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INFORMATION

From:	General Secretariat of the Council
To:	Delegations
Subject:	Meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Seeds, Propagating and Planting Materials; PRM) on 1 and 2 October 2025 - Presentation of the Commission services on official controls

Delegations will find in the annex the presentation of the Commission services concerning official controls on plant reproductive materials, which was presented during the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Seeds, Propagating and Planting Materials; PRM) on 1 and 2 October 2025.



Official controls on Plant Reproductive Material

DG SANTE

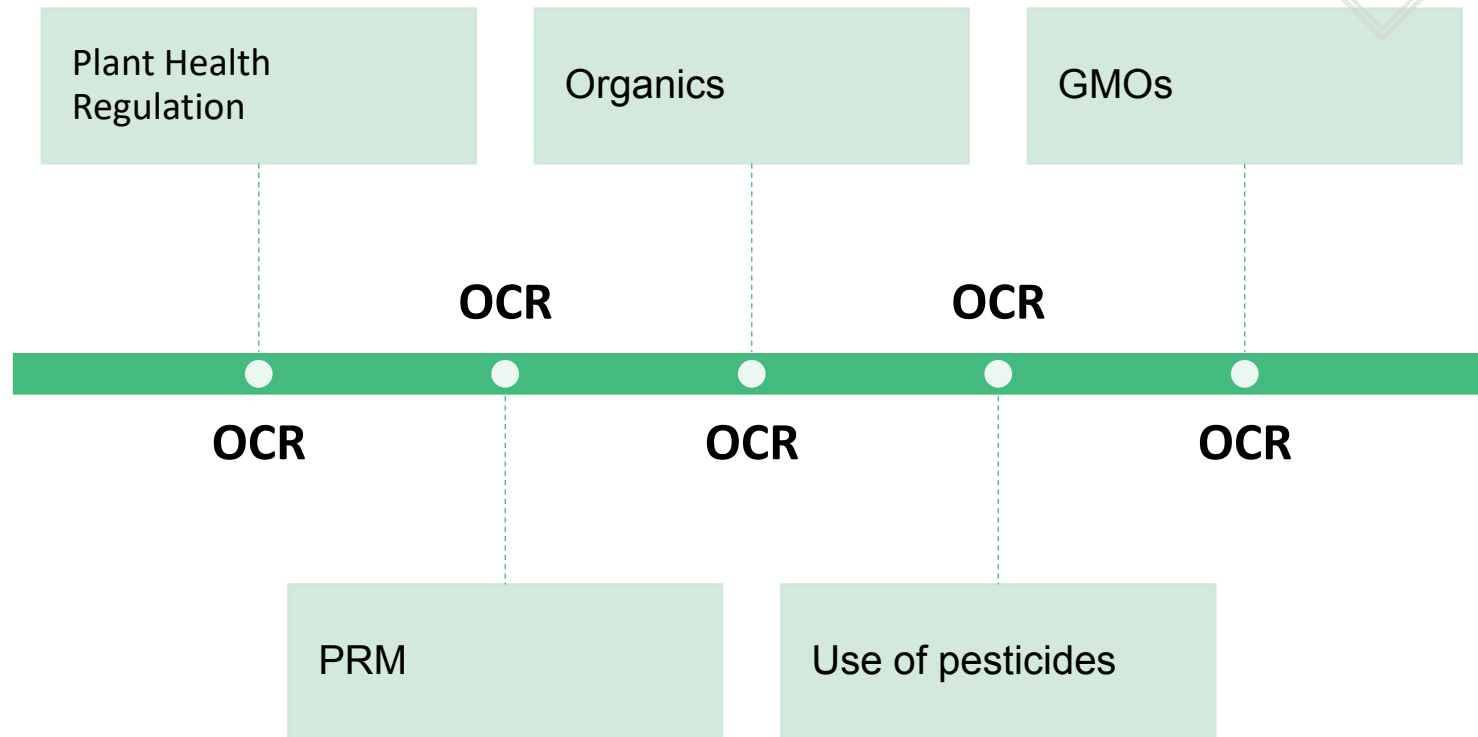
*Working Party on Genetic Resources and Innovation in Agriculture
(Seeds, Propagating and Planting Materials)*

1 – 2 October 2025



OCR vs. sectoral rules

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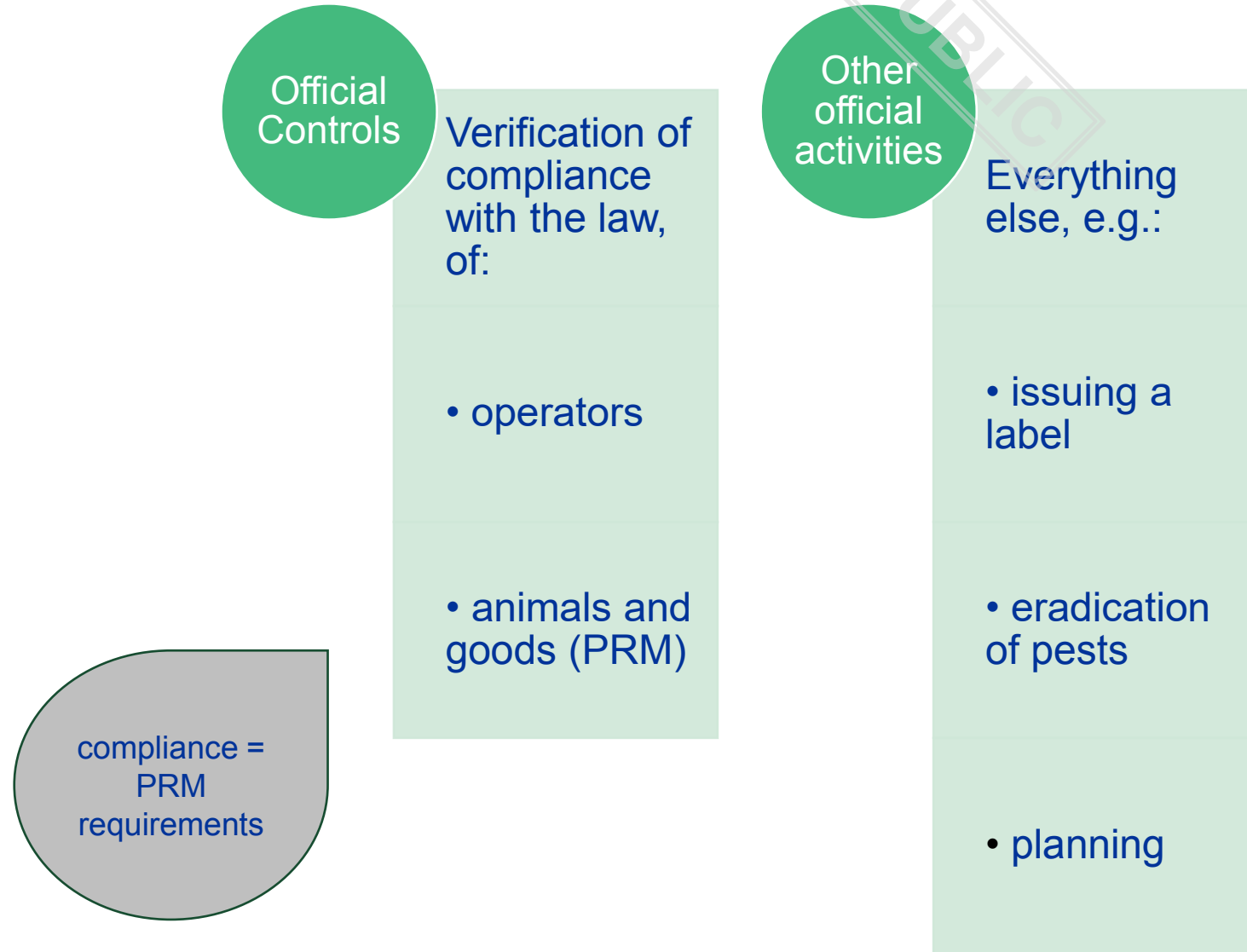
Sectoral rules

Backbone -
official controls rules

Sectoral rules



OCR – Article 2



Official controls and other official activities in OCR

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OC

All articles of OCR

OOA

4: Designation of CA

5: CA obligations

6: Internal audits

8: Confidentiality

12.2 & 12.3: Documented procedures

15: Obligation of operators

22a: Article to be introduced by the PRM Regulation

31-33: Delegation

34: Sampling, analyses, tests and diagnoses methods

37-42: Official laboratories

78: general rules for financing

80: other fees possible

86-91: official certification

92-99: EURL

100-101: NRL

102- 108: Administrative assistance

112.b: Coordination of control

130: Staff training

131-136: IMSOC

137-141: Enforcement and penalties



Official controls and other official activities - PRM

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Official controls by the CA on:

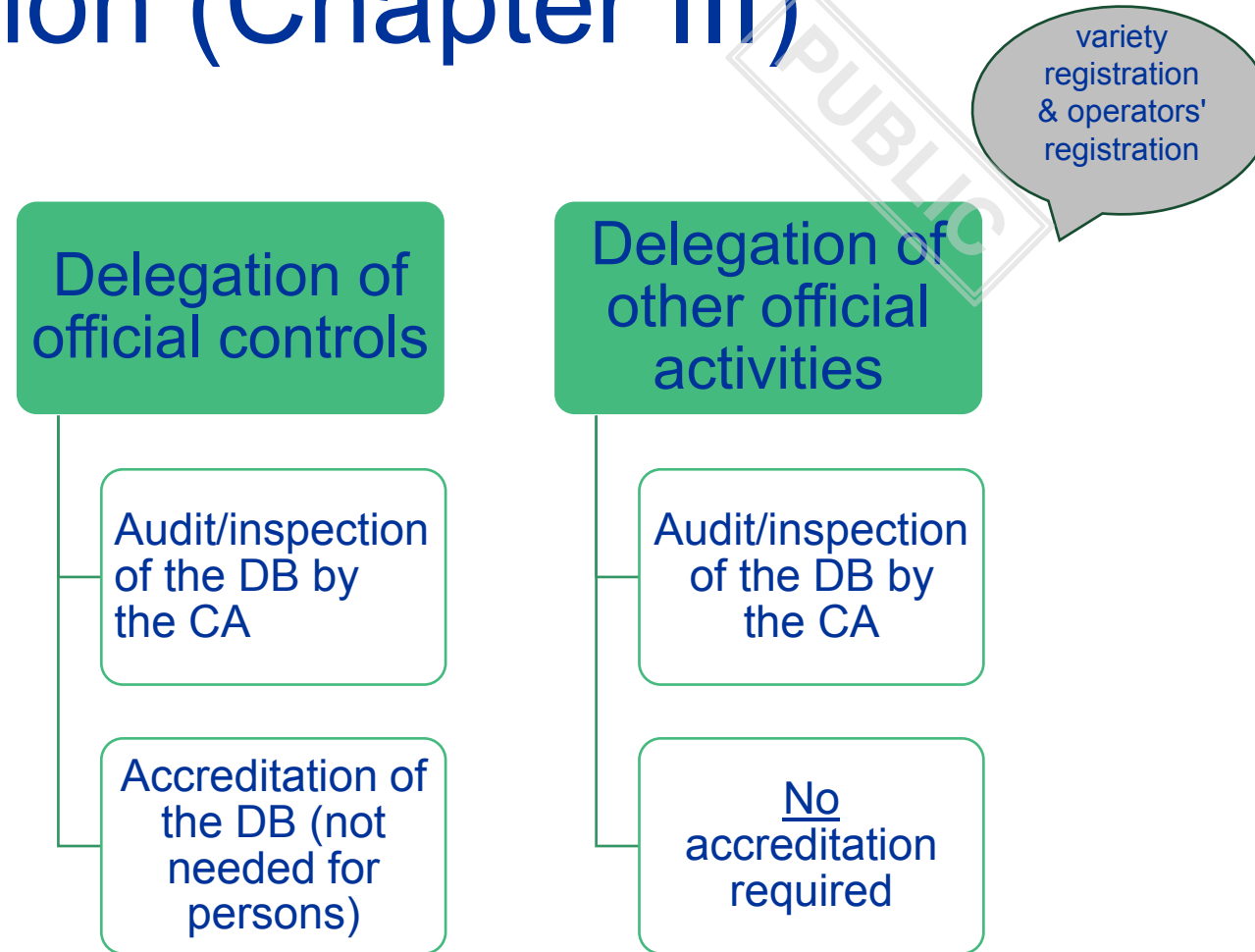
- PRM certification process (official or under official supervision)
- Audit for authorisation of operators
- Packages, seals and labels
- Control plot tests
- Market and import
- Traceability and record keeping
- Controls on maintainers
- Checks for maintenance of variety

Other official activities (OOA)

- Registration of varieties (DUS&VSCU)
- Registration of operators
- Penalties
- Notifications and reporting
- Issuance of official label
- Risk analysis
- Training



Delegation (Chapter III)



There cannot be a delegation to the operator.

Operators acting under official supervision of the competent authority is not a delegation.



Imports controls (I)

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OCR – Art.44

- Border controls not mandatory
- At BCP (can be combined with PH controls) or elsewhere
- Risk – based, then if selected 100% documentary check, and **risk-based** identity and physical checks
- Notification of arrival via IMSOC (optional in OCR but empowerment to adopt specific rules)
- In case of fraud, rapid system (iRASFF)
- General measures if PRM is no-compliant (e.g. destruction, withdrawal)

PRM

- Requirements for imported PRM
- Equivalence
- Sampling and detention of PRM (traceability through an Implementing Act)



Imports controls (II)

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- OCR Requirements
 - Planning and transparency
 - Documented procedures and penalties
 - CA requirements (sufficient staff and resources; internal audits)
 - Written records of official controls and reports upon request/non-compliance
 - Official laboratories should be designated [accredited but PRM derogation] and audited
 - Right of appeal and second expert opinion
 - Fees, optional* at MS level, should be public, transparent, fair and related to the cost of the OC.
- OCR Tools
 - Seed fraud network (iRASFF)
 - Information on imports (IMSOC-Traces)
 - EU Training (BTSF)
 - MS Assistance and cooperation (ACN)
- PRM tools
 - Equivalence and OECD rules
 - EU Plant Variety Portal



Registration of varieties (OOA)

DUS

Only performed by the CA (or delegated body)

Sectoral rules on the procedure (PRM)

OCR

- Other official activity (product authorisation)
- delegation, internal audits, confidentiality, staff training.

VSCU

Performed by the CA (or DB) or by the applicant under supervision by the CA (Art 61 PRM)

Sectoral rules on the procedure (PRM)

Rules for supervision by the CA in PRM Regulation

OCR

- Other official activity (product authorisation)
- delegation, internal audits, confidentiality, staff training.



Certification of PRM (OC)

- Certification of PRM will be an Official Control, that will lead to an official attestation (official label)
- The controls should check the compliance of the production process and the final product with the PRM Regulation
- These controls could be all done by the CA; or by the operator under official supervision of the CA (all or some steps)
- The CA can delegate this control to other bodies or persons (not to the operator) and will need to audit and control the delegated body (or person) following a risk-based approach
- OCR does not set an additional control layer to PRM, but frames the controls established in the PRM regulation
- The requirements to control are set in the PRM Regulation (e.g. 100% PB&Basic, risk-based for certified categories)



Certification of PRM (OC)

- PRM, PH and GMO requirements may be checked at the same time / MANCP coordination and coherence
- The CA should be designated by the MS, should have adequate procedures, staff and resources
- The CA should carry out internal audits
- OC should be documented, transparent, recorded and reported upon request (or upon non-compliance)
- Fees, optional* at MS level, should be public, transparent, fair and related to the cost of the OC.
- Official laboratories should be designated and audited, but see Art. 80 of PRM derogation
- Right of appeal and second expert opinion



OFFICIAL CERTIFICATION by the CA

OC by the COMPETENT AUTHORITY

OPERATOR

Field declaration

-

Declaration to CA

Field inspection

100% field inspection

Own checks

Seed sampling

100% control

Own checks

Seed testing

100% control

Own checks

Labelling

100% issuance and printing
Risk based control of the affixing

Affixing



CERTIFICATION UNDER OFFICIAL SUPERVISION

OC by the COMPETENT AUTHORITY

OPERATOR (under official supervision)

Field declaration

-

Declaration to CA

Field inspection

Risk based field inspection

100% field inspection

Seed sampling

100% prebasic & basic seed*
Risk based certified seed*

100% certified seed*

Seed testing

100% prebasic & basic seed*
Risk based certified seed*

100% certified seed*

Labelling

100% issuance
Risk based control on printing and affixing

100% printing and affixing

(* According to the last text presented in the PRM WP, not the COM proposal)



Control plot test (OC) – (I)

- Pre and post controls are official controls
- Only official controls by the CA (cannot be done by operator under official supervision)
- 100% for pre-basic and basic categories
- Risk based for certified categories
- Risk based for standard (only post controls following market and import controls)
- Only from samples taken by the CA



Control plot test (OC) - (II)

- OCR Requirements
 - Planning (MANCP)
 - Transparency, confidentiality
 - Right of appeal and second expert opinion
 - Documented procedures and penalties
 - CA requirements (sufficient staff and resources; internal audits)
 - Official laboratories should be designated and audited
 - Written records of official controls / reports upon request/non-compliance
 - Fees, optional* at MS level, should be public, transparent, fair and related to the cost of the OC.
- OCR Tools:
 - Seed fraud network (iRASFF)
 - Information from imports (IMSOC-Traces)
 - EU Training (BTSF)
 - MS Assistance and cooperation
- PRM tools:
 - EU centralised platform "EU seed hub"
 - EU Plant Variety Portal



Market controls (OC) - (I)

- Risk-based controls to the PRM in the market:
 - Certified PRM (domestic or imported)
 - Standard category PRM
 - PRM subject to derogations (final users, conservation varieties, etc)
 - PRM in bulk
 - Mixtures
- What to control:
 - Germination, varietal purity, analytical purity
 - Fastening and sealing;
 - Labelling, identification of packages and lots
 - Composition of mixtures
 - Compliance with rules on derogations (conservation networks, exchange in kind, final users...)
- Where/How to control:
 - Post-controls
 - Laboratories



Market controls (OC) - (II)

- OCR Requirements
 - Planning (MANCP)
 - Transparency, confidentiality
 - Right of appeal and second expert opinion
 - Documented procedures and penalties
 - CA requirements (sufficient staff and resources; internal audits)
 - Official laboratories should be designated and audited
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Registration of Operators (OOA)

- Registration of operators
 - Control the requirements for registration



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Thank you



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