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Better Training for Safer Food
Initiative

Import Controls on Animal by-products and Genetics

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Genetic Material – overview

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European Commission

Genetic Material – Overview
What? Where? Why? How?

- What is Genetic material?
- Why is Genetic material of interest for BCP's
- Where is a risk?
- Checks to be done – basic legislation
- Under discussion - Critical points today and perhaps tomorrow

What is Genetic material?

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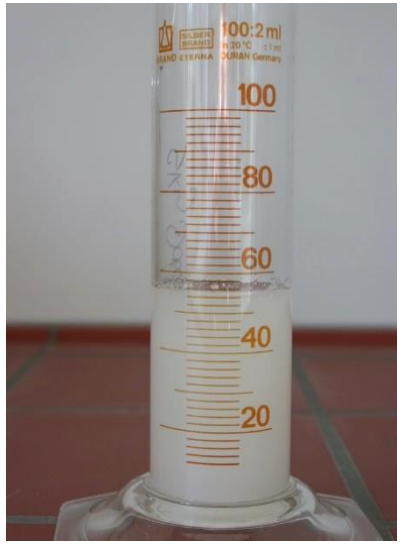
What is Genetic material?

Germinal products (GP):
Definition Reg. (EU) 2016/429 Art.4
‘germinal products’ means:
(a) semen, oocytes and embryos intended for artificial reproduction;
(b) hatching eggs



But what about semen, oocytes and embryos for other purposes ?

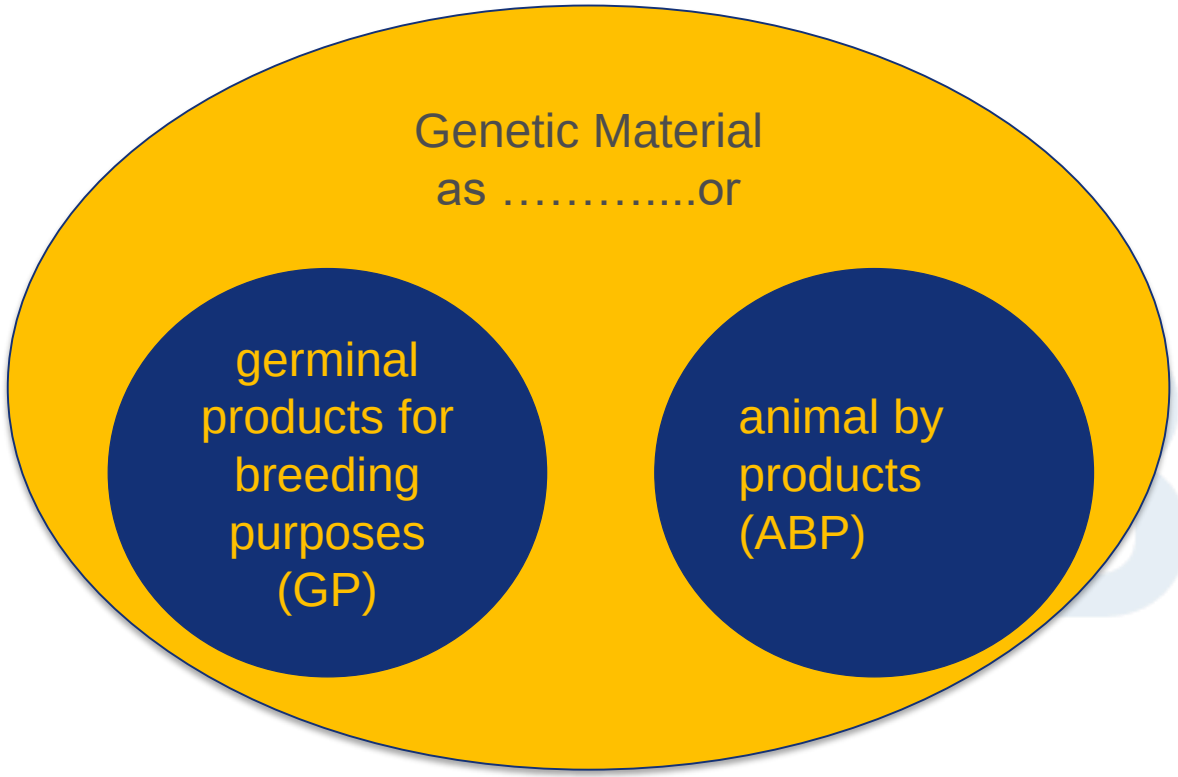
Animal by-products (ABP):

Definition Reg. (EU) 2016/429 Art.4

‘animal by–products’ means entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, excluding germinal products;

Consequences for BCP

Genetic material (semen, oocytes and embryos) is **object of vet. checks under different perspectives :**



BTSF Why is genetic material of interest for BCP's ?

- Biosecurity is influenced by area, health status of donor, facility, collection process, lab-processing, used preservatives, identification, knowledge of staff, storage, transport, …

Semen :
fresh / **frozen**
conventional / sexed
/mixed

Embryos:
fresh / **frozen**
flushed / IVF

Oocytes:
fresh

Semen :
fresh / frozen
conventional / sexed

Embryos:
fresh / frozen
flushed / IVF

Oocytes:
fresh

Semen :
fresh / (frozen)
conventional / mixed

Embryos:
(fresh / frozen)

Semen :
fresh / frozen
conventional

Embryos:
(fresh / frozen)

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BTSF Why is genetic material of interest for BCP's ?

- Biosecurity
- Global exchange
- Responsibilities
- Evaluation of risks
- Traceability
- Volume of movements
- Variation of species / products /establishments
- Sensitivity of products

- Example bovine semen :
- EU export to third countries 2020:
- 11.872.061 units, 39.360.384 €
- EU trade within MS 2020:
- 13.315.223 units, 68.010.676 €
- Third country imports into EU 2020:
- 9.965870 units, 65.030.089 €
- Mainly from US and Canada

BTSF Why is genetic material of interest for BCP's ?

Health status of country of origin- e.g. USA

Disease (selection)	Notifiable	Status
Bluetongue	No	Disease present
Bov. genital campylobacteriosis	No	Disease limited to one or more zones
Bovine tuberculosis	Yes	Disease limited to one or more zones
Bovine viral diarrhoea	No	Disease present
Brucellosis (Brucella abortus)	Yes	Absent (since 11/2015) in domestic
Brucellosis (Brucella suis)	Yes	Disease limited to one or more zones
Enzootic bovine leucosis	No	Disease present
Epizootic haemorrhagic disease	No	Disease limited to one or more zones
Equid herpesvirus-1 (EHV-1)	No	Disease present
Equine infectious anaemia	Yes	Disease limited to one or more zones
Equine viral arteritis	No	Disease present
Inf.bov.rhinotracheit. (IBR/IPV)	No	Disease present
Maedi-visna	Yes	Disease present
Rabies	Yes	Disease present
Scrapie	Yes	Disease present
Trichomonosis	No	Disease present (OIE 2016)

BTSF Why is genetic material of interest for BCP's ?

Health status of country of origin – e.g. Canada

Disease (selection)	Notifiable	Status
Bluetongue	Yes	Disease suspected, not confirmed
Bov. genital campylobacteriosis	No	Disease suspected, not confirmed
Bovine tuberculosis	Yes	Disease limited to one or more zones
Bovine viral diarrhoea	No	Disease present
Brucellosis (Brucella abortus)	Yes	Absent (since 1989) in domestic
Brucellosis (Brucella suis)	Yes	Absent
Enzootic bovine leucosis	No	Disease present
Epizootic haemorrhagic disease	Yes	Absent
Equid herpesvirus-1 (EHV-1)	No	Disease present
Equine infectious anaemia	Yes	Disease present
Equine viral arteritis	No	Disease present
Inf.bov.rhinotracheit. (IBR/IPV)	No	Disease present
Maedi-visna	No	Disease present
Rabies	Yes	Disease present
Scrapie	Yes	Disease present
Trichomonosis	No	Disease suspected, not confirmed

(OIE 2016)

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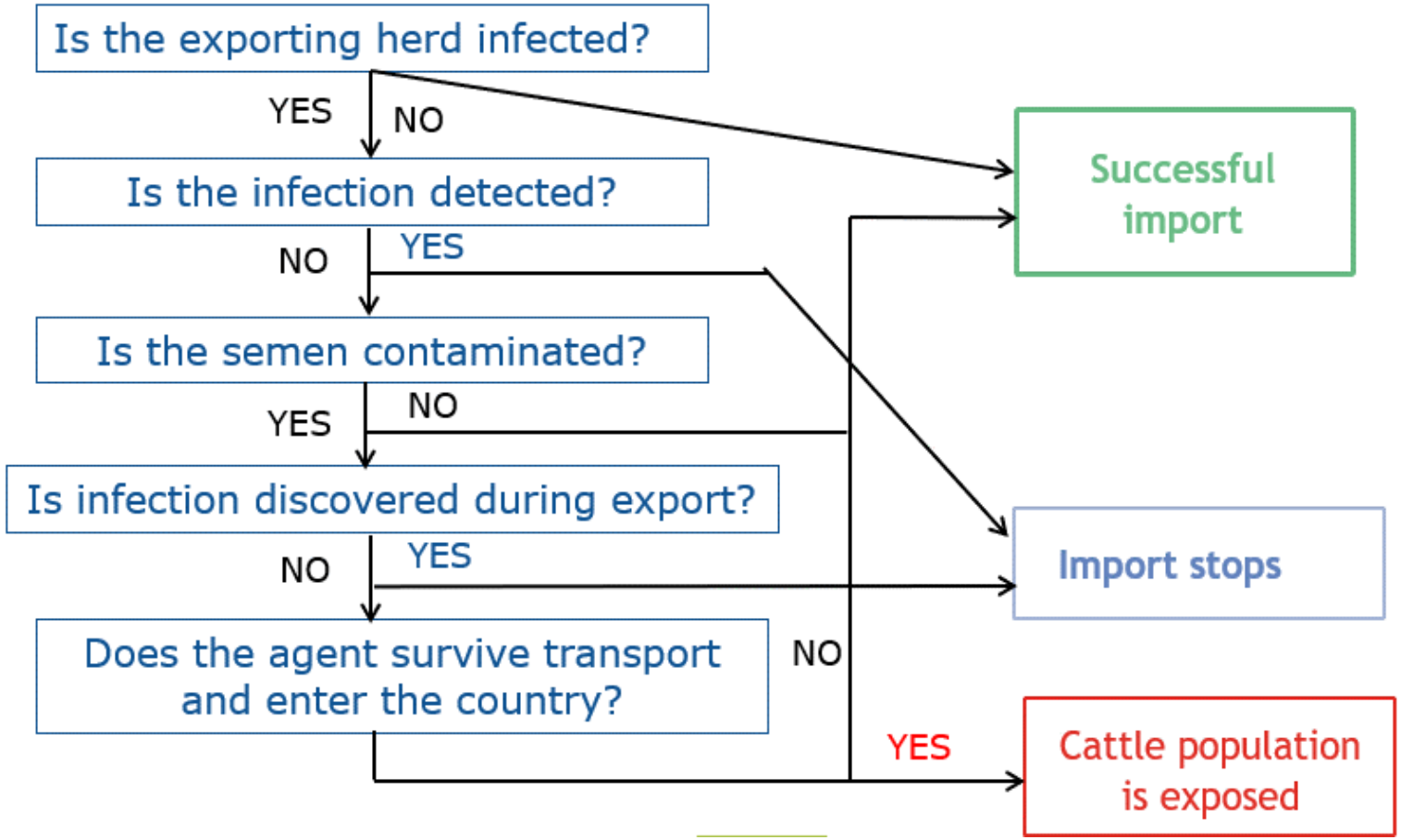
Why is Genetic material of interest for BCP's ?
Questions need to be evaluated responsibly !



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Why is genetic material of interest for BCP's ?

Background AI studs of exporting third countries

Mostly at one location:

- **Quarantine** for **donors** qualifying **for EU** health requirements
- **Quarantine** for **donors** acceptable **for domestic** market
- **Production barn** for donors qualifying **for EU** health requirements
- **Production barn** for donors acceptable **for domestic** market
- Lab, processing unit, store **mostly separately**
- **sometimes** additionally **custom freezing**

The AI-Centre veterinarian responsible for the stud is also, after being accredited by the official authorities, responsible for issuing and signing the export certificates related to shipments.

The certificates will be transmitted to the official authorities, validated and sent back to the centre to accompany the shipments.

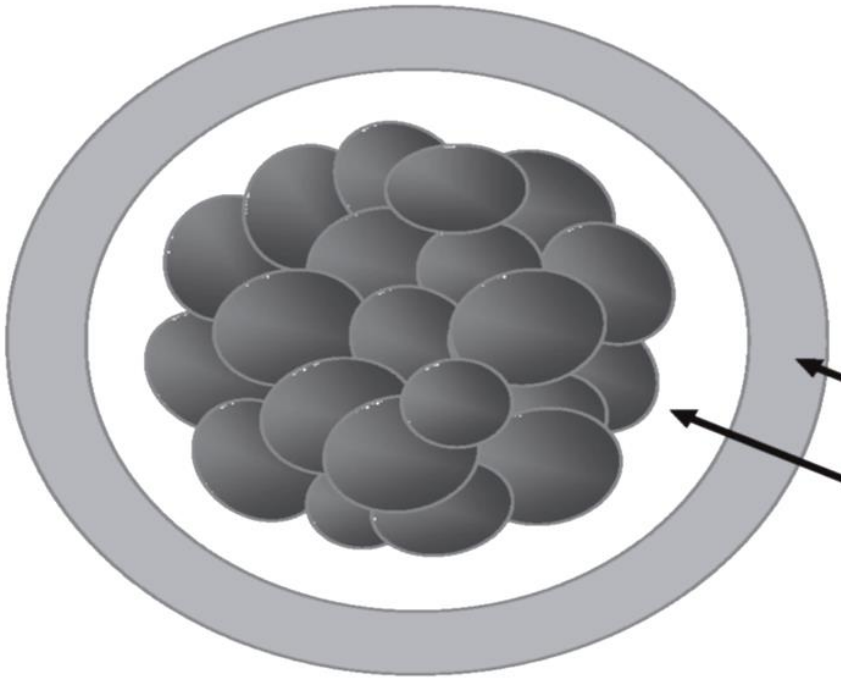
Global acting AI-centres export **their** shipments in many cases to **their** official accredited semen storage centres in different EU MS for distribution within that country or for further intra community movement.

(OIE 2016)

Why is Genetic material of interest for BCP's ?

What about health status of Embryos / Oocytes ?

Transmission of pathogens by ET could result from :



- Contaminated personnel, instruments, or equipment
- Carriage in flushing or transport media
- Adherence to the zona pellucida
- Penetration across the zona pellucida (with/without replication in the embryo)

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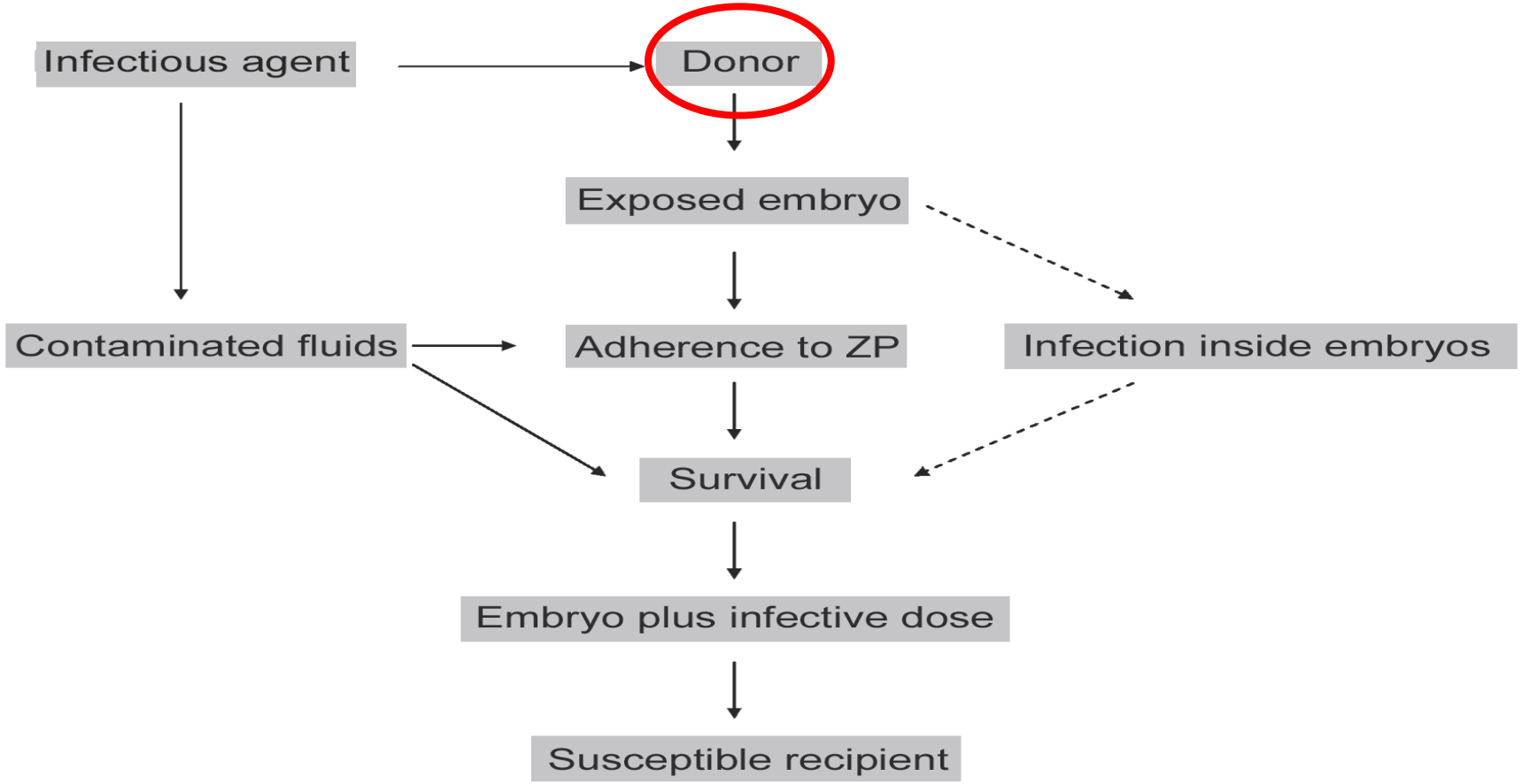
Why is Genetic material of interest for BCP's ?

What about health status of Oocytes / used semen / Embryos ?



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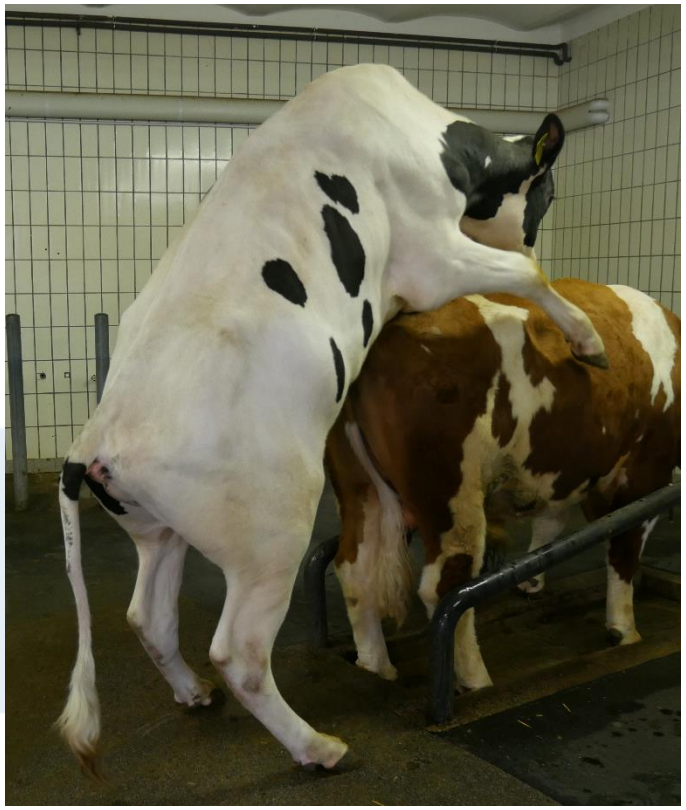
BTSF Risks concerning bovine semen ?

Risk of transmission of infectious bovine diseases through A.I.

Listed animal diseases (CIR (EU) 2018/1882) with evidence that risk of transmission is **moderate to high**

Disease	Presence of disease agent
Foot and mouth disease (A+D+E)	+
Infection with rinderpest virus (A+D+E)	+
Infectious bovine rhinotracheities/infectious pustular vulvovaginitis (C+D+E)	+
Bovine viral diarrhoea (C+D+E)	+
Infection with *Mycobacterium tuberculosis* complex (B+D+E)	+
Bovine genital campylobacteriosis (D+E)	+
Infection with *Brucella abortus* (B+D+E)	+
Trichomonosis (D+E)	+



+: Presence of disease agent in bull semen demonstrated, Off. Int. 16 (1)

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BTSF Risks concerning bovine semen ?

Risk of transmission of infectious bovine diseases through A.I.

Listed animal diseases (CIR (EU) 2018/1882) with some evidence that risk of transmission is **low**

Disease	Presence of disease agent
Infection with bluetongue virus (serotypes 1-24) (C+D+E)	+
Enzootic bovine leucosis (C+D+E)	+

+: Presence of disease agent in bull semen demonstrated,

Off. Int. 16 (1)

BTSF Risks concerning equine semen ?

Listed animal diseases (CIR (EU) 2018/1882)

Disease	Presence in semen	Risk of transmission
Contagious equine metritis (D+E)	+++	+++
Infection with equine arteritis virus (D+E)	+++	+++
Dourine (D+E)	?	??
Equine infectious anaemia (D+E)	+ ?	???
Equine encephalomyelitis (Eastern+Western) (E)	- ?	- ?

Equine Reprod.2011, Chapter 321 Diseases potentially transmitted with frozen or cooled semen

BTSF Risks concerning kept porcine semen

Selected listed kept porcine diseases (CIR (EU) 2018/1882) that have been identified in semen and those verified to have been transmitted via artificial insemination (AI)

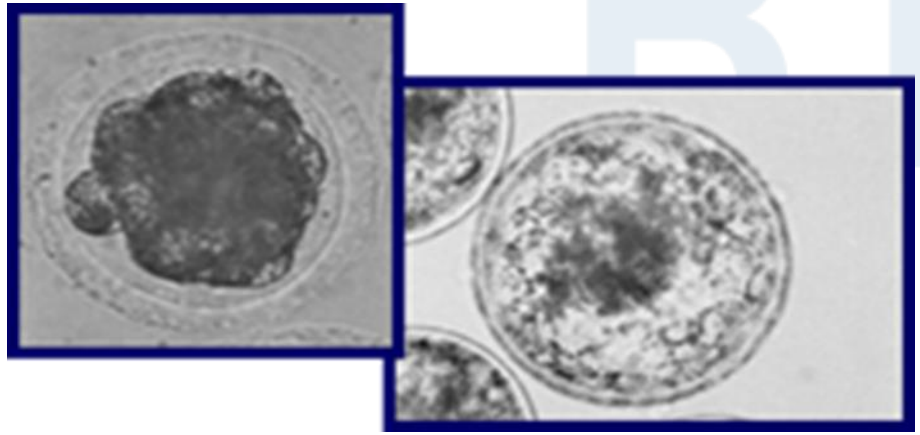
Disease	AI transmission
Aujeszky's disease (C+D+E)	No reports
Classical swine fever (A+D+E)	Yes (de Smit et al. 1999)
Foot and moth disease (A+D+E)	Yes (Madson et al. 1999)
Infection with porcine reproductive and respiratory syndrome virus (D+E)	Yes (Prieto et al. 1997)

GC Althouse and K Rossow, Reprod Dom Anim 46 (Suppl 2), 64–67 (2011)

BTSF Risks concerning embryos ?

Listed animal diseases (CIR (EU) 2018/1882) for which sufficient evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual.

- Aujeszky's disease (pseudorabies) (swine) : trypsin treatment required
- Bluetongue (cattle)
- Brucella abortus (cattle)
- Enzootic bovine leukosis
- Foot and mouth disease (cattle)
- Infectious bovine rhinotracheitis (BHV-1): trypsin treatment required



BTSF Requirements / Checks – GP basic legislation

AHL (EU)2016/429 ⟺ OCR (EU) 2017/625

Part IV

REGISTRATION, APPROVAL, TRACEABILITY AND MOVEMENTS

TITLE I

TERRESTRIAL ANIMALS, GERMINAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN FROM TERRESTRIAL ANIMALS

TITLE III

ANIMALS OF SPECIES OTHER THAN THOSE DEFINED AS TERRESTRIAL AND AQUATIC ANIMALS, AND GERMINAL PRODUCTS AND PRODUCTS OF ANIMAL ORIGIN FROM SUCH OTHER ANIMALS

PART V

ENTRY INTO THE UNION AND EXPORT

CHAPTER 1

Entry into the Union of animals, germinal products and products of animal origin from third countries and territories

Art. 43-76 Import controls

Art. 77-91 Financing& official certification

Art. 125-129 Entry into EU

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BTSF Requirements/Checks – GP basic legislation

AHL (EU)2016/429

Part IV

REGISTRATION, APPROVAL, TRACEABILITY AND MOVEMENTS

Del. Reg. (EU) 2020/686

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

Impl. Reg. (EU) 2020/999

regards to the approval of germinal product establishments and the traceability of germinal products of bovine, porcine, ovine, caprine and equine animals

PART V

ENTRY INTO THE UNION AND EXPORT

Del. Reg. (EU) 2020/692

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

OCR (EU) 2017/625

Art. 43-76 Import controls
(EU) 2021/632 -subjects for BCP controls
(EU) 2019/2130 -rules on checks
(EU) 2019/2129 -frequency of checks
(EU) 2019/2124 -goods in transit
(EU) 2019/1013 -prior notification
(EU) 2019/1014 -requirements on BCP
(EU) 2019/1873 -intensified off. Controls
(EU) 2019/1666 -monitoring from BCP to destination
Art. 77-91 Financing& official certification
Art. 125-129 Entry into EU
(EU) 2020/2235 – off. certificates model

BTSF Requirements/Checks– GP basic legislation

AHL (EU)2016/429 ⟺ OCR (EU) 2017/625

Del. Reg. (EU) 2020/692

- Art.3: MS have to check.., GP,.. if TC/ territory/ zone is listed, has certified health requirements, documents are complete
- Art. 4: no entry before TC/territory/zone is listed
- Art.5: operators obligations: presentation for off. controls, comply with health requirements, responsibilities
- Art.6: requirements on legislation and animal health systems of the third country or territory of origin
- Art.7: general requirements on health status of animals, germinal products and products of animal origin
- Art.8: general requirements on the establishment of origin of the animals
- Art.9: sampling, laboratory tests and other tests (for GP in compliance with (EU) 2020/686)
- Art.10: disease freedom of the place of origin and specific conditions (in compliance with 2020/689)
- Part III animal health requirements for entry into the union of germinal products **Art. 79 - 97**

BTSF Requirements/Certificates– GP basic legislation

AHL (EU)2016/429 ⟺ OCR (EU) 2017/625

Reg. (EU) 2021/403 rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 as regards model animal health certificates and model animal health/official certificates, for the entry into the Union and movements between MS of consignments of certain categories of terrestrial animals and germinal products thereof, official certification regarding such certificates

(EU) 2021/404 lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429

Critical points from audits on germinal products

-Level of detail: standards left to interpretation, not enforceable by non-EU countries
-Approvals:
    What is approved? Address, layout, limits, (quarantine premises ??)
    What ‘s about modifications of location/buildings/mobile lab/vet
    Withdrawal/suspension? Release of material produced before possible??
    Non-EU countries issue temporarily, and keep status listed
-Establishments:
    if housing=pasture, what’s about cleaning + disinfection?
    Centres work under dual standards (EU/non EU) separation??
-Supervision: centre/team vet. Responsibilities? What means permanent supervision
-Processing :
    Antibiotics - concentration not respected, dilution rate varies
    Embryos - trypsin washings not a standard procedure
    Hygienic controls- on fluids for embryos yes/not for semen, value??
-Identification: straws- variety of coding, multiple donors/processing establishments
-Storage:
    GP qualified for EU/Non EU same container? same room? same premises?
    semen of various species, embryos allowed in the same premises?
-Health guarantees:
    controllable? Changing environment- history of territory e.g. BT
    adequate testing regime for donor? Or movement of donor?

BTSF Critical points from audits on germinal products

- Sampling / Testing : level of supervision?? Further sampling in case of + result ??
  transport of samples (campylobacter/trichomonas) ??
  (additional) tests in private labs or different countries –results??
  action in case of positive results? Assessment of GP just dispatched??
- Off. controls: frequency set or risk-based?? Linked or not linked to trade intensity??
- Certification: level of identity/physical checks? Conditions concerning viability of GP
- Transport: embryos and semen or of different species in the same container??
- Mobile semen processing lab.: used under approved semen collec. centre (horses)

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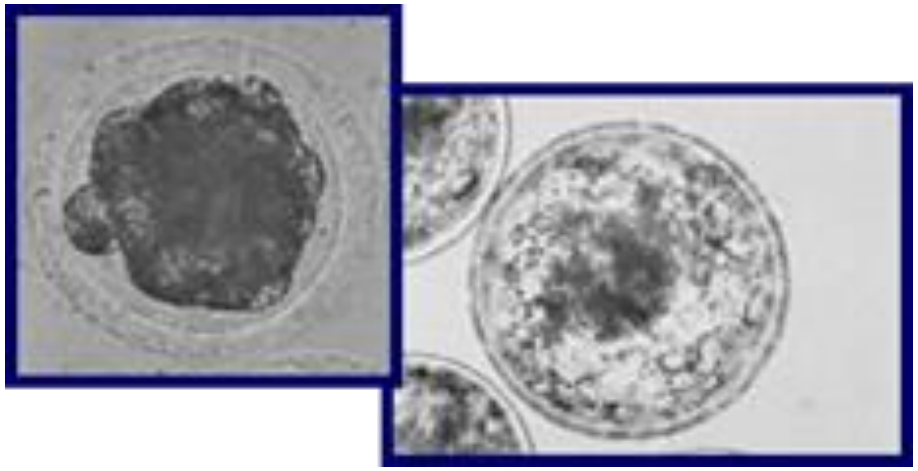
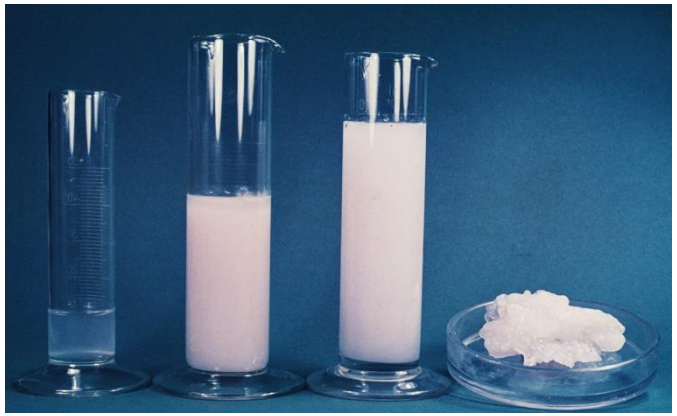
Objects for Border controls of imports into the EU

……..let's have a look ……





Boar

Bull

Stallion

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Thank you

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