



## INFORMATION SHEET

# INTERNATIONAL SANITARY REGULATIONS MEANING FOR EUROPEAN LIVESTOCK CONSERVATION BREEDERS

*(developed in the frame of the project IMAGE (EU-H2020 n° 677353))*

## INTRODUCTION

The conservation of genetic resources, the development and the improvement of livestock breeds are at the crossroads of various obligations: to conserve the agrobiodiversity and to make it available for development and improvement - and at the same time the international obligation to prevent outbreaks of diseases.

The exchange of genetic material is becoming increasingly difficult due to international and national regulations to prevent the outbreak of epidemic diseases. Legal and regulatory requirements are becoming stricter. In 2020, the World Organization for Animal Health (OIE) listed 117 epidemically relevant infections and infestations worldwide: 24 diseases that occur in different species, 13 in cattle, 11 in sheep and goats, 11 in equidae, 6 in pigs, 13 avian infectious diseases ([www.oie.int/en/animal-health-in-the-world/oie-listed-diseases-2020/](http://www.oie.int/en/animal-health-in-the-world/oie-listed-diseases-2020/)).

The EU-Council Directive 92/65 lays down the conditions for the exchange of animals, semen, ova and embryos.

## OIE

OIE (Office International des Epizooties, since 2003 "World Organisation for Animal Health")

- Founded in 1924 because of an outbreak of Rinderpest in 1920 in Belgium after Zebus spread it in Antwerp during their transport from India to Brazil.
- 182 Countries are members (2020)
- Intergovernmental active to prevent epizootic diseases and their spread.
- Institutional and financial autonomous (depends NOT on the UN system)
- Permanent relations with 45 other international and regional organisations (e.g. FAO, WHO, International Federation for Animal Health, World Veterinary Association).
- The OIE Terrestrial Animal Health Code is binding for all countries. Therefore regulations are adapted continuously.
- OIE terrestrial Health Code: Chapter 4 "Disease prevention and control" defines the main rules of exchange and trade, also for Semen, Embryos. Tissues etc.

In context with gene bank material (Semen, ova; tissues) animals need to have a perfect health status according to the recent rules. This is difficult to prove at old material.

## **EU ANIMAL HEALTH LAW REGULATION (EU) 2016/429**

on transmissible animal diseases and amending and repealing certain acts in the area of animal health. The EU regulation picks up the rules of the OIE.

The European Parliament and the Council adopted the Regulation on transmissible animal diseases (“Animal Health Law”) in March 2016. The Regulation is applicable in 2021

## **SANITARY REGULATIONS AND GENE BANK MATERIAL**

It depends on the different status of the genebanks which sanitary policy they follow:

### **AI (artificial insemination) and ET (embryo transfer) centers:**

- Are acknowledged for national trade, sometimes for intra EU trade
- Have to comply with the current regulations and rules
- The material for trade has to be free of notifiable diseases
- At present the only institutions allowed to produce/store/sell germplasm material for breeding
- With a national derogation these centers are allowed to store/sell germplasm material not complying with EU Animal Health Law if storage, handling and transport are separated completely from other material
- Other institutions with a national derogation are allowed to store/sell/use germplasm material which is not complying with EU Animal Health Law under the particular conditions stated in the national derogation.

## **CONSERVATION BREEDING AND GENE BANK MATERIAL**

The current Sanitary and Veterinary Rules on germplasm are not tailored for genebanking and local endangered breeds:

- Non-compliant material is not tradeable and cannot be used in conservation breeding
- Material from rare breeds is not able to comply with sanitary policies:
  - The material maybe from not tested field collections or old genebank material is required for breeding.
  - For sanitary reasons according to exchange, trade and cryoconservation it is necessary to establish health status of each farm respective herd.

## **USE OF GENE BANK MATERIAL**

Interventions within the framework of the IMAGE project influenced the provisions of the Animal Health Act, particularly with regard to genebank material:

- The use of genebank material on a national level which is not complying with the Animal Health Law depends on national derogations.
- The cross-border use of genebank material which is not complying with the Animal Health Law may be regulated by the countries involved on a bilateral basis.
- **A close cooperation with the national responsible authorities is mandatory.**

## **STORAGE OF GENE BANK MATERIAL**

To avoid problems, material in genebanks should be stored as follows:

- Material with the same sanitary status of one species can be stored in one tank (e.g.cattle semen, ova and embryos from acknowledged collection centres).
- Material of sheep and goats with the same sanitary status can be stored in one tank.
- Passing over of cooling agents from one tank to another of different sanitary status or different species in the same room must be avoided.
- Store a sufficient number of blood/tissue samples or germplasm for future testing.

## **EU legislation: Semen, Ova, Embryos**

### **Conditions for the exchange of animals, semen, ova and embryos**

**Council Directive 92/65/EEC**

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31992L0065&from=EN>

### **Regulation (EU) 2016/429 on transmissible animal diseases**

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0429&from=EN>

**Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of 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 (Text with EEA relevance) (Text with EEA relevance)**

[https://eur-lex.europa.eu/eli/reg\\_del/2020/686/oj](https://eur-lex.europa.eu/eli/reg_del/2020/686/oj)

### **Intra Union trade, approved collection centres**

**Directive 2008/73/EC**

[https://ec.europa.eu/food/animals/semen/porcine\\_en](https://ec.europa.eu/food/animals/semen/porcine_en)

### **Commission Decision 2012/137/EU**

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012D0137&from=EN>

### **Trade, approved collection and transfer teams**

**Directive 2008/73/EC**

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010R0176&from=EN>

### **Import third countries**

**Commission Decision 2008/636/EC**

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008D0636&from=EN>

### **Certificate for intra Union trade**

**Commission Decision 2010/470/EU**

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010D0470&from=EN>

### **Import third countries**

**Commission Decision 2010/472/EU**

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010D0472&from=EN>

### **Intra Union trade**

**Directive 2008/73/EEC ()**

[https://ec.europa.eu/food/animals/semen/porcine\\_en](https://ec.europa.eu/food/animals/semen/porcine_en)

### **Health certificates**

**Commission Decision 2010/470/EU**

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010D0470&from=EN>

### **Import**

**Commission Decision 2004/2011/EU**

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004D0211&from=EN>

**Porcine – fresh and frozen ova & embryos**  
**Council Directive 92/65/EEC (intra Union trade)**

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31992L0065&from=EN>

**Porcine – Intra Union trade**  
**Council Directive 90/429/EEC)**

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31990L0429&from=en>

**Ovine & Caprine – fresh and frozen semen, ova, embryos**

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010R0176&from=EN>

**Equine – fresh and frozen semen, ova, embryos**  
**Council Directive 92/65/EEC**

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31992L0065&from=EN>

**Other species - fresh and frozen semen, ova, embryos**

**National measures according to the general principles of Council Directive 92/65/EEC**

<https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1992L0065:20040703:EN:PDF>

## **References**

IMAGE (Innovative Management of Animal Genetic Resources) H2020 project: [www.imageh2020.eu/](http://www.imageh2020.eu/)

World Organization for Animal Health (OIE): <https://www.oie.int/en/>

EU animal health and welfare: [https://ec.europa.eu/food/animals/health\\_en](https://ec.europa.eu/food/animals/health_en)

EU Animal Health Law: [https://ec.europa.eu/food/animals/health/regulation\\_en](https://ec.europa.eu/food/animals/health/regulation_en)

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