TRADE in and IMPORTS of SEMEN, OVA and EMBRYOS

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union

European Commission - DG for Health and Food Safety
Directorate G – Crisis management in food, animals and plants
Unit G2 - Animal Health and Welfare
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Health and Consumers

European Commission

Legislation

Bovine animals

		SEMEN	EMBRYOS
	Trade and import rules	Council Directive **88/407/EEC**	Council Directive **89/556/EEC**
TRADE	List of approved establishments in Member States	https://ec.europa.eu/food/animals/live_animals/approved-establishments_en	
	Model certificate	in Annex D to the Directive	in Annex C to the Directive
IMPORTS	List of third countries	Commission Implementing Decision **2011/630/EU**	Commission Decision **2006/168/EC**
	List of approved establishments in third countries	https://ec.europa.eu/food/animals/semen/bovine_en	
	Model certificate	Commission Implementing Decision **2011/630/EU**	Commission Decision **2006/168/EC**

Porcine animals

		SEMEN	OVA and EMBRYOS
	Trade and import rules	Council Directive **90/429/EEC**	Council Directive **92/65/EEC**
TRADE	List of approved establishments in Member States	https://ec.europa.eu/food/animals/live_animals/approved-establishments_en	
	Model certificate	In Annex D to the Directive	Commission Decision **2010/470/EU**
IMPORTS	List of third countries	Commission Decision **2012/137/EU**	Commission Decision **2008/636/EC**
	List of approved establishments in third countries	https://ec.europa.eu/food/animals/semen/porcine_en	Not available
	Model certificate	Commission Decision **2012/137/EU**	Not available

Ovine and Caprine animals

		SEMEN	OVA and EMBRYOS
	Trade and import rules	Council Directive **92/65/EEC**	
TRADE	List of approved establishments in Member States	https://ec.europa.eu/food/animals/live_animals/approved-establishments_en	
	Model certificate	Commission Decision **2010/470/EU**	
IMPORTS	List of third countries	Commission Decision **2010/472/EU**	
	List of approved establishments in third countries	https://ec.europa.eu/food/animals/semen/ovine_caprine_en	
	Model certificate	Commission Decision **2010/472/EU**	

Equine animals

		SEMEN	OVA and EMBRYOS
	Trade and import rules	Council Directive **92/65/EEC**	
TRADE	List of approved establishments in Member States	https://ec.europa.eu/food/animals/live_animals/approved-establishments_en	
	Model certificate	Commission Decision **2010/470/EU**	
IMPORTS	List of third countries	Commission Implementing Regulation (EU) **2018/659**	
	List of approved establishments in third countries	https://ec.europa.eu/food/animals/semen/equine_en	
	Model certificate	Commission Implementing Regulation (EU) **2018/659**	

General requirements

I. Trade in Semen

- Species: bovine, porcine, ovine, caprine, equine animals;
- Collected, processed and stored in a semen collection centre, or, if needed, stored in a semen storage centre, approved and supervised by the competent authority of the Member State for the purposes of intra-Union trade, complying with the following requirements:
  - **Supervised by the centre veterinarian;**
  - **Having adequate semen collection facilities (animal housing, including isolation facilities, room for cleaning and disinfection or sterilisation of equipment, semen processing room, semen storage room);**
  - **Prevented from contact with livestock from outside;**
  - **Keeping of records of all animals and semen in the SCC/SSC;**
  - **Regularly, at least twice a year, inspected by official veterinarian;**
  - **Employing competent and trained staff.**

II. Trade in Semen

Collected from animals whose health status complies with requirements laid down respectively in:

- ✓ Council Directives 88/407/EEC (bovine) or 90/429/EEC (porcine) or 92/65/EEC (ovine, caprine, equine);
- ✓ 'trade' Directives, 64/432/EEC (bovine, porcine) or 91/68/EEC (ovine, caprine) or 2009/156/EC (equine);
- ✓ And which:
  - showed no clinical signs of disease on the date of admission to quarantine accommodation and/or SCC/SSC and when semen was collected;
  - were not used for natural breeding during at least 30 days prior to the date of first semen collection and between date of first sample for tests foreseen by relevant Directives.

III. Trade in Semen

Donor animals (bovine, porcine, ovine, caprine)

- shall come from holding/ quarantine accommodation which:
  - is situated in an area in which there has been no outbreak of foot-and-mouth disease (FMD) for the last 30 days within a 10 kilometre radius;
  - has for the past three months been free from FMD and brucellosis;
- during the 12 months prior to the date of the semen collection either not vaccinated against FMD, or vaccinated against FMD at least 30 days prior to the collection, in which case 5% (with a minimum of 5 straws) of each semen collection shall be submitted to a virus isolation test for FMD with negative result.

IV. Trade in Semen

- Donor animals (bovine, porcine, ovine, caprine, equine animals) shall come from holding/ quarantine accommodation which has for the past 30 days been free from Rabies, Anthrax and the following other compulsory notifiable diseases:

✓ Bovine, porcine, ovine, caprine - FMD, Brucellosis,

✓ Bovine - Bovine tuberculosis, Contagious bovine pleuropneumonia, Enzootic bovine leukosis, Vesicular stomatitis

✓ Porcine - SVD, ASF, CSF, Vesicular stomatitis

✓ Equine – AHS, glanders, dourine, equine encephalomyelitis of all types, EIA, Vesicular stomatitis

- Semen shall be

✓ Collected, processed, stored and transported in accordance with requirements set down respectively in above mentioned Directives;

✓ Accompanied, during transport to the Member State of destination, by an animal health certificate (paper and electronic version – TRACES).

Trade in Ova and Embryos (*in vivo* and *in vitro*)

Species: bovine, porcine, ovine, caprine, equine animals

- Collected and processed and stored by an embryo collection/ production team approved and supervised by the competent authority of the Member State for the purposes of intra-Union trade
- Collected from animals whose health status complies with requirements laid down respectively in:
  - **Council Directive 89/556/EEC (bovine) or 92/65/EEC (porcine, ovine, caprine, equine);**
  - **'trade' Directives, 64/432/EEC (bovine, porcine) or 91/68/EEC (ovine, caprine) or 2009/156/EC (equine)**
- Collected, processed, stored and transported in accordance with requirements laid down respectively in above mentioned Directives
- Accompanied, during transport to the Member State of destination, by an animal health certificate (paper and electronic version – TRACES)

TRADE: Associated legislation

Species: bovine, porcine, ovine, caprine, equine animals

Commission Decision 2009/712/EC establishing i.e.:

- model lists of semen collection and storage centres approved by Member States in accordance with the relevant provisions of Council Directives: 88/407/EEC (bovine semen), 90/429/EEC (porcine semen) and 92/65/EEC (equine, ovine and caprine semen),

and

- model lists of embryo collection and production teams approved by Member States in accordance with the relevant provisions of Council Directives: 89/556/EEC (bovine embryos) and 92/65/EEC (equine, ovine, caprine and porcine ova and embryos).

Trade in Semen, Ova and Embryos

Species: bovine, porcine, ovine, caprine, equine animals

List of approved establishements in the Member States:

https://ec.europa.eu/food/animals/live_animals/approved-establishments_en

Member States shall establish Internet-based information pages in order to make electronically available to the other Member States and to the public the lists of the approved semen collection/storage centres and the approved embryo collection/production teams and communicate the Internet address of these information pages to the Commission.

The Commission provides a website with direct links to the required information created by each Member State on its national website.

Bovine animals

Trade in Bovine Semen

Collected from animals whose health status complies with requirements of Annex B to Directive 88/407/EEC:

- coming from herds officially free from bovine tuberculosis, bovine brucellosis and bovine enzootic leukosis as defined in Directive 64/432/EEC;
- subjected to quarantine at least 28 days in special approved accommodation; and within period of quarantine subjected to the tests with negative results for: bovine brucellosis, IBR/IPV, BVD/MD (possible seropositive), *Campylobacter fetus* ssp. *venerealis* and *Trichomonas fœtus*;
- within the 28 days preceding the period of quarantine, subjected to the tests with negative results for: bovine tuberculosis, bovine brucellosis, bovine enzootic leucosis, IBR/IPV and BVD/MD (possible seropositive);
- subjected at least once a year in the SCC, with negative results, to the tests for 7 above mentioned diseases.

Trade in Bovine Embryos (*in vivo* and *in vitro*)

Collected from animals whose health status complies with requirements of Annex B to Directive 89/556/EEC:

- coming from herds officially free from bovine tuberculosis, bovine brucellosis and bovine enzootic leucosis as defined in Directive 64/432/EEC;
- during the previous year, not been present in a herd/s where animals have shown any clinical sign of IBR/IPV.

Porcine animals

Trade in Porcine Semen

- There is no semen storage centres in case of porcine animals;
- Collected from animals whose health status complies with requirements of Annex B to Directive 90/429/EEC:
  - coming from herds free from brucellosis and where no case of Aujeszky's disease has been detected in the last 12 months;
  - subjected to quarantine at least 30 days in special approved accommodation; and within period of quarantine subjected to the tests with negative results for: Aujeszky's disease and porcine brucellosis;
  - within the 30 days preceding the period of quarantine, subjected to the tests with negative results for: porcine brucellosis, Aujeszky's disease and classical swine fever;
  - subjected to routine tests in the SCC, with negative results, to the tests for 3 above mentioned diseases:
  - ✓ At least 25% of the animals every three months, or
  - ✓ All animals immediately prior to leaving the SCC, or upon arrival at the slaughterhouse, no later than 12 months after the date of admission to the SCC.

Trade in Porcine Ova and Embryos (*in vivo* and *in vitro*)

Collected from animals whose health status complies with requirements of Annex D(IV) to Directive 92/65/EEC:

- the requirements of Directive 64/432/EEC for animals for breeding and production;
- the requirements for Aujeszky's disease laid down in accordance with Art. 9 (*compulsory national control programme*) or 10 (*the territory or a part of territory of a Member State free from a disease*) of Directive 64/432/EEC, except *in vivo* derived embryos subject to a trypsin treatment.

Ovine and caprine animals

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Trade in Ovine and Caprine Semen

Collected from animals whose health status complies with requirements of Annex D(II)(II) to Directive 92/65/EEC:

- coming from holdings officially free from brucellosis (*B.melitensis*);
- coming from holdings where during the 60 days preceding the period of quarantine, have been subjected to serological test with negative result for contagious epidydimitis (*B.ovis*);
- subjected to quarantine at least 28 days in special approved accommodation; and within period of quarantine subjected to the tests with negative results for: brucellosis (*B.melitensis*), contagious epidydimitis (*B.ovis*), Border disease (possible seropositive);
- within the 28 days preceding the period of quarantine, subjected to the tests with negative results for: brucellosis (*B.melitensis*), contagious epidydimitis (*B.ovis*), Border disease (possible seropositive);
- subjected to at least once a year in the SCC, with negative results, to the tests for 3 above mentioned diseases.

Trade in Ovine and Caprine Ova and Embryos (*in vivo* and *in vitro*)

Collected from animals whose health status complies with requirements of Annex D(IV) to Directive 92/65/EEC:

- the requirements of Directive 91/68/EEC for animals for breeding and production.

Equine animals

Trade in Equine Semen

Collected from animals whose health status complies with requirements of Annex D(II)(I) to Directive 92/65/EEC:

- kept in holdings for the 30 days prior to date of semen collection where no equine has shown any clinical sign of EVA or CEM during that period;
- not used for natural matching during 30 days prior to the first semen collection and during the collection period;
- subjected to the tests for: EIA, EVA and CEM, according to the one of testing programmes, depending on a residency status at SCC of the donor stallion.

Trade in Equine Ova and Embryos (*in vivo* and *in vitro*)

Collected from animals whose health status complies with requirements of Annex D(IV) to Directive 92/65/EEC:

- the requirements of Directive 2009/156/EEC for animals for breeding and production;
- subjected with negative result for equine infectious anaemia carried out on a blood samples taken initially during the past 30 days prior to the date of first collection of ova or embryos and then every 90 days during the collection period;
- subjected for contagious equine metritis by isolation of *Taylorella equigenitalis* carried out on samples collected from mucosal surfaces of the clitoral fossa and clitoral sinuses on two consecutives oestrus periods, and during one of oestrus periods an additional culture specimen taken from the endomertial cervix, all with negative results after a cultivation of 7 to 14 days;
- not used for natural breeding during at least 30 days prior to the date of collection of embryos or ova and between date of first sample for tests for equine infectious anaemia and contagious equine metritis.

Other animals

Semen, ova and embryos of other animal species are subject to the general principles of **Directive 92/65/EEC**, i.e., to the minimum requirements to be satisfied by the EU countries when adopting national measures.

I. Imports of Semen, Ova and Embryos
(*in vivo* and *in vitro*)

Species: bovine, porcine, ovine, caprine, equine animals

- The **same requirements** for approval and supervision of SCC/SSC and ECT/EPT **as in intra-Union trade**
- Only from **third countries** which appear on the **species specific list**
- Accompanied, during transport to the Member State of destination, by an **animal health certificate**

II. Imports of Semen, Ova and Embryos
(*in vivo* and *in vitro*)

Species: bovine, porcine, ovine, caprine, equine animals

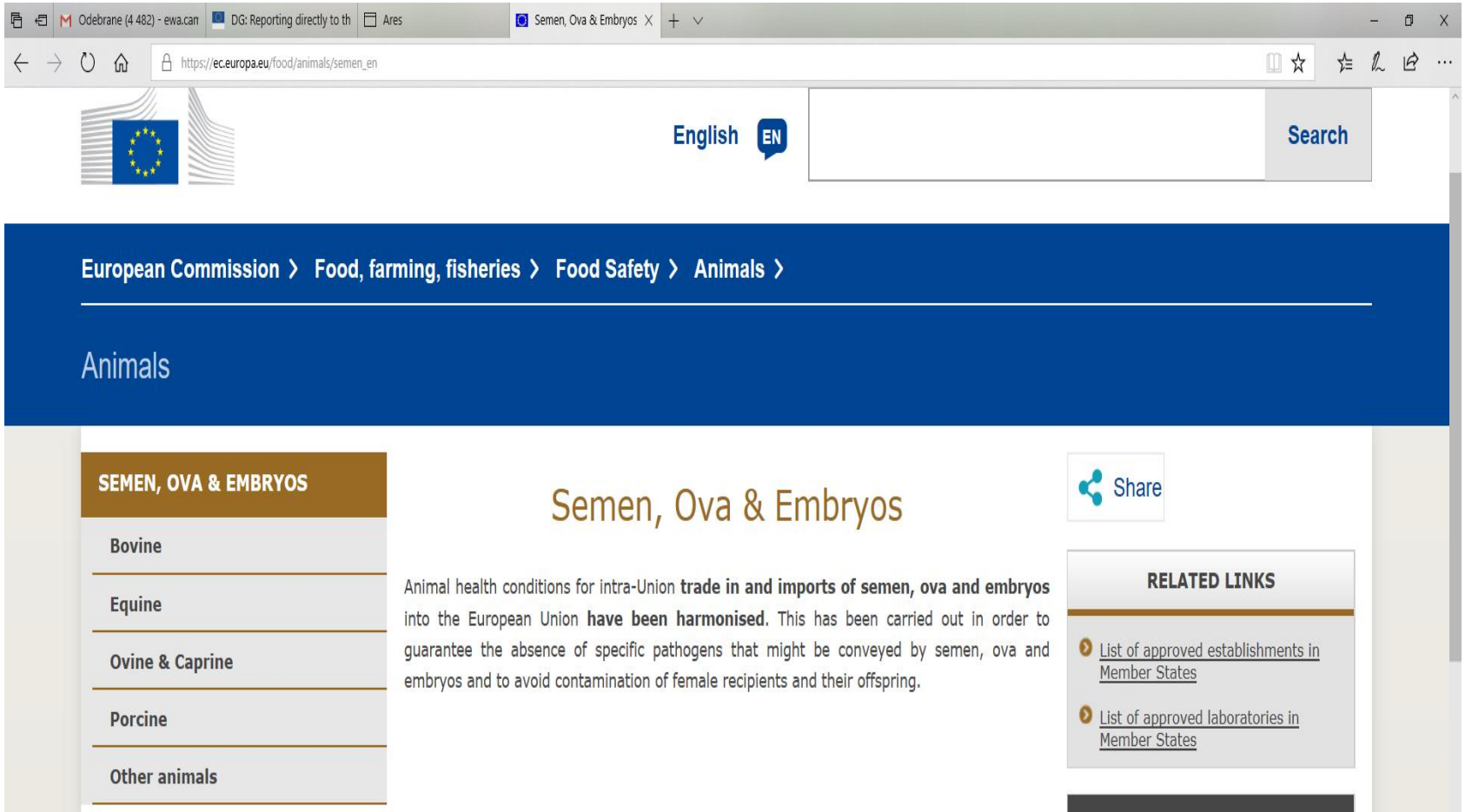
- The **list of approved SCC/SSC and ECT/EPT** that the competent authority of the third country has approved and from which semen and ova and/or embryos may be dispatched to the Union shall be communicated to the Commission:

✓ Procedure for listing in **Directive 2008/73/EC**;

✓ Certificates and **questionnaires** for the approval, confirming that requirements are fulfilled

The Commission webpage

✓ https://ec.europa.eu/food/animals/semen_en



I. New upcoming legislation

1. ***Animal Health Law*** *(Regulation (EU) 2016/429 of the European Parliament and of the Council):*
   - Applicable as of **21 April 2021;**

   Relevant Parts:
   - Chapter 1, Title I, Part IV: registration, approval, record-keeping and registers;
   - Section 2, Chapter 2, Title I, Part IV: traceability requirements;
   - Chapter 5, Title I, Part IV: requirements for movement within the Union;
   - Part V: entry into the Union.

II. New upcoming legislation

2. ***Commission Delegated Regulation*** *on movement within the EU of germinal products:*

- Draft available at the Better Regulation Portal:

https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-112597_en#isc-2018-06861

- Stakeholders consultations carried out during the period 9 January – 6 February 2019.

III. New upcoming legislation

3. ***New provisions in Commission Delegated Regulation*** *on movement within the EU of germinal products:*
   - New type of germinal product establishment – germinal product processing establishment (processing and storage of germinal products);
   - Special rules for cessation of activities of approved germinal product establishment;
   - Because of the new list of diseases: i.e. rules in relation to PRRS and surra, no rules for Border disease nor vesicular stomatitis.

IV. New upcoming legislation

4. ***New provisions in Commission Delegated Regulation*** *on movement within the EU of germinal products:*

- Animal health, certification and notification requirements for movement of consignments of germinal products of dogs, cats, animals of the families Cervidae and Camelidae;
- Rules for transport of different types of germinal products (semen, oocytes and embryos) of the same species in one container;
- Rules for granting derogations by competent authorities for movement between MS of consignments of germinal products for scientific purposes and germinal products stored at gene banks.

Thank you for your attention

QUESTIONS?

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