Safety

Official controls, European Commission guidelines on reg. EU 2017/625

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On 8 December 2022, the European Commission published the guidelines for the implementation of the reg. EU 2017/625 on official controls in the agri-food chain (so-called *Official Controls Regulation*, OCR. See notes 1,2,3).

The document contributes to the understanding and harmonized application of the OCR by EU Member State and government authorities *stakeholders*, for the purposes of official controls and other official activities (4,5).

1) EU Reg. 2017/625, guidelines of the European Commission. The cardinal points

The guidelines of the European Commission on the reg. EU 2017/625 focus on five key points:

- distinction between official controls and other official activities (OCR, art. 2),
- delegation of certain tasks of the competent Authorities

2) 'Official controls' and 'other official activities'

The distinction between 'official controls' and 'other official activities' entrusted to competent authorities is essential as different rules and conditions apply to them. Which are also relevant for evidentiary and risk analysis purposes, as seen in the case of monitoring activities which are not in themselves suitable for justifying sanctions or warning notifications. (6)

The "official controls" and the "other official activities", it is recalled, must in any case always be performed by a "competent authority", or by a "delegated body" or a natural person to whom "certain tasks" relating to official controls or other official activities (EU regulation 2017/625, article 2).

2.1) Official controls, the three requirements

The "official controls" subject to the uniform discipline of the reg. EU 2017/625 are performed in order to verify compliance by operators - and thus, compliance of animals and goods - with the requirements of the OCR and the legislation referred to therein.

The three elements that an activity must satisfy at the same time in order to be qualified as "official control" therefore primarily concern the purpose of:

- verify the compliance of
- activities of the operators (and/or animals and goods) al
- reg. EU 2017/625 and/or the legislation referred to therein.

In the event of non-compliance, the activities aimed at verifying their extent, origin or responsibility of the operator are qualified as "official controls" in relation to these purposes. Table 1 of the guidelines gives some practical examples of official controls and other official activities.

3) Delegation of certain tasks of the competent authorities

The reg. EU 2017/625 establishes the conditions for the delegation of certain tasks relating to official controls and other

3.1) Accreditation of delegated bodies

accreditation of delegated bodies is foreseen to ensure that the impartiality, quality and consistency of official controls are maintained. The granting of the proxy is in any case subject to specific checks (*audit*. See paragraph 3.2). even in case of accreditation.

Provisional delegation of certain tasks to the delegated bodies can be admitted even pending their accreditation, under certain conditions which include the successful presentation of the relevant application (EU regulation 2017/625, art.1).

3.2) *Audit* of the delegated bodies

Delegated bodies they must be subjected to *audit* and/or inspections, including to ensure compliance of non-relevant activities that have not been considered in the *audit* of accreditation.

In cases confirmation of non-compliance, the competent authority may order the partial or full revocation of the delegation (EU regulation 2017/625, art. 33).

The conditions for delegation of official controls and other official activities, verification procedures and measures *follow-up* in the event of non-compliance, they are subject to continuous monitoring.

4) Methods of sampling and analysis

A hierarchy of criteria – so-called «cascade method» – must be followed to identify the methods of sampling and analysis, testing or laboratory diagnosis, to be applied to official controls and other official activities:

- in the absence of official criteria, e
- regardless of whether some methods are already used by the competent authorities, their delegates or by official laboratories (OCR, art. 34. See Fig. 1).

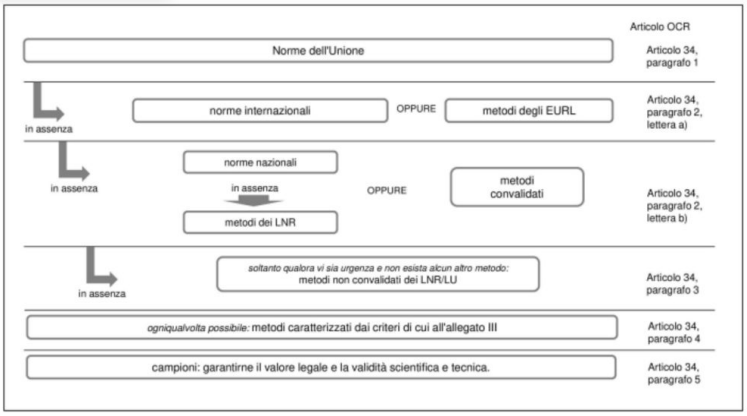

Figure 1 "Cascade" for laboratory analysis, testing and diagnostic methods in the context of official controls and other official activities

NB: the choice of methods other than those indicated in the basic hierarchy is in any case permitted if they are envisaged by sector regulations (*lex specialis*)

5) Official laboratories

The official laboratories must in turn follow the hierarchy described above to identify sampling methods, sample preparation, laboratory analyses, tests or diagnoses, sampling methods and for sample preparation, in the absence of applicable standards (7,8) .

The basic criteria for the sampling methods they must in any case respond to the provisions of Annex III allo *Official Controls Regulation*. The guidelines, in Table 2, also provide an overview of the methods to be applied.

5.1) Designation of official laboratories

The authorities authorities of the Member States:

- designate in writing the official laboratories, which must be accredited in accordance with the international standard EN ISO/IEC 17025,
- they can perform *audit* regular accreditation assessments, to verify that the official laboratory continues to meet the requirements.

Is provided the possibility of designating official laboratories located in another EU state or in a country of the EEA (European Economic Area). To this end, reference is made to the CIRCABC platform.

tests or diagnoses performed for official controls, not also in other official activities.

The competent authorities they must in any case intervene immediately where there is a need to eliminate or mitigate the health risks for humans, animals and plants, or the risks for animal welfare or for the environment (e.g. GMOs, plant protection products) . (5)

6.1) Rights of operators

The right to counter-expertise can be expressed by operators, pursuant to reg. EU 2017/625, by request of:

- document review by a recognized and suitably qualified expert,
- taking a sample, by the competent authority, for a second counter-expertise analysis,
- collection of another sample, by the competent authority, for further analysis to be entrusted to a different official laboratory - if provided for by national law, despite the uniformity of the rules - in the event of a dispute on the initial analysis and/or counter-expertise.

6.2) Limits and duties of information

The limits to the right of counter-expertise and analysis review are configured where the taking of a sufficient quantity of sample is not «appropriate, relevant and technically feasible».

Upon the occurrence of these conditions of sampling, actually foreseen by the reg. EU 2017/625, the authority must in any case:

- motivate the act, based on specific elements that consider the type of matrix (or animal), the contingencies and the type of analysis to be performed,
- inform the operator and/or operators concerned.

7) Financing of official controls and other official activities

Rates or fees are foreseen to cover the costs incurred by the

Costs of the 'other official activities', on the other hand, do not envisage any form of compulsory direct reimbursement by the operators, in the form of tariffs or fees.

7.1) Calculation of costs

Rates or fees compulsory official controls must comply with the cost level calculated in the reg. EU 2017/625 (OCR, art. 82), or the amounts shown in its Annex IV. However, a combination of the two methods is not permitted.

It's possible calculate a lump sum for a specific sector, activity or category of operators, based on the overall costs of official controls that fall within the scope of reg. EU 2017/625 (OCR).

OCR establishes which charges are included in costs and when they may form part of the official controls concerned. Referring to 'staff salaries', 'cost of facilities and equipment', 'cost of training', 'travel expenses' including overheads incurred in carrying out official controls. In addition to the costs of organizing and supporting the planning and execution of official controls.

7.2) Cost reduction

Member States may reduce the amount of fees or charges, taking into account:

- interests of operators with low production capacity,
- traditional methods used for production, treatment and distribution,
- needs of operators located in regions subject to specific geographical constraints, e
- compliance records of operators, as verified by official controls.

7.3) Transparency of funding

Maximum transparency official controls must also be guaranteed on the tariffs or charges levied on operators, in order to allow citizens and businesses to understand the method and data used to establish the tariffs or charges.

diagnoses performed in the context of official controls and other official activities.

The EURCs, reference centers of the EU, instead have the function of promoting scientific and technical skills in the areas of integrity and authenticity of the agri-food chain as well as animal welfare. And thus promote scientific sharing as a basis for official controls and other official activities.

8.1) EURL and LNR, accreditation and notification

accreditation according to the EN ISO/IEC 17025 standard – please note, also with regard to laboratory analysis, test or diagnosis methods – is:

- mandatory for EURLs (*European Union reference laboratory*) and LNRs (*National reference laboratory*),
- not mandatory for EURCs (*European Union reference centre*), as they have a supporting function.

The list update of the names and addresses of the NRLs must be published and communicated to both the other Member States and the relevant EURLs.

9) Presentation of Commission reports and controls

EURL and EURC are subject to controls by the Commission, for the verification of compliance of their activities. Their work in the field of official controls is also subject to desk review of reports, based on their annual or multiannual work programmes.

It is the faculty of the Commission have on-the-spot checks of the EURCs, on a case-by-case basis, to verify the compliance of the laboratories and the correct implementation and reporting of the annual or multi-annual programs submitted. The NRLs, on the other hand, are not subject to controls by the Commission.

The results of inter-laboratory comparative tests (*ring test*) and of the evaluation ones of the NRLs are monitored by the EURL, periodically, through interlaboratory comparative tests or proficiency tests. Also on the basis of legal prescriptions in

Dario Dongo and Giulia Pietrollini

Footnotes

(1) Commission Notice on the implementation of Regulation (EU) 2017/625 (2022/C 467/02) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022XC1208%2801%29

(2) EU Reg. 2017/625, *on official controls and other official activities carried out to ensure the application of legislation on food and feed, rules on animal health and welfare, plant health and plant protection products.* Consolidated version dated 28.1.22 on Eur-Lex https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0625-20220128&qid=1672780701484

(3) Dario Dongo, Giulia Torre. Official public controls, EU regulation 2017/625 is underway. *GIFT (Great Italian Food Trade).* 18.12.19

(4) Dongo Dongo, Amaranta Traversa, Sarah Lanzilli, Claudio Biglia. Official controls, Legislative Decree 27/21. Implementation of reg. EU 2017/625. *GIFT (Great Italian Food Trade).* 14.3.21

(5) Dario Dongo, Andrea Sodero. Official controls. Law 71/2021, converting Legislative Decree 42/2021, and warning of operators. *GIFT (Great Italian Food Trade).* 22.5.21

(6) Fabrizio De Stefani, Dario Dongo. Official controls, sampling and analysis methods. Vademecum of the Regions. *GIFT (Great Italian Food Trade)*. 27.4.21

(7) An example of a uniform and complete regulation of sampling and analysis methods is offered by the current regulation of official controls on olive oils. See Dario Dongo, Giulia Pietrollini. Olive oils, compliance checks. EU Reg. 2022/2105. *GIFT (Great Italian Food Trade).* 11.12.22

(8) A problematic example concerns the DNA extraction method for PCR analyzes to check for the presence of GMOs. In the absence of a shared method, the use of different solvents or solvent mixtures in the various laboratories can lead to contradictory results on matrices where DNA is practically absent (eg lecithins, refined oils). Another example, of great importance for the guarantee of food safety and public health,

(10) From theory to practice, a widespread criticality already reported on this site concerns the methods of sampling and analyzing food matrices aimed at ascertaining and measuring the presence of allergens. See Dario Dongo. Allergens and RASFF, European blackout. *GIFT (Great Italian Food Trade).* 13.7.22

(11) Dario Dongo, Giulia Pietrollini. WHO Global Strategy for food safety 2022-2030. *GIFT (Great Italian Food Trade)*. 30.10.22

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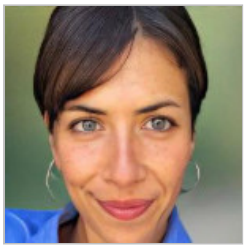

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