proficiency tests (CTs/PTs) in accordance with Article 94(2)(c) of the OCR, in particular where there is a legal requirement for the use of certain methods. NRLs are obliged to participate in CTs/PTs by virtue of Article 101(1)(a) of the OCR. In cases where there are no legal requirements or no safety concerns in relation to the analyte/hazard in focus, NRLs should do their utmost to ensure participation in EURL CTs/PTs or provide a justification for non-participation.

Where necessary, NRLs or EURLs can request another NRL or official laboratory representing the Member State to participate in a CT/PT (Article 94(2)(c) and Article 38(2) of the OCR). In cases where there is no CT/PT participation or the justification for non-participation is not accepted by the EURL, Member States should be informed to take action.

81 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

For cases of underperformance of an NRL in CTs/PTs organised by EURLs, appropriate follow-up procedures should be in place. In general, these procedures should follow a two-step approach. In a first phase, the NRL should be requested to take corrective action in order to alleviate the issues identified. In a second phase, if corrective actions still result in underperformance, or if the NRL does not fully collaborate to correct the issues identified in the first phase, the EURL should inform the Commission. The Commission will decide which further steps to take and may require the competent authority of the Member State to take action.

4 TITLE VII – ENFORCEMENT ACTION

4.1. CHAPTER I – Actions by the competent authorities and penalties

4.1.1. Reporting of infringements (Article 140 of the OCR)

Compliance with Union rules may be enhanced by mechanisms that enable and encourage persons to bring new information on breaches of Union rules to the attention of competent authorities, thus assisting the competent authorities in the detection of infringements and enabling them to take appropriate follow-up measures. However, persons who could report on infringements might be deterred by a lack of procedures for reporting, or by fear of negative consequences, such as privacy violations, retaliation or discrimination, in particular in cases where the information is acquired in a work-related context ("whistleblowers").

In this context, Directive (EU) 2019/1937[82] ('Whistleblower Directive') provides for a common framework for the reporting of breaches of Union law and the protection of whistleblowers, in areas where whistleblowing is considered to strengthen the enforcement of Union law and where breaches of Union law can cause serious harm to the public interest. The OCR itself and several other Union acts laying down agri-food chain rules are included in the scope of the Whistleblower Directive (Article 2(1) and Annex of the Whistleblower Directive).

At the same time, Article 140 of the OCR provides for a general obligation imposed on Member States to establish effective reporting mechanisms in the competent authorities within the meaning of the OCR, including in particular procedures for receiving reports and protecting from retaliation when reporting on infringements of the OCR.

Hence, while it is the OCR itself that requires competent authorities to have in place effective reporting systems and protection of reporting persons, it is the Whistleblower Directive which complements Article 140 of the OCR and establishes detailed provisions on reporting channels and specific measures of support to and protection of reporting persons falling under the scope of that Directive.

The Whistleblower Directive does not affect the application of Union or national law relating to rules of criminal procedure, particularly those aiming at safeguarding the integrity of the investigations and proceedings or the rights of defence of persons concerned (Article 3(3)(d) and recital 28 of the Directive). The following paragraphs describe in more detail the scopes of Article 140 of the OCR and the Whistleblower Directive and the requirements for the design of reporting channels.

82 Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law (OJ L 305, 26.11.2019, p. 17).

4.1.1.1 Material scope: type of infringements that can be reported

Article 140 of the OCR

Reporting of infringements

1. *Member States shall ensure that competent authorities have effective mechanisms to enable reporting of actual or potential infringements of this Regulation.*

2. *The mechanisms referred to in paragraph 1 shall include at least:*

   (a) procedures for the receipt of reports of infringements and their follow-up;

   (b) appropriate protection for persons reporting an infringement against retaliation, discrimination or other types of unfair treatment; and

   (c) protection of personal data of the person reporting an infringement in accordance with Union and national law.

Article 140 of the OCR establishes an obligation for Member States to enable the report of infringements of "this Regulation", i.e., infringements of the rules for the performance of official controls and other official activities laid down in the OCR. This may include, among others, infringements of the rules regarding the planning, organisation, performance, documentation or financing of official controls and other official activities, infringements of the rules regarding obligations of operators laid down in the OCR, as well as the conduct, impartiality, or qualification of staff of entities subject to OCR rules.

The acts listed in the Annex to the Whistleblower Directive are included *in toto* in the material scope of that Directive. Thus, the entire OCR is covered by the material scope of the Whistleblower Directive.

While Article 140 of the OCR does not lay down requirements for the protection of persons who report infringements of rules laid down in other legislative acts in the areas referred to in Article 1(2) of the OCR, some of those acts are included in the material scope of the Whistleblower Directive (see Table 6: Legal acts subject to the Whistleblower Directive). In other words, reports on breaches of Union law falling within the areas referred to in Article 1(2) of the OCR are only covered by the Whistleblower Directive to the extent that they relate (a) to a breach of the OCR, e.g., as regards the official controls to be performed, or (b) to a breach of the Union legal acts that are listed in the Annex to the Whistleblower Directive.

It should also be recalled that the Commission encourages Member States, when transposing the Whistleblower Directive, to consider extending its scope of application to other areas, and more generally to ensure a comprehensive and coherent framework at national level.

Table 6: Indicative list of EU legal acts within the areas referred to in Article 1(2) of the OCR that are subject to the Whistleblower Directive. In addition, the OCR itself is also included in the scope of the Whistleblower Directive.

	Areas referred to in Article 1(2) of the OCR	**Legal acts included in the scope of Directive (EU) 2019/1937 (Article 2(1) and Annex)**
a)	food and food safety	Regulation (EC) No 178/2002
b)	deliberate release into the environment of Genetically Modified Organisms (GMOs) for the purposes of food and feed production	-
c)	feed and feed safety	Regulation (EC) No 178/2002
d)	animal health requirements	Regulation (EU) 2016/429 Regulation (EC) No 1069/2009
e)	animal by-products and derived products	Regulation (EC) No 1069/2009
f)	welfare requirements for animals	Council Directive 98/58/EC[83] Council Regulation (EC) No 1/2005 Council Regulation (EC) No 1099/2009 Council Directive 1999/22/EC[84] Directive 2010/63/EU[85]
g)	protective measures against pests of plants	-
h)	plant protection products and the sustainable use of pesticides	-
i)	organic production and labelling of organic products	Regulation (EU) 2018/848
j)	use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed.	-

83 Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes (OJ L 221, 8.8.1998, p. 23).

84 Council Directive 1999/22/EC of 29 March 1999 relating to the keeping of wild animals in zoos (OJ L 94, 9.4.1999, p. 24).

85 Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

4.1.1.2 Reporting mechanisms

Article 140 of the OCR establishes the obligation of the competent authorities to enable effective reporting channels to report breaches of the OCR and it refers, in general terms, to "reporting of actual or potential infringements" and to "persons reporting an infringement". Furthermore, recital 91 of the OCR clarifies that "any person" who alerts the competent authorities to possible infringements should be protected. Thus, the reporting channels implemented under the OCR, should be consistent with the standards of the Whistleblowing Directive.

When setting up reporting channels, clear "signposting"[86] is crucial, i.e., providing accurate and easily available information to the general public about reporting channels and the associated levels of protection, in particular where confidential channels in line with the requirements of the Whistleblower Directive are available in addition to less confidential means of providing the information.

The following paragraphs focus on the implementation of reporting mechanisms in accordance with the Whistleblower Directive by the competent authorities within the meaning of the OCR.

4.1.1.3 Written procedures

The Whistleblower Directive requires that procedures for the receipt of reports of infringements and their follow-up are established.

This implies that clear written procedures that determine how reports can be submitted, how they are being processed and handled, which mechanisms of protection are applied and how reports are followed-up should be in place within the competent authority.

These safeguards aim to ensure the correct processing of information, including confidentiality and personal data protection within the competent authority, as well as the provision of information to potential reporting persons on the possibilities for reporting and the procedures for processing reports, which should be easily and publicly accessible, in order to encourage potential reporting persons and to reassure them as regards the confidential treatment and effective follow-up of their report.

86 Recital 89 of the Whistleblower Directive: *"[..] Member States should ensure that relevant and accurate information in that regard is provided in a way that is clear and easily accessible to the general public. Individual, impartial and confidential advice, free of charge, should be available on, for example, whether the information in question is covered by the applicable rules on whistleblower protection, which reporting channel might best be used and which alternative procedures are available in the event that the information is not covered by the applicable rules, so-called 'signposting'. [..]"*

4.1.1.4 Contact persons, receipt and handling of reports

The reporting mechanisms provided for in Article 140 of the OCR to be established by competent authorities designated under the OCR fall under the concept of "internal reporting channels" (Articles 7-9 of the Whistleblower Directive)[87] "Internal reporting" also includes cases where the entities operating the reporting channel have authorised third parties to receive reports of breaches on their behalf (Article 8(5) of the Whistleblower Directive).

Whilst it is for the entity (competent authorities) to decide whether to authorise third parties to receive reports on their behalf or not, in any case, the persons receiving and handling reports should offer appropriate guarantees of respect for independence, confidentiality, data protection and secrecy (recital 54 of the Whistleblower Directive).

All reports received by entities (competent authorities within the meaning of the OCR) should be treated confidentially. Article 9 of the Directive requires that the entities (competent authorities) acknowledge the receipt of the report towards the reporting person within seven days, and the reporting person should receive feedback about the follow-up action taken or envisaged, within a reasonable timeframe not exceeding three months from the acknowledgment of receipt or, if no acknowledgement was sent to the reporting person, three months from the expiry of the seven-day period after the report was made. Follow-up means any action taken by the recipient of a report or any competent authority, to assess the accuracy of the allegations made in the report and, where relevant, to address the breach reported, including through actions such as an internal enquiry, an investigation, prosecution, an action for recovery of funds, or the closure of the procedure (Article 5(12) of the Whistleblower Directive).

4.1.1.5 Personal data protection

Requirements for the design of reporting channels under the Whistleblower Directive[88] serve to ensure that the entities that operate reporting channels, treat the identity of the reporting person with the utmost confidentiality, because safeguarding the confidentiality of the identity of the reporting person is fundamental to preventing retaliation[89].

Personal data must be processed in accordance with rules for data protection at national or Union level, and mainly, with the rules stipulated in Regulation (EU) 2016/679 (General Data Protection Regulation, GDPR) and in Directive (EU) 2016/680. It should be noted that in this regard, 'personal data' is any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (Article 4(1) of the GDPR and Article 3(1) of Directive (EU) 2016/680).

87 It should be noted that in addition to "internal reporting channels", the Whistleblower Directive requires Member States to establish "external reporting channels", and, for that purpose, to designate the authorities competent to receive, give feedback and follow up on reports (see in particular Article 11 of the Directive). External reporting in accordance with the Whistleblower Directive is not covered by this document.

88 Article 16 of the Whistleblower Directive.

89 Recital 82 of the Whistleblower Directive.

The content of a report is likely to contain personal data of both the reporting person and the person concerned, or persons connected to the reporting person. Under the Whistleblower Directive, the reporting channels must be designed to ensure that the identity of the reporting person and of the person concerned (i.e., natural or legal person who is referred to in the report as a person to whom the breach is attributed or with whom that person is associated) is protected[90]. Consequently, internal access to the information at hand as part of the investigation of the allegations must be granted only to designated staff[91].

In addition, specific rules are to be followed for the record keeping of the reports. Reports shall be stored for no longer than it is necessary and proportionate in order to comply with the requirements imposed by the Whistleblower Directive or other requirements imposed by Union or national law[92], including rules on the collection of personal data that is relevant to the allegation, the definition of retention period of personal data depending, among others, on the outcome of the whistleblowing procedure and the nature of outcome of the case[93] or the implementation of appropriate security measures[94].

It is recommended that competent authorities within the meaning of the OCR, when making information on reporting channels available to potential reporting persons, include information on how personal data contained in reports is processed.

Furthermore, it is recommended that organisations consider the data protection implications of new whistleblowing processes at the design stage (data protection by design principle of Article 25 GDPR). By involving the data protection officer (DPO) early in the process, the relevant organisations will be able to adapt their whistleblowing procedures to data protection requirements.

4.1.1.6 Anonymous reporting

The Whistleblower Directive leaves the possibility of accepting and following up on anonymous reporting to the choice of the Member States[95]. However, the Whistleblower Directive clearly underlines[96] that irrespective of whether Member States choose or not to follow-up on anonymous reports, if persons who reported information anonymously suffer retaliation once their identities are revealed, they must receive the protection as provided under Chapter VI of the Directive.

The advantage of anonymous reporting is that it may reduce the inhibition hurdle to make a report in the first place for persons who, despite the confidentiality guarantees, would still not trust that their identity would not be revealed.

90 Article 22(3) of the Whistleblower Directive.

91 Articles 9(1)(a) and 12(1)(a) of the Whistleblower Directive.

92 Article 18(1) of the Whistleblower Directive.

93 Article 5 (1) (e) of Regulation 2016/679, which introduces the general principle to keep personal data "… in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed…".

94 Article 5 (1) (f) of Regulation 2016/679, which stipulates that the personal data is to be "…processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures ('integrity and confidentiality')".

95 Article 6(2) of the Whistleblower Directive.

96 Article 6(3) of the Whistleblower Directive.

Technological solutions that allow persons to initially report anonymously, while allowing for two-way communication, may help to reduce the initial inhibition to report and still allow authorities to ask the reporting persons for additional information. Regardless of the technical means of communication, mechanisms that ensure confidentiality and protection against retaliation must be in place to ensure protection once the reporting person's identity has been revealed.

Table 7: Examples of available technologies for reporting[97]

Tool	Advantages	**Disadvantages / challenges**
Letterbox / post	• easy to implement	• confidential delivery to contact person must be ensured
e-mail	• easy to implement	• access to email account must be restricted to contact person • e-mail provider must ensure data protection
Telephone / voice messaging / physical meeting	• easy to implement • direct communication with contact person	• confidentiality and impartiality at receiving end and during handling must still be ensured
Digital solutions / IT platforms	• low inhibition hurdle • data security • two-way communication • anonymous reporting can be easily provided for	• confidentiality and impartiality at receiving end and during handling must still be ensured

97 The Whistleblower Directive lays down certain requirements as regards the design of reporting channels. For example, oral reporting must be possible by telephone or other voice messaging systems, and, upon request by the reporting person, by means of a physical meeting (Articles 9 and 12 of the Whistleblower Directive).

4.1.1.7 Protection against retaliation

Retaliation, discrimination, or other types of unfair treatment may include any direct or indirect act (or omission) to the detriment of the reporting person. Persons who work for the competent authority may, for example, experience dismissal, suspension or demotion. Persons reporting from outside the competent authority may also experience negative consequences, for example, through the publication of their identity or other personal details in relation to a report, or through the denial of services or other unfair treatment in relation to the activities of the competent authorities.

Article 19 of the Whistleblower Directive sets out a non-exhaustive list of retaliatory measures that Member States are to prohibit, and its Articles 20 and 21 establish a number of measures of support and measures of protection against retaliation to ensure that reporting persons suffering retaliation are adequately protected. Furthermore, in order to prevent retaliation, the impartiality of the contact person and the confidential treatment of reports as described above are crucial to protect the identity and personal data of the reporting person. Clear written procedures and targeted training may help to raise awareness among employees and management staff and should aim to prevent discriminatory and unfair behaviour.

The protections foreseen in the Whistleblower Directive take account of the power imbalance between reporting persons and the organisation where the breach occurred, in cases where the information was obtained in a work-related context. Where reports are made by persons who obtained the information on breaches outside a work-related context, such a power imbalance may be less relevant. Nevertheless, as described above, Article 140 of the OCR acknowledges that reporting persons who obtained information on breaches outside a work-related context can also provide valuable information, in particular, by reporting through the confidential reporting channels.