



OCR guidance

Commission Notice on the
implementation of Regulation (EU) 2017/625
(2022/C 467/02)

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SANTE Advisory Group, 12 May 2023

OCR guidance note

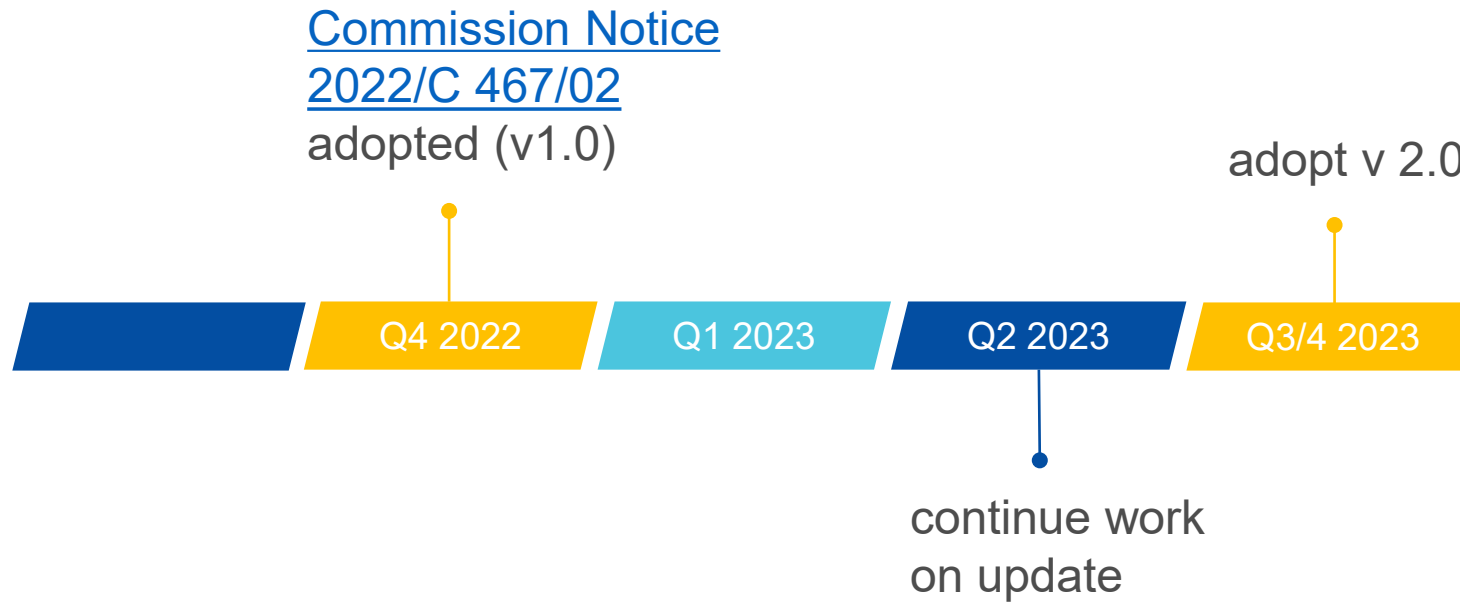
compile clarifications on OCR provisions into **single, comprehensive guidance document**



- covering basic act, delegated and implementing acts as relevant
- merge existing guidance documents where appropriate

target group:
Member States and stakeholders

OCR guidance note



OCR guidance note

Commission Notice 2022/C 467/02

- Official controls vs. other official activities (Art. 2 OCR)
- Delegation of official control tasks (Art. 28-33 OCR)
- Laboratories, methods and accreditation (Art. 34, 37-42 OCR)
- Reference laboratories/centres (Art. 92-101 OCR)
- Second expert opinion (Art. 35 OCR)
- Financing of controls (Art. 78-85 OCR)

Other existing guidance documents

- Audits of competent authorities (Article 6 OCR)
- Requirements for the MANCP (Articles 109-111 OCR)
- Food Safety Management Systems
- Intensified official controls (Article 65 OCR)
- [SANTE food safety guidance platform](#)

OCR guidance note

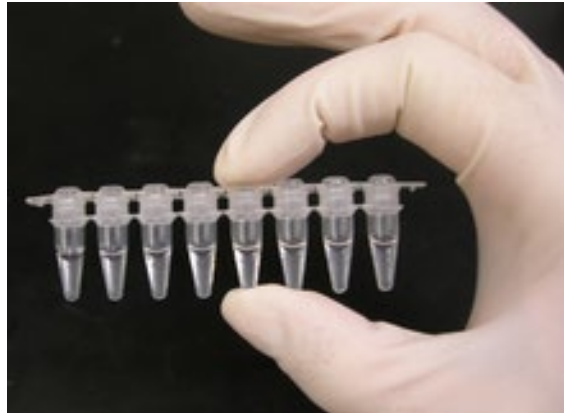
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- Official controls vs. other official activities (Art. 2 OCR)
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v2.0 (in preparation)

- Audits vs. inspections (Art. 14 OCR)
- Delegation / accreditation of delegated bodies (Art. 28-33 OCR)
- Official veterinarian / official auxiliary (Art. 17-18 OCR)
- E-commerce controls (Art. 36 OCR)
- Controls on marketing standards for agricultural products (Art. 1(4)(a) of the OCR)
- Reporting of infringements (Art. 140 OCR)

Second expert opinion - Article 35 OCR



What?

- operators whose goods are subject to sampling, analysis, test or diagnosis have the right to a second expert opinion

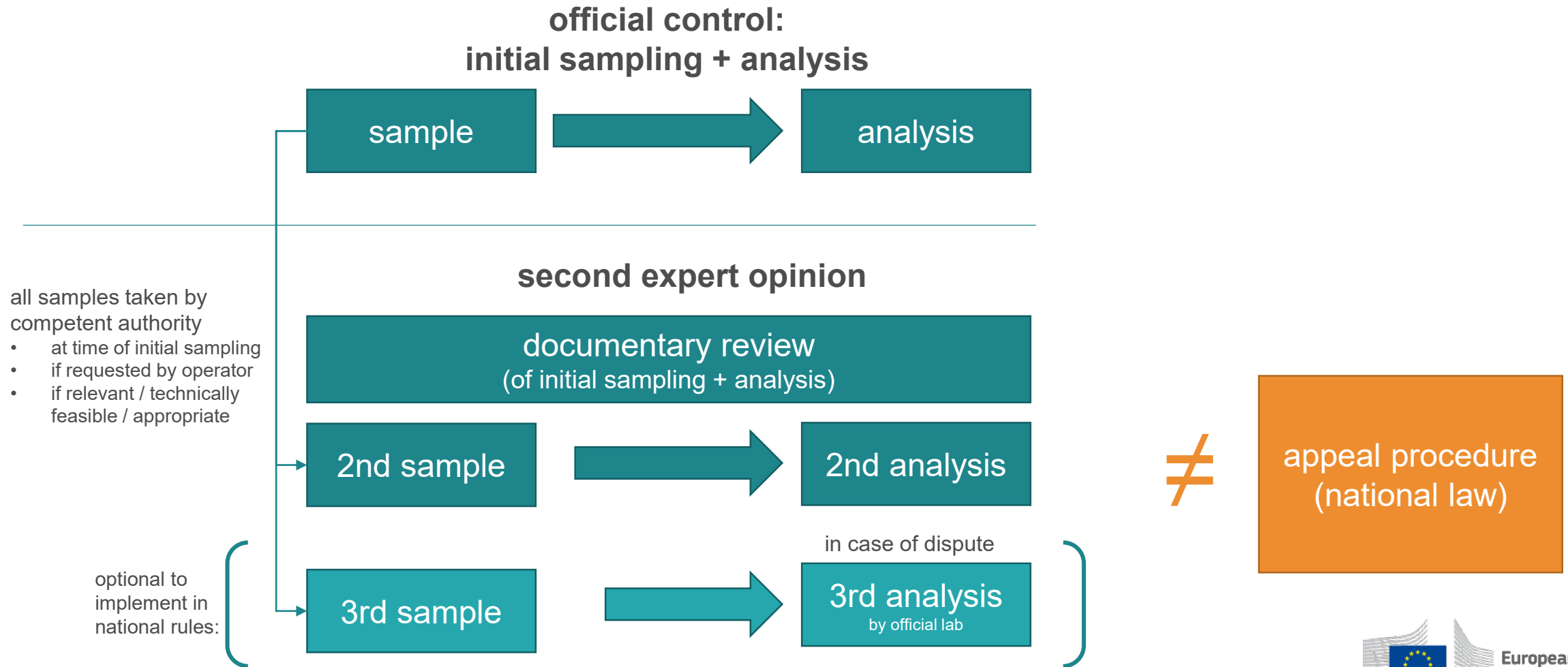
Why?

- safeguards operators' legitimate rights, in particular their right of appeal against measures taken by CA
- provides for a sound factual basis for decision of operator
- SEO ≠ appeal procedure

Who?

- operator(s) that are the addressees of measures taken by CA

Second expert opinion - Article 35 OCR



Audits vs. inspections (Article 14 OCR)

Article 14 OCR: Methods and techniques for official controls

inspections	audits (→ Article 3(30) OCR)
<ul style="list-style-type: none">• “close examination” = direct observations by inspector• verification of compliance with specific requirements at a given moment (→ checklists)• e.g. equipment, facilities, places, animals, goods, materials, data, activities, processes• cf. ISO/IEC 17000	<ul style="list-style-type: none">• compliance with planned arrangements;• effective application of those arrangements;• suitability of arrangements to <u>systematically</u> achieve objectives.• cf. ISO/IEC 17000 ; ISO 19011

E-commerce controls

- Article 9 OCR: horizontal obligation for Member States to carry out official controls at all stages of production, processing and distribution, taking into account health risks, the likelihood that consumers are misled, and possible intentional violations;
- Article 15(5) OCR: obligation for operators to inform CA about all e-commerce channels;
- Article 36 OCR: anonymous distance shopping for the purpose of official controls;
- Digital Services Act (Regulation (EU) 2022/2065; in force, application from 17 Feb 2024);
- Best practices for e-commerce control strategies.

Reporting of infringements (Article 140 OCR)



- material scope (which infringements?)
- personal scope (who can report?)
- design of reporting channels
- protection against retaliation

→ OCR is complemented by Directive (EU) 2019/1937 ('Whistleblower Directive')



Thank you

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