COMMISSION NOTICE

on the implementation of Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation)

(2022/C 467/02)

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.

Contents

ABBREVIATIONS

BCP	Border control post: As defined in point 38 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.
EURC	European Union reference centre
EURL	European Union reference laboratory
HACCP	Hazard analysis and critical control points
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
TRACES-NT	TRACES 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.

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 (MS) 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 Commission Notice is to compile clarifications and best practices 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. This notice is without prejudice to the exclusive competence of the Court of Justice of the European Union to authoritatively interpret Union law.

([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).

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***
>
> *1. 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:*
>
> *(a) compliance by the operators with this Regulation and with the rules referred to in Article 1(2); and*
>
> *(b) 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.*
>
> *2. 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 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' ([2]) 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 ([3]) 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:

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. finalising 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.

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

([3]) 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.

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 ([1]))
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
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
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
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 ([2])	**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 finalisation of official control
29	Inserting the results of checks on animals and goods entering the Union in TRACES-NT	**OC**		Part of finalisation 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.
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)
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
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 based on completed official control (cf. Article 2(2) of the OCR)
49	Preparing inspection/audit/laboratory report (outcome of official control)	**OC**		Integral part of official control activity

50	Monitoring of contaminants in food or feed ([3]) 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**		Activity aimed at verification of compliance with the rules referred to in Article 1(2) of the OCR
51	Monitoring of contaminants in food or feed[1] 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 ([4])		**OOA**	Non-targeted monitoring activity not aimed at verifying compliance with the rules referred to in Article 1(2) of the OCR

([1]) 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).

([2]) 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).

([3]) 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.

([4]) 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).

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

2.1. 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.

2.1.1. *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.

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 are to grant the delegation of official controls based on on-site controls of the candidate delegated bodies, including in the case where such bodies are accredited in accordance with Article 29, point (b)(iv), of the OCR.

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

(i) Such provisional delegation is permitted 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 ([4]);

(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.

As the accreditation standard under which the delegated body operates might not be fully relevant for all delegated tasks it undertakes, and accreditation audits might not cover all aspects of the OCR, competent authorities that have delegated certain official control tasks to delegated bodies must organise audits or inspections of such bodies, as necessary and avoiding duplication with any accreditation audits (Article 33(a) of the OCR), and 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.

([4]) The actual operation of the delegated body in accordance with the relevant standards referred to in Article 29(b)(iv) is to be verified during the accreditation process referred to in that provision.

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

2.2.1. *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 ([5]) 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 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.

([5]) 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).

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.

Table 2 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.

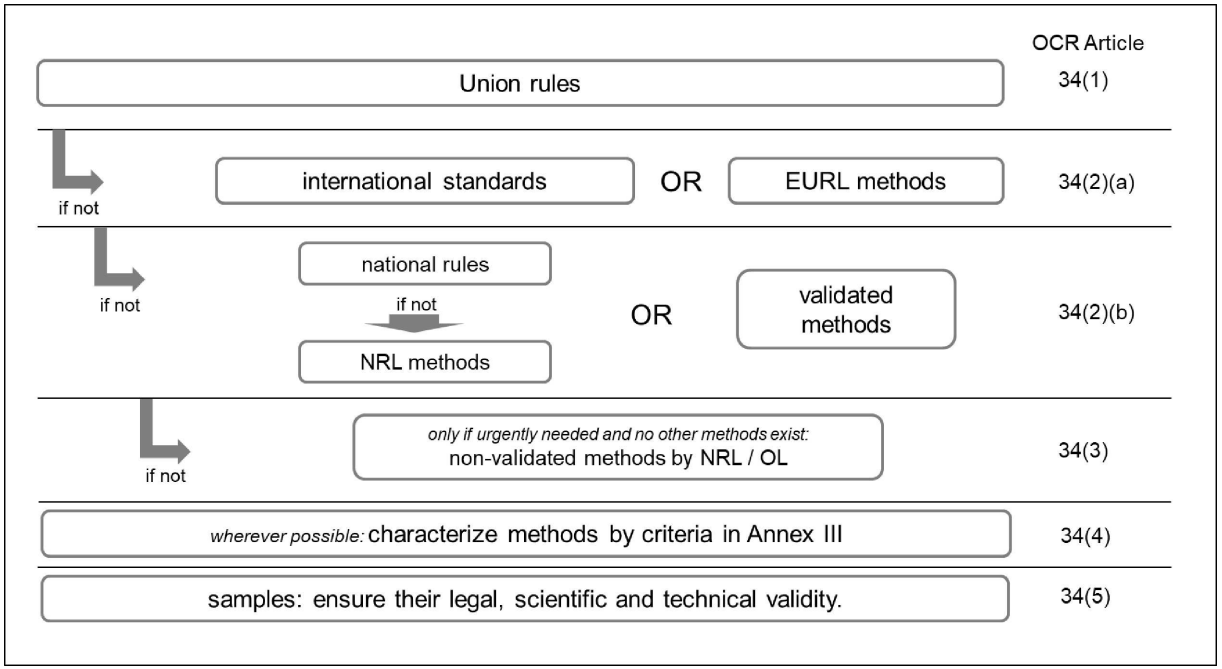
Figure 1

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 2

'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 Table 2)



2.2.2. *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 ([6]) ([7]) ([8]) 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 ([9]), 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;

([6]) 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).

([7]) 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).

([8]) 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).

([9]) 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.

— 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.

2.2.2.1. 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 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 ([10]);

'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 a 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 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

([10]) https://ec.europa.eu/eusurvey/runner/contactform/DGSANTE_official_labs_R2017_625.

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 analysed 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).

2.2.2.2. 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.

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

2.2.3.1. 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 2.2.3.2 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.

2.2.3.2. 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 ([11]) (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* ([12]) 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 ([13]) 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 ([11]));

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

([11]) '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).

([12]) 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

([13]) 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).

2.2.3.3. 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 [link to CIRCABC list]. 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.

2.2.3.4. 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 ([14]). 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.

2.2.3.5. 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 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'.

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

2.3.1. *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.

([14]) https://ec.europa.eu/eusurvey/runner/contactform/DGSANTE_official_labs_R2017_625.

2.3.2. *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.

2.3.3. *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.

2.3.4. *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 ([15]) (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 ([16]) (e.g. official controls in slaughterhouses). This means that Member States may determine fees or charges at the level of the costs calculated in accordance with Article 82(1) of the OCR with regard to some consignments referred to in Chapter I of Annex IV to the OCR of animals or goods belonging to the same category (e.g. official controls on consignments of meat) or with regard to some activities referred to in Chapter II of Annex IV to the OCR belonging to the same category (e.g. official controls in cutting plans) and at the amounts provided for in Annex IV to that Regulation, with regard to consignments of animals or goods belonging to another category (e.g. official controls on consignments of meat products, poultry meat, wild game meat, rabbit meat or farmed game meat) or with regard to activities belonging to another category (e.g. official controls on milk production). However, 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 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*.

([15]) There are 8 (eight) categories of animals and goods listed in points I to VIII of Chapter I of Annex IV to the OCR.
([16]) There are 5 (five) categories of activities listed in points I to V of Chapter II of Annex IV to the OCR.

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 ([17]) *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.

2.3.5. *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;*

([17]) CJEU, 19 December 2019, Exportslachterij J. Gosschalk, C-477/18 and C-478/18, para 66.

(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.*

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.

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 [18] by means of implementing acts can narrow the scope of an EURC to certain areas of expertise.

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

The mandatory tasks to be carried out by EURLs and EURCs, as well as the requirements for their 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 ([19]), 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.

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 2.2.3.2 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);

([19]) OJ L 29, 31.1.2020, p. 7.

(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 ([20]));

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

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 empowerment foreseen in Article 41 of the OCR on establishing derogations from mandatory accreditation ([21]). 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.

([20]) '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).

([21]) 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).

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 ([22]) and Regulation (EU) 2018/1725 of the European Parliament and of the Council ([23]), 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.

([22]) 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).

([23]) 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.