

Commission Notice on the implementation of Regulation (EU) 2017/625 - Official Controls Regulation

SANTE Advisory Group, 8 May 2024

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OCR guidance

- I → Sections
- II → Operators' rights
- III → Operators' obligations

Guidance on OCR - Published

Official controls/
other official
activities

Delegation

Sampling/analyses:
SEO, methods,
official labs

Financing

EURLs, EURCs

Guidance on OCR – New parts

Consignments entering the Union [Chapter V]

Official veterinarian [Art.18]

Official certification [Chapter VII]

Delegation (accreditation) [Chapter III]

E-commerce [Art.9, 36]

Reporting of infringements [Art. 140]

Listing of operators [Art.10]

Audit vs inspection [Art.14]

Derogations from accreditation - OL [Art. 41]

Commercial storage facilities [Art. 64, IA (EU) 2019/1014]

Final discussions with LS

Operators' rights – OCs vs OOAs

Art. 1(5), consequences



OCR Articles that only apply for OCs

- Right to appeal Art.7
- General rules OCs Art.9
- Subjects of OCs Art.10
- Transparency Art.11
- Documented control procedures Art.12
- Written records Art.13
- Methods, techniques Art.14
- Delegation Art.28-30
- Second expert opinion Art.35
- Sale by distance communication Art.36
- OCs on entering the Union Chapter V
- All rules on fees (Art.79-85, mandatory)
- Planning and reporting Art.109-115
- Commission controls Art.116-124
- Conditions for entry Art.125-129



OCR Articles that also apply to OOAs

- CA Art.4
- General obligations Art.5
- Internal Audits Art.6
- Confidentiality Art.8
- Control verification procedures, corrective actions Art.12(2), (3)
- Operators' obligations Art.15
- OCs in certain areas Art.18-27
- Delegation Art.31-33
- Methods on sampling analysis Art.34
- OLs Art.37-42
- General rules on fees Art.78, 80
- Official certification Art.86-91
- EURLs EURCs Art.92-101
- AAC Art.102-108
- IAs on collection of data Art.112(b)
- Training of staff Art.130
- IMSOC 131-136
- Enforcement actions and penalties Art.137-140
- Union enforcement measures Art.141

Operators' rights – SEO, Art. 35, 36, 69 OCR

Second expert opinion

Operators, whose animals or goods are subject to “sampling, analysis, test or diagnosis” have the right to a second expert opinion:

documentary review **and/or**

second analysis **and**

third analysis in case of dispute, **if** implemented in national law

Operators' rights – SEO, Art. 35, 36, 69 OCR

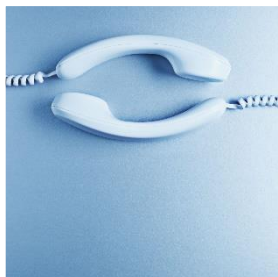
Second expert opinion

sector specific rules prevail

'relevant, appropriate, technically feasible'

elimination and containment of risks precede the right [Art. 35(4)]

Reporting of infringements



OCR Art. 140 OCR

- Mechanism, Procedures
- Protection of persons
- Protection of personal data

Scope: OCR



‘Whistleblower Directive’
(EU) 2019/1937

- Reporting channels
- Support and protection of persons
- Receipt, follow-up, feedback

Scope: in Annex,
most sectors under
OCR + OCR

Operators' rights – animals and goods

entering the Union

History of compliance [Art. 44]

Minimum burden – place of controls [Art. 44]

Authenticated or electronic copy of official certificates and docs [Art.50]

Upon measures, to consider operator's views **if** no risk [Art. 66]

Operators' obligations – Art. 10, 15(5) OCR

Listing

Lists or registers

Name, legal form, activities, places

Areas under the OCR scope

Sector specific rules (Plant Health Law, Organics)

TRACES

Operators' obligations – Art. 15(5), 36 OCR

e-commerce

Same principles in e-commerce activities

Listing: info on channels of distance communication (e.g. social networks), to permit OCs

DSA [Digital Services Act (EU) 2022/2065]: very large online platforms and search engines.

Intermediary service providers – hosting: certain actions, “compliance by design”

Regulation (EU) No 1169/2011: Fair commercial practices

Operators' obligations – animals and goods

entering the Union

Use of CHED and prior notification (Part I) [Art. 47]

Correct CN codes

Access equipment, means of transport, premises, IMS, animals and goods, docs, information [paper, electronic] [Art. 15]

Presentation of a duly finalized CHED to the customs [Art. 57]

Taking of measures [Art. 66, 69], arrangements for re-dispatch [Art. 72]

Operators' obligations – official certification

Official certificates

Facts and data from own control systems
Regular official controls [Art. 88]

Official attestations

Supervision of operators issuing official attestations [Art. 91]

Operators' obligations – Art. 79,81,82

mandatory fees

- Consignments of animals and goods of Art. 47 (1), (a), (b), (c)
- Activities of Chapter II of Annex IV

Fixed amounts of Annex IV
OR

Calculation of Art. 82 (1)

- Consignments of animals and goods of Art. 47 (1), (d), (e), (f)
- At operator's request to obtain approval of Art. 1- Reg. (EC) 183/2005

- Not planned, following non-compliance

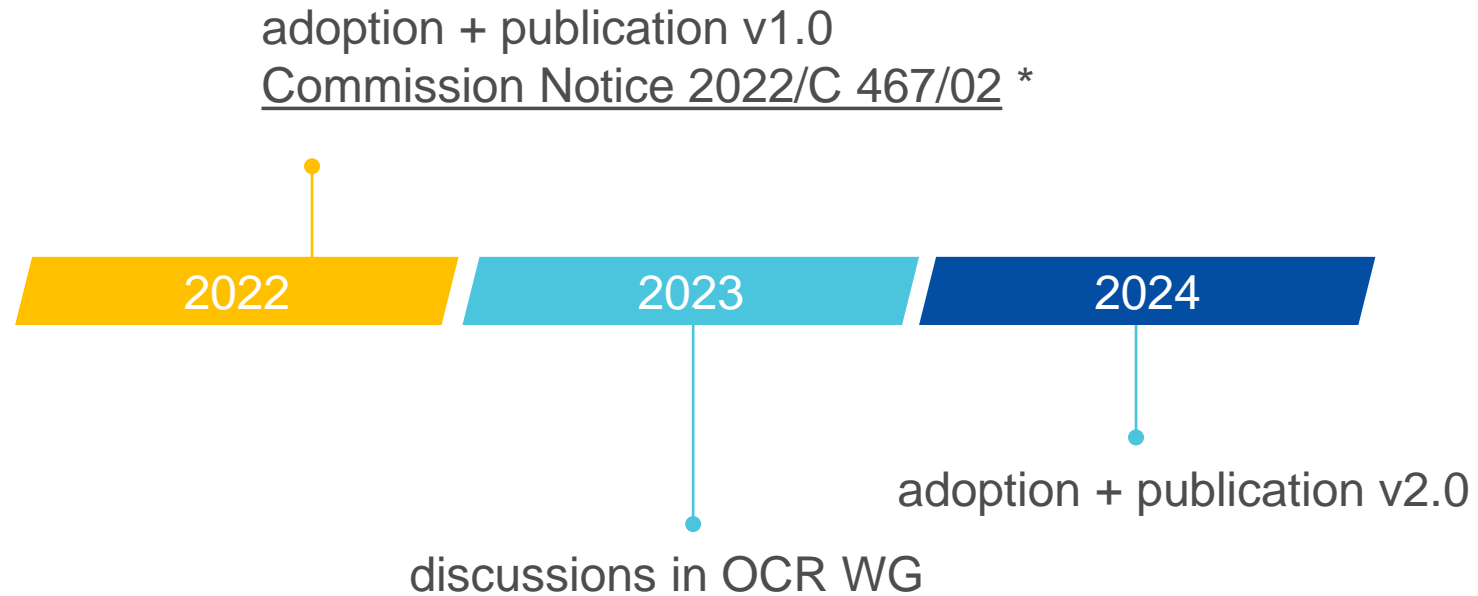
Calculation of Art. 82 (1)

Flat rate based on overall costs

OR

Actual costs per operator
(Past record)

OCR guidance



* [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022XC1208\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022XC1208(01))

Thank you!

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