



Animal Health Law

Amendments to Delegated Regulations (EU) 2019/2035, 2020/686, 2020/687, 2020/688, 2020/689 and 2020/692

Animal Health and Advisory Committee

29 October 2020

Unit G2 – Animal Health

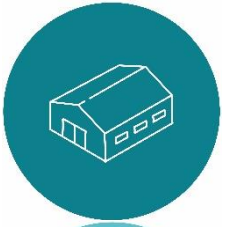


COMMISSION DELEGATED REGULATION (EU) .../...

**amending Delegated Regulation (EU) 2019/2035
supplementing Regulation (EU) 2016/429
of the European Parliament and the Council
as regards rules for establishments keeping terrestrial animals
and hatcheries, and the traceability of certain kept
terrestrial animals and hatching eggs**

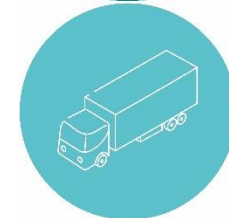
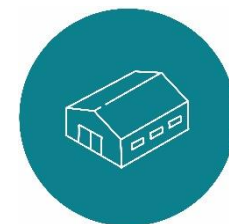
Amendment to REGULATION 2019/2035 (I)

- The rules for registration and approval of establishments from which hatching eggs or poultry are moved to another Member State (**Article 4**)
 - Derogation from approval requirement for “less than 20 heads of poultry other than ratites” and “less than 20 hatching eggs of poultry other than ratites”
- The traceability provisions of bovine, ovine and caprine animals (**Articles 38, 45 and 48**)
 - Article 269 of the AHL provides for Member States to apply national measures within their territories which are in addition to or stricter than those laid down in Regulation (EU) 2019/2035. The amendment introduces references to the authorisation by the Member State for derogations provided to the operators, in order to reflect this principle



Amendment to REGULATION 2019/2035 (II)

- The rules for the marking of hatching eggs sent to another Member State (**Article 80**)
 - Hatching eggs not moved to another MS and “less than 20 hatching eggs other than ratites” are exempted from the requirement to be marked with the approval number of the establishment of origin
- The criteria for approval of establishments for assembly operations of ungulates (Annex I, Part 1)
 - Make it possible to keep animals of different species or category at the same time in epidemiologically separate animal accommodation areas
 - Make it possible to keep bovine and caprine animals together





COMMISSION DELEGATED REGULATION (EU) .../...

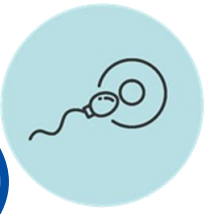
**amending Delegated Regulation (EU) 2020/686
supplementing Regulation (EU) 2016/429
of the European Parliament and the Council
as regards the approval of germinal product establishments
and the traceability and animal health requirements for
movements within the Union of germinal products
of certain kept terrestrial animals**

Amendment to REGULATION (EU) 2020/686 (I)



- Articles 30 and 39 – **deletion of validity period of certificates**
- Article 49 – **transitional measures for germinal products collected or produced, processed and stored before 21 April 2021** and fulfilling the requirements laid down in Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC – to allow their movement to other Member States
- Annex II, Part 1, Chapter I - **a gamma-interferon assay**, in addition to a intradermal tuberculin test, for testing of bovine semen donor for **infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*)**

Amendment to REGULATION (EU) 2020/686 (II)



- Annex II, Part 5, Chapter II – clarification what is meant by a Member State or zone thereof free from **infection with bluetongue virus (serotypes 1-24) - *no case of infection with bluetongue virus (serotypes 1-24) has been confirmed during the last 24 months in the targeted animal population***
- Annex III, Part 1 – **antibiotics:**
 - Point 3 - Correction of a mistake in the list of antibiotics
 - Points 4 and 5 - Clarification that those are antibiotics or mixtures of antibiotics referred to in point 3 or **antibiotics or mixtures of antibiotics with a bactericidal activity at least equivalent to that of the antibiotics or their mixtures referred to in point 3**

Amendment to REGULATION (EU) 2020/686 (III)



Part 1 of Annex III, point 3 - antibiotics

correction

3. Where necessary, the antibiotics or mixtures of antibiotics with a bactericidal activity at least equivalent to that of the following antibiotics or their mixtures in each ml of semen, may be added to semen or contained in semen diluents:

- (a) a mixture of lincomycin-spectinomycin (150/300 µg), penicillin (500 IU) and streptomycin (500 µg); or
- (b) a mixture of gentamicin (250 µg), tylosin (50 µg), lincomycin-spectinomycin (150/300 µg); or
- (c) a mixture of amikacin (75 µg) and divekacin (25 µg); or
- (d) in the case of semen of ovine and caprine animals, gentamicin (250 µg) or a mixture of penicillin (500 IU) and streptomycin (500 µg).



COMMISSION DELEGATED REGULATION (EU) .../...

**amending Delegated Regulation (EU) 2020/687
supplementing Regulation (EU) 2016/429
of the European Parliament and the Council
as regards rules for the prevention and control of certain
listed diseases**

Amendment to REGULATION 2020/687

- ✓ **Article 22(5):** limitation of the obligation to issue a certificate for movements from the restricted zone of animal by-products originating from animals of listed species for the relevant listed diseases
- ✓ **Article 112:** addition of Directive 2000/75/EC, which lays down specific provisions for the control and eradication of bluetongue, to the list of Directives that will cease to apply from 21 April 21



COMMISSION DELEGATED REGULATION (EU) .../...

**amending Delegated Regulation (EU) 2020/688
supplementing Regulation (EU) 2016/429
of the European Parliament and the Council
as regards animal health requirements for movements
within the Union of terrestrial animals and
hatching eggs**

Amendment to REGULATION (EU) 2020/688

- **Article 34** – residency period for *productive poultry for the production of other products*
- **Article 37** – MS of origin should inform MS of destination when less than 20 day-old chicks have been hatched from hatching eggs that have entered into the Union
- Residency period in relation to assembly operations
- Derogation from animal health certification requirement when MS of destination has granted a derogation under Article 139 of AHL (recreational use, sporting and cultural events, work near borders and grazing)
- **Article 101** – clarification that certain requirements apply only to wild ungulates
- **Annex II** – alignment of testing regimes for *Mycobacterium tuberculosis* complex between caprine, camelid and cervid animals in pre-movement programmes for animals coming from an establishment where disease is reported



COMMISSION DELEGATED REGULATION (EU) .../...

**amending Delegated Regulation (EU) 2020/689
supplementing Regulation (EU) 2016/429
of the European Parliament and the Council
as regards rules for surveillance, eradication programmes,
and disease-free statuses for
certain listed and emerging diseases**

Amendment to REGULATION (EU) 2020/689 (I)

- **Article 83:** scope expanded

- Article 83 provides for derogations from the approval by the Commission for certain disease-free statuses for aquatic animal diseases (from Commission approval to Member States' self-declaration)
- This derogation should be expanded to include the approval of certain eradication programmes to make it easier and quicker for Member States to have the eradication programme approved

- **Article 86:** additional act repealed

Commission Decision 2010/367/EU lays down minimal requirements for surveillance programmes for avian influenza and it should be repealed as it has been updated by Annex II to the Regulation

- **Part VI of Annex IV** (BVD eradication)

Wrong cross-reference

Amendment to REGULATION (EU) 2020/689 (II)

HPR-deleted ISAV

Section 5, Chapter II of Annex VI: Replaced by new text

RATIONALE

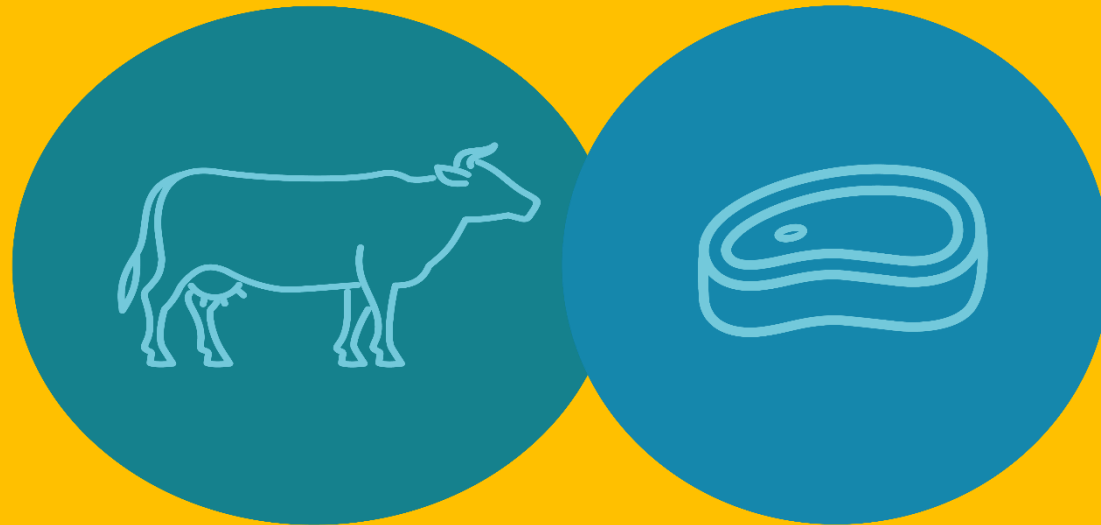
- Changes **requested by EURL** in order to:
 - align with current OIE Manual
 - allow infection with HPR-deleted ISAV to be managed more efficiently
 - make other minor clarifications
- Current text in Delegated Regulation (EU) 2020/689 requires a positive PCR result to be confirmed by either a specific antibody test or by virus isolation
- Proposed amendments **allow a positive PCR result to be confirmed by a second molecular test** which targets a different part of the genome, followed by sequencing, or by a specific antibody test or by virus isolation
- Quite a bit of text but in reality, minimal changes



COMMISSION DELEGATED REGULATION (EU) .../...

**amending Delegated Regulation (EU) 2020/692
supplementing Regulation (EU) 2016/429
of the European Parliament and the Council
as regards rules for entry into the Union,
and the movement and handling after entry
of consignments of certain animals, germinal products
and products of animal origin**

Ungulates and products of animal origin thereof



Amendment to REGULATION (EU) 2020/692

- ✓ **Article 26:** addition of the possibility to move animals to slaughter during the standstill period of 30 days after the entry
- ✓ **Article 125(c):** correction ('before the loading of carcasses for dispatch ~~to the Union~~ to the game handling establishment')
- ✓ **Article 154(2):** addition of a paragraph to cover the exemptions from the residency period for the animals from which the milk was obtained
- ✓ **Article 162:** correction of the omission of colostrum-based products contained in composite products

Amendment to REGULATION (EU) 2020/692

- ✓ **Article 163(1):** inclusion of composite products containing gelatine and collagen in the derogation provided for in Article 163 as regards the requirement to enter the Union accompanied by an official certificate
- ✓ **Article 163(2):** addition of the possibility to sign the declaration required in Article 163 (instead of the official certificate), not only for the operator of the third country or territory of origin of such composite products but also for the operator responsible of the entry into the Union (alignment with OCR)
- ✓ **Annex VIII:** correction of the omission of the reference to the IA on listing (and to rules provided for in Article 10) in footnote (**) regarding EHD.

Dogs, cats and ferrets



Amendment to REGULATION (EU) 2020/692

- ✓ **Article 74:** correction of a wrong reference to non-existing legislation for a reference to Annex II to Regulation (EU) No 576/2013

Poultry and Captive birds

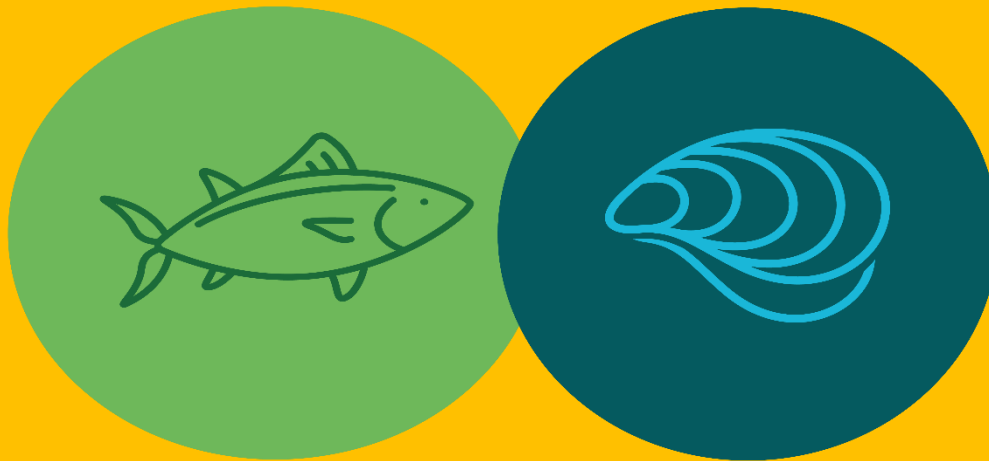


Amendment to REGULATION (EU) 2020/692



- **Article 13(1)** – inspection prior to dispatch should not apply to flock of origin of day-old chicks
- **Articles 49 & 110** – clarification of requirements for means of transport, containers, vaccination against HPAI and disinfection for less than 20 poultry and hatching eggs other than ratites
- Clarification of requirements in relation to vaccination against infection with Newcastle disease virus for poultry (**Annex XV**) and captive birds (**Article 57**)
- Article 61 – Handling and movement of racing pigeons after entry into the Union
- **Article 111** – requirement that SPF eggs originate in approved establishments
- **Annex III** – residency periods for *productive poultry for the production of other products* and for *day-old chicks*

Aquatic animals and products of animal origin thereof



Amendment to REGULATION (EU) 2020/692

- ✓ **Article 1(6):** exclusion of products of animal origin intended for direct human consumption from the scope of Part V
- ✓ **Article 2(48):** correction of the definition of well-boat to align it with Regulation (EU) 2020/990
- ✓ **Annex 167(a) and (d):** correction of the reference to ‘the establishment of origin’ for ‘the place of origin’ since aquatic animals may be dispatched to the Union from an aquaculture establishment or from a habitat
- ✓ **Article 169(3)(b):** PAO for direct human consumption excluded from scope but those intended for further processing in the EU are not. Add ‘*after further processing*’ to labelling statements to differentiate

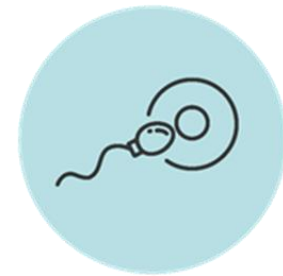
Amendment to REGULATION (EU) 2020/692

- ✓ **Article 172 and 174(3):** correction of reference to Article 170(1) – animals must come from registered or approved establishment
- ✓ **Article 175 and Annex XXIX:** inclusion of diseases for which Member States have national measures in accordance with Article 226 of Regulation (EU) 2016/429 => include diseases which are not listed in Implementing Regulation (EU) 2018/1882 and those listed in Cat E i.e. koi herpes virus disease

Germinal products from ungulates



Amendment to REGULATION (EU) 2020/692



- **Article 80(a)** – correction of residency period of donor animals prior to the date of collection (6 months – bovine, ovine, caprine animals; 3 months – porcine and equine animals)
- New Article on inspection of consignment of germinal products prior to dispatch to the Union – visual examination of transport container and documentary check – similar to Articles 30 and 39 of DR 2020/686
- Transitional measures for germinal products collected or produced, processed and stored before 21 April 2021 and fulfilling the requirements laid down in Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC – to allow their entry into the Union

Thank you



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