



# Revision of EU rules on germinal products

*AHAC meeting of 28 October 2022*

*Agenda point 5*

# Drafts and timeframe

- Revision is close to end
- 2 expert groups with Member States
- Draft amending CDR (EU) 2020/686:
  - SANTE/7338/2021 + Annex
  - To enter into public feed-back soon: „Have your say”
- Germinal elements amending CDR (EU) 2020/692:
  - Previously circulated to MS as PLAN/2021/13117
  - Merged with another initiative also amending CDR (EU) 2020/692

# „Oocytes teams”

- Issue raised:
  - There are collection teams which collect only oocytes but no embryos. Current definition and rules do not recognise such activity
- Proposed solution:
  - Addition of „oocytes” to the definition of „embryo collection team”
  - Name remains the same
  - Addition of „oocytes” to requirements for embryo collection teams in Part 2 of Annex I

# Article 19 of CDR (EU) 2020/686

- Provides a derogation from Article 18(b):
  - Baseline: admission into a semen collection centre (SCC) only via a quarantine accommodation
  - Derogation: admission from another SCC without a quarantine
- Article 19 is applicable
  - Admissions from the same Member State
  - Admissions from other Member States
- Uncertainty linked to certificate POR-INTRA-X:
  - animals from a quarantine accommodation to a SCC?
  - animals from a pre-quarantine to a quarantine accommodation?

# Proposed way ahead

- Article 19 is largely fine for movements between two SCCs
- Movements from quarantine accomodation into a SCC is regulated by Article 18(b)
- Pre-quarantine is regulated in several Articles (e.g. Article 21 for porcine)
- All are under the responsibility of centre veterinarian of SCC + operator(s)
- Fine-tuning of current Article 19, reducing official role
  - Eliminate authorisation of movement by competent authority of SCC of origin
- (From relevant intra-EU certificates Part II.4 will also be removed
  - BOV-INTRA-X, POR-INTRA-X, OV/CAP-INTRA-X, EQUI-INTRA-IND, EQUI-INTRA-CON)

# Germinal products of dogs and cats

- Previously: national rules or nothing
- Currently: harmonised in CDR (EU) 2020/686, several Articles
- Problems raised with Article 36 + with certification:
  - *Echinococcus granulosus*, rabies: non-vaccinated animals in free countries, procedure for official certification, problems handling fresh dog semen, etc.
- Proposed way ahead: de-regulate, streamline harmonisation
  - Keep Article 11 of CDR (EU) 2020/686: traceability, marking
  - Delete Article 36 + related elements for certification
  - (delete the relevant Article 13(e) and GP-CANIS-FELIS-INTRA certificate from CIR (EU) 2021/403))
- GPs of dogs/cats will move with self-declaration

# Testing for CSF

- Testing either in pre-quarantine or in quarantine, *depending* on status of MS/zone
- Compulsory routine testing in SCCs, *regardless* of status of MS/zone
- Entry rules refer to intra-EU rules
- Drivers for change:
  - WOAH, comments from trading partner third countries, to reduce burden
- Proposed way ahead:
  - delete intra-EU requirements in free MS/zones for
    - testing in quarantine
    - compulsory routine testing
  - Entry requirements automatically change
  - Follow-up in certificates

# Testing for PRRS

- Raised current problems during quarantine (drivers)
  - False positives
  - Obligation to immediately remove positive animals
- Opportunity for change:
  - Generic case definitions in Article 9 of CDR (EU) 2020/689
- Proposed way ahead:
  - Proportionate approach, following Article 9 of CDR (EU) 2020/689
    - In case virus confirmed: disease confirmation, followed by immediate removal
    - In other cases: suspicion, immediate isolation and investigation

# Antibiotics in semen

- Currently:
  - Partially compulsory, partially voluntary
  - Prescriptive: certain combinations or equivalent
- Considerations and drivers for change
  - ABs mitigate risk of non-listed diseases
  - Foreseen change in WOH standards
  - Existence of private standards
  - Proportionality, subsidiarity, simplification
  - Fight against AMR in the EU
- Proposed way ahead: de-regulate, only ask for information

# Issues for entry into the Union

- Directly covered by amendment of CDR (EU) 2020/692
  - Definition of embryo collection team
  - Derogation for foot and mouth disease vaccination
  - GPs of certain animals intended for confined establishments
- Indirectly covered via amendment of CDR (EU) 2020/686
  - Testing for classical swine
  - Infection with epizootic haemorrhagic disease virus
    - Name of disease
    - Possibility for vector-free period

# Summary

- Fine-tuning of already fit rules
- Based on experience of stakeholders, Member States, third countries
- Better regulation: to reduce burden and to increase legal certainty