



# Amendment DR (EU) 2023/361 on Vaccination (Cat. A diseases)

New and revised annexes – Updates and corrections in articles

*First Expert group meeting, 24 January 2025*

# Pour mémoire

- Already shortly after first adoption, a revision was considered to update annexes.
- Scheduled for 2024 and adoption in Q1 2025, but postponed due to 2024 Animal Health situation, mainly PPR and SPGP.
- New events (SPGP), or scientific/technical data (ASF) and EFSA opinion (HPAI) made these changes even more relevant.

# Amendments: articles and annexes

## 1. Articles:

- Definition of 'recovery period' changed to 'waiting period' and slightly modified for consistency;
- Articles 3, 4, 7, 9, 13 and 16 modified for clarity and consistency;

## 2. Annexes:

- Annexes VIII (RVF) and X (PPR): small changes in Part 1;
- Annex IX (LSD): substantial changes in Parts 1 and 3;
- Revised Annex XII for CSF
- New Annexes XV (CSF wild), XVI (ASF), XVII (ASF wild) and XVIII (SPGP)

# Amendments: article 2 - Definitions

- **Definition of ‘waiting period’:** more consistent with rules and intent
  - ✓ No ‘animal health status’ granted for category A diseases = no ‘recovery’
  - ✓ The period is meant to demonstrate the absence of disease before lifting the movement restrictions measures
  - ✓ ‘waiting period’ means the necessary period of time required to demonstrate absence of the category A disease after emergency protective vaccination against the disease has been carried out in a vaccination zone;
- **This implies corrections** in article 16 and in all the annexes
  - ✓ Parts 3 and/or 4 of annexes: replacement of ‘recovery period’ with ‘**waiting period**’ (as well as removal of any references to WOAH terrestrial code chapters for diseases with WOAH granted official status)

# Amendments: other articles

## ➤ **Article 3:** correct reference and syntax

- ✓ ‘first subparagraph’ becomes ‘first **paragraph**’
- ✓ that **which** the Member States may allow outside **irrespective of** the official disease prevention and control measures referred to in paragraph 1,

## ➤ **Article 4:** addition

- ✓ ‘**types and**’ added before ‘use comply with the conditions’

## ➤ **Article 7:** consistent terminology

- ✓ In 1.(a)(ii), ‘which is’ replaced by ‘**and**’, and ‘affected’ deleted
- ✓ In 2., ‘zones’ is replaced by ‘**areas**’, and ‘**or area**’ is added after ‘zone’

# Amendments: other articles

## ➤ **Article 9:** consistency

- ✓ In paragraph 1, point (b)(i), deletion of ~~'in order to prevent spreading of the category A disease from affected areas to non-affected areas'~~
- ✓ Addition of **'or when the whole country is a vaccinated zone,'**

## ➤ **Article 13:** consistency, relevance

- ✓ In paragraph 2, addition of **'and c'**, and deletion of ~~'they are either: (i) not subject to prohibitions of movements; or (ii) they are subject to prohibitions of movements but'~~
- ✓ In paragraph 3, deletion of ~~': (a) they are not subject to prohibitions of movements; or (b)'~~

# Amendments: other articles

## ➤ **Article 13 (ctd):** consistency, relevance

- ✓ In paragraph 6, addition of ‘if they are situated in a restricted zone in accordance with Delegated Regulation (EU) 2020/687,’

## ➤ **Article 16:** consistency

- ✓ Title is changed ‘**Waiting** periods’ etc.
- ✓ In point 1, replacement of ‘recovery’ with ‘**waiting**’
- ✓ In point 1, addition of ‘**Articles 13 to 15 apply and**’

# Amendments: Annexes not scheduled for substantive amendments

## ➤ Annex VII (FMD)

- ✓ Deletion of **reference to WOAH** Terrestrial Code...
- ✓ Replacement of **'recovery'** with **'waiting'**

## ➤ Annex XI (AHS)

- ✓ Deletion of **reference to WOAH** Terrestrial Code...
- ✓ Replacement of **'recovery'** with **'waiting'**



# Amendments: Annex yet to be drafted

## Annex XIII (HPAI)

- ✓ mainly **based on EFSA** scientific opinion
- ✓ vaccination / peri-vaccination **zones**
- ✓ update **surveillance** requirements:
  - appropriate sensitivity for early detection and confidence for disease freedom
  - for captive birds
- ✓ **movement requirements** for vaccinated captive birds from confined establishments

# Amendments: Annexes drafted

## ➤ Annex VIII (RVF): **no specific rules for the size**

- ✓ Part 1, paragraph (1): '1. Size of the vaccination zone: **No specific rules.**'
- ✓ Better to have a less restrictive approach – RVF never occurred in Europe hence difficult to know in advance what will be the best choice of vaccination zone

## ➤ Annex X (PPR): **minimum standards for vaccine coverage**

- ✓ PPR : Category A disease – Subject to swift eradication
- ✓ Vaccination approach (if ever implemented) : high vaccine coverage in short period to stop disease spread and then stop vaccination when confident about disease control – back to freedom.
- ✓ Sub-optimal vaccine coverage : compatible with PPR endemicity (not desirable)

# Amendments: Annexes drafted

## ➤ Annex IX (LSD): **2 issues that need to be addressed**

- ✓ Absence of rules/procedure for changing a Vaccination zone II to vaccination zone I
- ✓ Movements of animals during the waiting period

# Amendments: Annexes drafted

## ➤ Annex XVIII *tbc* (SPGP): **new annex**

- ✓ No specific rules on SPGP vaccination to date at EU level
- ✓ No specific rules on SPGP vaccination to date at WOAH level
- ✓ SPGP vaccination is now more relevant in view of the latest SPGP epidemics, especially those involving many animals in large areas (e.g. recent events in Greece, Spain, etc.)
- ✓ Same approach as PPR

# Amendments: Annexes drafted

- Annex XII (CSF): **revision**
- Annex XV *tbc* (CSF wild): **new** annex
- Annex XVI *tbc* (ASF): **new** annex
- Annex XVII *tbc* (ASF wild): **new** annex
- Annex XVIII *tbc* (SPGP): **new** annex

# Revision of Annex XII (CSF in kept porcine animals)

- ✓ Addition of further requirements
- ✓ Part 1: **size** of the vaccination zone and minimum **coverage**
- ✓ Part 2: reinforced clinical and laboratory **surveillance**
  - Different in **peri-vaccination/vaccination** zones
- ✓ Part 3: **28 days** after repopulation for lifting all restrictions= two incubation periods
- ✓ Part 4: restyling

# NEW Annex XV *tbc* (CSF in wild porcine animals)

- ✓ Drafted to fill a gap
- ✓ Requirements based on:
  - ✓ **effective oral** mass **vaccination** implemented to control CSF in wild boar in Germany between 2002 and 2025
  - ✓ scientific reviews and guidelines from the Commission

# NEW Annexes XVI and XVII *tbc* (ASF in kept and wild porcine animals)

- ✓ Currently there are **no safe and effective ASF vaccines** for kept and wild porcine animals worldwide
- ✓ The annexes will provide a structured approach to the potential use of ASF vaccines, ensuring that (when available and holding a centralised **marketing authorization** granted by the Commission in accordance with Article 44(9) of Regulation 2019/6) they will be applied in compliance with the EU's legal and policy frameworks



# Next steps

1. First Expert Group today, 24 Jan: discussion, comments
2. Written comments by Monday 17 February, to be sent to: [SANTE-ANIMAL-HEALTH-LAW@ec.europa.eu](mailto:SANTE-ANIMAL-HEALTH-LAW@ec.europa.eu), copy to: [etienne.bonbon@ec.europa.eu](mailto:etienne.bonbon@ec.europa.eu)
3. New revised draft sent to MSs around Monday 10 March
4. 2<sup>nd</sup> meeting Expert Group: Wednesday 2 April
5. Possibility 3<sup>rd</sup> EG June 2025
6. Adoption expected by the end of summer

# Thank you



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