ANNOTATED AGENDA

Expert Group on germinal products

24 April 2017, 10.00-18.00

Berlaymont – Rue de la Loi 200 – Bruxelles, WHALL - WALTER HALLSTEIN

I. DRAFT AGENDA

1. Introduction, opening: SANTE Unit G2.
2. Exchange of views on a content of Regulation (EU) 2016/429 of the European Parliament and of the Council ("Animal Health Law") and suggestions for a future Commission Delegated Regulation supplementing Animal Health Law in relation to germinal products, and in particular as regards:
   a. Registration and approval of germinal product establishments
      – Registration for national market and approval if germinal products are moved to another Member State;
      – Semen storage centres for semen of porcine animals;
      – An option for a germinal product establishment:
        - to form a compartment;
        - to be a part of a confined establishment or a confined establishment is to be considered equivalent to a germinal products establishment for exotic species;
      – An approval of semen sexing units and rules for transport of semen to and from such units (in the Member State of semen collection or in a different Member State);
      – Rules for storage and movement of germinal products collected by germinal product establishment which ceases its activity;
   b. Diseases relevant for movement within the Union and for entry into the Union of germinal products, including those of exotic species in confined establishments;
   c. Movement within the Union and entry into the Union of bovine oocytes (and ovaries);
   d. Movement within the Union of mixed/pooled semen (porcine/ bovine animals);
   e. Rules on movement within and entry into the Union of germinal products;
   f. Rules on marking of straws (traceability of germinal products);
   g. Samples for testing
      – Samples for official examination for bacterial and viral contamination resulting from activities of an embryo team;
      – Rules for sampling;
      – Rules for sending to another Member State the samples for testing (free service market) and recommended methods for testing;
   h. Official controls of germinal product establishments (including clarification on links to the new EU Official Controls Regulation).
3. Miscellaneous.

II. NOTES

This document has been established for information purposes only. It has not been adopted or in any way approved by the European Commission and should not be regarded as representing the views of the Commission Services either. The European Commission does not guarantee the accuracy of the information provided, nor does it accept responsibility for any use made thereof.

1. Aims of the Expert Group meeting

The purpose of the meeting is to provide for a focused exchange of views, experience and good practices among representatives of the competent authorities of the Member States (MS) responsible for animal health policy development and implementation in area of germinal products and of the stakeholders in that sector. Our objective is that the exchanges during the meeting will help the MS to learn together for the best implementation of existing rules (and beyond). It will provide also feedback to the Commission on the perceived state of art of the EU policy (and beyond). As such, it will facilitate its improvement via further dedicated work. In addition, views and needs of the industry will be expressed and confronted.

In particular, outcomes from the discussions may be channelled towards, and used later on, in the context of the Animal Health and Welfare Section of the Standing Committee on Plants, Animals, Food and Feed (PAFF)[1] and/or during further Commission work towards delegated acts under the EU Animal Health Law (AHL)[2]. Nevertheless, this meeting is neither a working group of the Standing Committee on PAFF, nor a dedicated meeting on delegated acts for the AHL. It is simply meant to cater for more thorough and technical discussions by experienced representatives of the MS and of the industry on a variety of issues related to germinal products, than could be done in either forum.

This meeting will be based on two pillars:

1. The existing EU legislation covering germinal products, where provisions that shall be either preserved or improved should be identified,
2. The upcoming legislation based on AHL with its new provisions, where decisions shall be taken as regards a way of their implementation.

These notes provide background information on the current situation, on what has been done or is planned at EU level concerning legislation on germinal products and raise particular questions to explore various aspects and possible scenarios. The participants of the meeting are asked to complement this effort by coming prepared and to scrutinise beforehand their rules, practices and experiences from these specific angles.

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1 http://ec.europa.eu/food/animals/health/regulatory_committee_en

2 Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1)

These notes frame the majority of the discussions during the meeting. They are not all-inclusive though. If the participants of the meeting feel that important element(s) have been omitted, they shall feel free to raise those either during the meeting, before or after. Should you have any relevant documents, data etc., feel free to bring them along. Similarly, if you have any questions or want to send written comments, either before or after the meeting, please e-mail to ewa.camara@ec.europa.eu (DG SANTE Unit G2, Animal Health and Welfare).

2. Description of items under point 2 of the draft agenda

a. Registration and approval of germinal product establishments

Legal base in Directive 88/407/EEC[3]

Article 3
Each Member State shall ensure that only semen meeting the following general conditions is sent from its territory to the territory of another Member State
(a) it must have been collected and processed and/or stored if need be in a collection or storage centre or centres approved for the purpose in accordance with Article 5(1), with a view to artificial insemination and for the purposes of intra-Community trade;
Article 5
1. The Member State on whose territory the semen collection or storage centre is situated shall ensure that the approval provided for in Article 3(a) is granted only where the provisions of Annex A are observed and where the semen collection or storage centre is able to satisfy the other provisions of this Directive. The Member State shall also ensure that the official veterinarian supervises the observance of those provisions and shall withdraw approval when one or more of the provisions is no longer observed.
2. All semen collection or storage centres shall be registered, each centre being given a veterinary registration number. Each Member State shall draw up and keep up to date a list of semen collection or storage centres and their veterinary registration numbers and make it available to the other Member States and to the public.

Legal base in Directive 89/556/EEC[4]

Article 3
Each Member State shall ensure that embryos shall not be sent from its territory to that of another Member State unless they meet the following conditions:
(c) they must have been collected, processed and stored by an embryo collection team approved in accordance with Article 5(1);
Article 5
1. Approval of an embryo collection team as provided for in Article 3(c) shall be granted only where the provisions of Annex A, Chapter I are observed and where the embryo collection team is able to satisfy the other provisions of this Directive. Any major change in the organization of the team is to be notified to the competent authority. The approval of the team shall be renewed whenever the team veterinarian is replaced or whenever any major changes are made in its organization or the laboratories or equipment at its disposal. The official veterinarian shall supervise observance of the provisions outlined above. Approval shall be withdrawn where one or more of the provisions is no longer observed.
2. The competent authority of each Member State concerned shall register embryo collection teams and give a veterinary registration number to each team. Each Member State shall draw up and keep up to date a list of embryo collection teams and their veterinary registration numbers and make it available to the other Member States and to the public.
2a. Approval of an embryo production team for embryos derived by *in vitro* fertilization shall be granted only where the provisions of the relevant Annex to this Directive are observed and where the embryo production team is able to satisfy the other relevant provisions of this Directive and in particular the provisions of paragraphs 1 and 2 of this Article, which shall apply *mutatis mutandis*.

[3] Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species (OJ L 194, 22.7.1988, p.10)

[4] Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species (OJ L 302, 19.10.1989, p.1)

Legal base in Directive 90/429/EEC[5]

Article 3
Each Member State shall ensure that only semen, meeting the following general conditions, is intended for trade:
(a) it must have been collected and processed, for the purpose of artificial insemination, in a collection centre approved from the point of view of animal health for the purposes of intra-Community trade in accordance with Article 5 (1);
Article 5
1. The Member State on whose territory the semen collection centre is situated shall ensure that the approval provided for in Article 3 (a) is granted only if it meets the conditions of Annex A and satisfies the other provisions of this Directive. The Member State shall also ensure that the official veterinarian supervises the observance of those provisions. The official veterinarian shall propose that approval be withdrawn when one or more of the provisions is no longer observed.
2. All semen collection centres shall be registered, each centre being given a veterinary registration number. Each Member State shall draw up and keep up to date a list of semen collection centres and their veterinary registration numbers and make it available to the other Member States and to the public.

Legal base in Directive 92/65/EEC[6]

Article 11
2. Semen of the ovine, caprine and equine species must, without prejudice to any criteria to be complied with for the entry of equids in stud books for certain specific breeds: — have been collected, processed and stored with a view to artificial insemination in a centre approved from the health point of view in accordance with Annex D(I), or, in the case of ovine and caprine animals by way of derogation from the above, in a holding satisfying the requirements of Directive 91/68/EEC,
3. Ova and embryos of the ovine, caprine, equine and porcine species must: — have been removed from donor females meeting the conditions laid down in Annex D(IV) by a collection team or have been produced by a production team approved by the competent authority of the Member State and satisfying the conditions to be established in Annex D(I) in accordance with the procedure referred to in Article 26,
4. The approved centres referred to in the first indent of paragraph 2 and the approved teams referred to in the first indent of paragraph 3 shall be registered by the competent authority of the Member State concerned, each centre and team being given a veterinary registration number. Each Member State shall draw up and keep up to date a list of those approved centres and teams and their veterinary registration numbers and shall make it available to the other Member States and to the public.

Legal base in AHL

Article 4 ***Definitions***
(28) ‘germinal products’ means: (a) semen, oocytes and embryos intended for artificial reproduction; (b) hatching eggs;
(37) ‘compartment’ means an animal subpopulation contained in one or more establishments and, in the case of aquatic animals, in one or more aquaculture establishments, under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases subject to appropriate surveillance, disease control and biosecurity measures;
(46) ‘germinal product establishment’ means:

5 Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species (OJ L 224, 18.8.1990, p.62)

6 Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p.54)

(a) in relation to semen, an establishment where semen is collected, produced, processed or stored;

(b) in relation to oocytes and embryos, a group of professionals or structure supervised by a team veterinarian competent to perform the collection, production, processing and storage of oocytes and embryos;

(c) in relation to hatching eggs, a hatchery;

(48) 'confined establishment' means any permanent, geographically limited establishment, created on a voluntary basis and approved for the purpose of movements, where the animals are:

(a) kept or bred for the purposes of exhibitions, education, the conservation of species or research;

(b) confined and separated from the surrounding environment; and

(c) subject to animal health surveillance and biosecurity measures;

Article 37

Compartments

1. A Member State may apply to the Commission for recognition of the disease–free status of compartments for listed diseases referred to in point (a) of Article 9(1), and for the protection of the disease–free status of such a compartment in the event of an outbreak of one or more of those listed diseases in its territory, provided that:

(a) the introduction of the listed disease or listed diseases covered by the application can be effectively prevented at compartment level, taking into account the disease profile;

(b) the compartment covered by the application is subject to a single common biosecurity management system designed to ensure the disease–free status of all establishments forming part of it; and

(c) the compartment covered by the application has been approved by the competent authority for the purposes of movements of animals and products thereof in accordance with:

(i) Articles 99 and 100 for compartments keeping terrestrial animals and products thereof;

(ii) Articles 183 and 184 for compartments keeping aquaculture animals and products thereof.

2. A Member State may apply to the Commission for recognition of the disease–free status of compartments for one or more of the listed diseases referred to in points (b) and (c) of Article 9(1), provided that:

(a) the introduction of the listed disease or listed diseases covered by the application can be effectively prevented at compartment level, taking into account the disease profile;

(b) one or more of the following conditions are complied with:

(i) the conditions laid down in Article 36(1) are fulfilled;

(ii) the establishments of the compartment covered by the application have started or resumed their activities and have established a common biosecurity management system designed to ensure the freedom from disease of that compartment;

(c) the compartment covered by the application is subject to a single common biosecurity management system designed to ensure the disease–free status of all establishments forming part of it; and

(d) the compartment covered by the application has been approved by the competent authority for the purposes of movements of animals and products thereof in accordance with:

(i) Articles 99 and 100 for compartments keeping terrestrial animals and products thereof;

(ii) Articles 183 and 184 for compartments keeping aquaculture animals and products thereof.

3. Applications by Member States for recognition of the disease–free status of compartments in accordance with paragraphs 1 and 2 shall include evidence demonstrating that the conditions laid down in those paragraphs are fulfilled.

4. The Commission shall, by means of implementing acts:

(a) recognise, subject to amendments where necessary, the disease–free status of compartments, when the conditions laid down in paragraph 1 or paragraph 2 and in paragraph 3 are fulfilled;

(b) determine for which of the listed diseases referred to in points (a), (b) and (c) of Article 9(1) the disease–free compartments may be established.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 266(2).

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning provisions supplementing those contained in this Article, on:

(a) the requirements for recognition of the disease-free status of compartments as provided for in paragraphs 1 and 2 of this Article, based on the profile of the listed diseases referred to in points (a), (b) and (c) of Article 9(1), concerning at least:
  (i) surveillance results and other evidence needed to substantiate freedom from disease;
  (ii) biosecurity measures;
(b) the detailed rules for the approval by the competent authority of the disease–free status of compartments as provided for in paragraphs 1 and 2; and
(c) rules concerning compartments which are located in the territory of more than one Member State.

Article 84

Obligation of operators to register establishments

1. Operators of establishments (…) collecting, producing, processing or storing germinal products shall, in order for their establishments to be registered in accordance with Article 93, before they commence such activities:
  (a) inform the competent authority of any such establishment under their responsibility;
  (b) provide the competent authority with the following information:
    (i) the name and address of the operator concerned;
    (ii) the location of the establishment and a description of its facilities;
    (iii) the categories, species and numbers or quantities of kept terrestrial animals or germinal products which they intend to keep on the establishment, and the capacity of the establishment;
    (iv) the type of establishment; and
    (v) any other aspects of the establishment which are relevant for the purpose of determining the risk posed by it.
2. Operators of establishments referred to in paragraph 1 shall inform the competent authority of:
  (a) any changes in the establishment in question concerning the matters referred to in point (b) of paragraph 1;
  (b) any cessation of activity by the operator or establishment concerned.

Article 93

Obligation of the competent authority concerning registration

A competent authority shall register:
(a) establishments in the register provided for in Article 101(1), where the operator concerned has provided the information required in accordance with Article 84(1);
The competent authority shall assign each establishment with a unique registration number.

Article 94

Approval of certain establishments and delegated acts

1. Operators of the following types of establishments shall apply to the competent authority for **approval** in accordance with Article 96(1) and shall not commence their activities until their establishment has been approved in accordance with Article 97(1):
  (b) **germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals are moved to another Member State**;
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:
  (c) special rules for the cessation of activities for germinal product establishments as referred to in point (b) of paragraph 1. *[germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals are moved to another Member State]*

Article 95

Approval of status of confined establishments

Operators of establishments wishing to obtain the status of a confined establishment shall:
(a) apply to the competent authority for approval in accordance with Article 96(1);
(b) move kept animals to or from their establishment in accordance with the requirements provided for in Article 137(1) and any delegated acts adopted in accordance with Article 137(2) only after their establishment has obtained an approval of that status from the competent authority in accordance with Articles 97 and 99.

Article 96

Obligation of operators to provide information with a view to obtaining approval and implementing acts

1. Operators shall, for the purposes of their application for approval of their establishment as provided for in Article 94(1) and point (a) of Article 95, provide the competent authority with the following information:

(a) the name and address of the operator concerned;
(b) the location of the establishment concerned and a description of its facilities;
(c) the categories, species and number of kept terrestrial animals or germinal products relevant for the approval which are kept on the establishment;
(d) the type of establishment;
(e) other aspects of the establishment, related to its specificity, which are relevant in determining the risk, if any, posed by it.

Article 97

Granting of, and conditions for, approval of establishments and delegated acts

1. Competent authorities shall only grant approval of establishments as provided for in Article 94(1) and point (a) of Article 95 where such establishments:
   (a) comply with the following requirements, where appropriate, in relation to:
      (i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in point (b) of Article 10(1) and any rules adopted pursuant to Article 10(2);
      (ii) surveillance requirements as provided for in Article 24 and, where relevant for the type of establishment concerned and the risk involved, in Article 25;
      (iii) record-keeping as provided for in Articles 102 and 103 and any rules adopted pursuant to Articles 106 and 107;
   (b) have facilities and equipment that are:
      (i) adequate to reduce the risk of the introduction and spread of diseases to an acceptable level, taking into account the type of establishment concerned;
      (ii) of a capacity adequate for the number of kept terrestrial animals or the volume of germinal products concerned;
   (c) do not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place;
   (d) have adequately trained personnel for the activity of the establishment concerned;
   (e) have in place a system which enables the operator concerned to demonstrate to the competent authority compliance with points (a) to (d).
2. The Commission shall adopt delegated acts in accordance with Article 264 concerning:
   (a) quarantine, isolation and other biosecurity measures as referred to in point (a)(i) of paragraph 1;
   (b) surveillance as referred to in point (a)(ii) of paragraph 1;
   (c) facilities and equipment as referred to in point (b) of paragraph 1;
   (d) responsibilities, competence and specialised training of personnel and veterinarians as provided for in point (d) of paragraph 1 for the activity of germinal products establishments and establishments for assembly operations of ungulates and poultry;
   (e) the necessary supervision by the competent authority of germinal products establishments and establishments for assembly operations of ungulates and poultry.
3. When establishing the rules to be laid down in the delegated acts to be adopted pursuant to paragraph 2, the Commission shall base those rules on the following matters:
   (a) the risks posed by each type of establishment;
   (b) the species and categories of kept terrestrial animals relevant for the approval;
   (c) the type of production concerned;
   (d) typical movement patterns of the type of establishment and species and categories of animals kept in those establishments.

Article 137

Kept terrestrial animals intended for confined establishments and delegated acts

1. Operators shall only move kept terrestrial animals to a confined establishment if the animals in question fulfil the following conditions:
   (a) they originate from another confined establishment;
   (b) they do not pose a significant risk for the spread of listed diseases as referred to in point (d) of Article 9(1) to listed species or to categories of animals at the confined establishment of destination, except where the movement in question is authorised for scientific purposes.
2. The Commission shall adopt delegated acts in accordance with Article 264 concerning:
   (a) detailed rules for movements of kept terrestrial animals into confined establishments in addition to those provided for in paragraph 1 of this Article;
   (b) specific rules for movements of kept terrestrial animals into confined establishments where the risk-mitigation measures in place guarantee that such movements do not pose a significant risk for the health of kept terrestrial animals within that confined establishment

and the surrounding establishments.

Explanation and/or potential questions to be discussed

– Registration for national market and approval if germinal products are moved to another Member State;

Note: Current legislation provides provisions on intra-Union trade in and imports into the Union of germinal products of bovine, porcine, ovine, caprine and equine animals. Requirements for germinal products to be moved nationally are laid down by Member States in their national legislation.

However, with the semen storage centres, EU legislation slightly affects also movement of semen within a Member State, even if the semen will be stored with the intention to ship it one day to another Member State.

AHL is largely preserving this situation. However, both types of germinal product establishments, i.e. those for national market and those involved in movements to other Member States should be included in the competent authorities' register of establishments as registered or approved establishments respective of their status.

i. Should a derogation for semen collection at a holding where animals are kept in case of ovine and caprine animals, foreseen in Directive 92/65/EEC, be preserved or semen for movement to other Member States should only be collected at the approved semen collection centre?
ii. Should all, out of three foreseen in Directive 92/65/EC (permanent residence at semen collection centre, occasionally leaving semen collection centre, 'walk-on stallions'), options of donor stallions be maintained?
iii. Should storage of oocytes and embryos collected or produced by an approved embryo collection/ production team be allowed at an approved semen collection/ storage centre? Should it be allowed to store semen of different species at one semen storage centre? If yes, what should be the conditions for such storage?
iv. What level of separation should be required for collection, production and storage of germinal products meeting national market requirements vs those for movements to other member States?

– Semen storage centres for semen of porcine animals;

Note: Directive 90/429/EEC does not provide provisions on semen storage centres for semen of porcine animals. AHL gives the possibility to lay down requirements for approval, storage and movement of semen into and from such semen storage centres. The Commission is considering to lay down provisions on semen storage centres for semen of porcine animals.

– An option for a germinal product establishment to form a compartment;
i. Has such a need been communicated by the industry?
ii. Would it be possible to ensure, taking into account vector borne diseases, by the operators and by the competent authorities that animal health status of the donor

animals and germinal products kept at the germinal product establishment is not compromised?

iii. Which types of establishments (semen collection centres, embryo collection/ production teams) and which species should be taken into consideration?

iv. What additional requirements should be established for approval and supervision of a germinal product establishment as a compartment?

– An option for a germinal product establishment to be a part of a confined establishment or a confined establishment is to be considered equivalent to a germinal products establishment for exotic species;

Note: The Commission intends to largely preserve the rules provided for in Directive 92/65/EEC (Article 13, Annex C and Part 3 of Annex E) for the movement of germinal products between approved bodies, institutes or centres as defined in Article 2(1)(c) of that Directive (now defined as confined establishments under AHL). Even if so, the above rules which cater for both live animals and germinal products from approved bodies, institutes or centres will have to be recreated under the delegated and implementing rules on germinal products, at least as references to the rules on live animals (if a confined establishment is accepted as place of production and origin and no special conditions are deemed to be needed) or in substance (if exotic species deemed to need specific rules for the collection, storage and movement of their germinal products).

i. How do you see the needs of, and the necessary rules for, the zoos and other confined establishments to send germinal products of exotic species to other EU MS?

ii. Do you agree that the simplest solution should be pursued given the potential administrative burdens?

– An approval of semen sexing units and rules for transport of semen to and from such units (in the Member State of semen collection or in a different Member State);

Note: Current legislation requires that the approved semen collection centre must have at least, amongst others, a semen processing room. Semen sexing unit may be considered as a part of such processing room/ facility. However, in a case when semen sexing unit is not on the same site as semen collection centre, current legislation is lacking detailed provisions on the approval and supervision of this part of semen collection centre, as well as on movement of semen to and from such semen sexing unit, in particular if it is located in a different Member State. AHL provides empowerments to the Commission to lay down requirements for the approval of germinal product establishments and movement of germinal products.

i. Is it acceptable that a semen sexing unit is located in a different Member State than a Member State of semen collection centre, where the semen was collected?

ii. What requirements as regards facilities and biosecurity measures a semen sexing unit should fulfil?

iii. Should such a semen sexing unit be treated as integral part of the approved semen collection centre or should it have more independent status?
iv. How should the process of approval of a semen collection centre which uses services of semen sexing unit look like?
v. Could such semen sexing unit be shared with other semen collection centres approved under distinct approval numbers?
vi. How the supervision of that semen sexing unit should look like?
vii. What should be the requirements for movement of semen for sexing and after the process, including rules on certification and marking of packages including semen? Should there be different conditions for national movement of such semen comparing to its movement between the Member States?

Note: It must be noted that traceability of such semen is a crucial element. In case a semen sexing unit is used by several semen collection centres, a potential disease may be spread widely.

– Rules for storage and movement of germinal products collected by a germinal product establishment which ceases its activity;

Note: It may often happen, in relation to germinal product establishments located both in the Union and in third countries, that a germinal product establishment ceases its activity but germinal products collected and stored at/by that establishment were not removed before its activity was ceased.

i. What should be approach to the listing of such germinal product establishment?
   - When it should be delisted?
   - If i.e. embryos collected by embryo collection team which ceases its activity are taken over by another approved embryo collection team how it should be reflected on the list of approved germinal product establishments?

ii. What should be the rules to move such germinal products?
   - Should they be immediately moved to another approved germinal product establishment (what type of germinal product establishment?; what if there is no i.e. approved semen storage centre in the Member State?)?
   - Should they be stored at the germinal product establishment which ceased its activity until they are dispatched to their final destination?
   - Should there be any special model certificate established for such purpose?

Additional points:

– Is there a need to lay down minimum standards of a biosecurity system which germinal product establishments should apply (i.e. responsibilities of centre/ team veterinarian in charge of the whole process and quality system, but not necessarily permanently there; internal biosecurity manual including geographical, structural and procedural standards; training; documentation; review; corrective actions, ect.)?
– Should we lay down the conditions for approval of quarantine premises used for animals before addition to a semen collection centre?

Note: In Directive 88/407/EEC it is only said that the animals must have been subjected to a period of quarantine of at least 28 days in accommodation specifically approved for the purpose by the competent authority of the Member State, and where only other cloven-hoofed animals having at least the same health status are present.

b. Diseases relevant for movement within the Union and for entry into the Union of germinal products, including those of exotic species in confined establishments.

Legal base in Directive 88/407/EEC

For semen of animals of the bovine species, animals:

- must have belonged to a herd which is officially **tuberculosis** free and officially **brucellosis** free;
- must come from a herd officially free of enzootic **bovine leukosis** or have been produced by dams which have been subjected to a test (the agar gel immuno-diffusion test (AGID) or by the enzyme-linked immunosorbent assay (ELISA)) with negative results, after removal of the animals from their dam. In the case of animals derived by embryo transfer, 'dam' means the recipient of the embryo;
  If this requirement cannot be fulfilled, the semen shall not be the subject of trade until the donor has reached the age of two years and has been serologically tested with a negative result;
- have been subjected to the following tests with negative results in each case, except for the BVD/MD antibody test,:
  - for **bovine tuberculosis**, an intradermal tuberculin test (within the 28 days preceding the period of quarantine before admission to a semen collection centre and at least once a year at semen collection centre);
  - for **bovine brucellosis**, a serological test (within the 28 days preceding the period of quarantine before admission to a semen collection centre; within the period of quarantine and at least once a year at semen collection centre);
  - for **enzootic bovine leukosis**, a serological test (within the 28 days preceding the period of quarantine before admission to a semen collection centre and at least once a year at semen collection centre);
  - for **IBR/IPV**, a serological test (whole virus) on a blood sample if the animals do not come from an IBR/IPV free herd (within the 28 days preceding the period of quarantine before admission to a semen collection centre; within the period of quarantine and at least once a year at semen collection centre);
  - for **BVD/MD**, (within the 28 days preceding the period of quarantine before admission to a semen collection centre; within the period of quarantine and at least once a year at semen collection centre):
    — a virus isolation test or a test for virus antigen, and
    — a serological test to determine the presence or absence of antibodies.
    Any animal (seronegative or seropositive) may only be allowed entry to the semen collection facilities if no sero-conversion occurs in animals which tested seronegative before entry into the quarantine station.
    If sero-conversion occurs, all animals that remain seronegative shall be kept in quarantine over a prolonged time, until there is no more sero-conversion in the group for a period of three weeks. Serologically positive animals may be allowed entry into the semen collection facilities.
    Prior to the initial dispatch of semen from BVD/MD serologically positive bulls, a semen sample from each animal shall be subjected to a virus isolation or virus antigen ELISA test for BVD/MD. In the event of a positive result, the bull shall be removed from the centre and all of its semen destroyed.
    Should an animal become serologically positive, every ejaculate of that animal collected since the last negative test shall be either discarded or tested for virus with negative results.
  - for ***Campylobacter fetus ssp. venerealis*** (within the period of quarantine and at least once a year at semen collection centre):
    — in the case of animals less than six months old or kept since that age in a single sex group prior to quarantine, a single test on a sample of artificial vagina washings or preputial specimen;
    — in the case of animals aged six months or older that could have had contact with females prior to quarantine, a test three times at weekly intervals on a sample of artificial vagina washings or preputial specimen;
  - for ***Trichomonas foetus*** (within the period of quarantine and at least once a year at semen collection centre):
    — in the case of animals less than six months old or kept since that age in a single sex group prior to quarantine, a single test on a sample of preputial specimen;
    — in the case of animals aged six months or older that could have had contact with females prior to quarantine, a test three times at weekly intervals on a sample of preputial specimen.

Legal base in Directive 89/556/EEC

For embryos of animals of the bovine species, animals:

- must come from herds which are:
  - officially **tuberculosis** free,
  - officially **brucellosis** free or brucellosis free,
  - **enzootic bovine leukosis** free,
    In derogation, they may come from a herd (or herds) which is/are not leucosis-free but for which certification has been obtained that there has not been any clinical case of enzootic bovine leucosis during the past three years;
- during the previous year, they must not have been present in a herd (or herds) which have shown any clinical sign of **infectious bovine rhinotracheitis/infectious pustular vulvovaginitis**.

Furthermore, the above conditions shall apply to live animals intended as donors of oocytes by ovum pickup or ovariectomy.

Legal base in Directive 90/429/EEC

For semen of animals of the porcine species, animals:

- must have been chosen from herds or holdings:
  - which are free of **brucellosis** in accordance with the Chapter on porcine brucellosis of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE);
  - in which no animal vaccinated against foot-and-mouth disease has been present in the preceding 12 months;
  - in which no clinical, serological, virological or pathological evidence of **Aujeszky's disease** has been detected in the preceding 12 months;
  - which are not situated in a restricted area defined under the provisions of Union legislation due to the emergence of an infectious or contagious disease in domestic pigs, including foot-and-mouth disease, swine vesicular disease, vesicular stomatitis, classical swine fever and African swine fever;
- not have been kept previously in any herd of a lower status than described above;
- have been subjected to the following tests with negative results:
  - as regards **brucellosis**, a buffered Brucella antigen test (rose Bengal test), or a cELISA or an iELISA (within 30 days preceding the period of quarantine before admission to a semen collection centre; during the last 15 days of the period of quarantine and routine testing at semen collection centre).
    If any of the animals proves positive in the tests for brucellosis, animals with negative results in the same holding must not be admitted in the quarantine accommodation until the brucellosis-free status of the herds or holdings of origin of the positive reactors was confirmed.
    If, during quarantine, any of the animals proves positive in the tests for brucellosis and the suspicion of brucellosis has not been ruled out, those animals must be removed immediately from the quarantine accommodation;
  - as regards **Aujeszky's disease** (within 30 days preceding the period of quarantine before admission to a semen collection centre; during the last 15 days of the period of quarantine and routine testing at semen collection centre):
    — in the case of non-vaccinated animals, an ELISA for detecting antibodies to the whole Aujeszky's disease virus or to its glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD) or a serum neutralisation test
    — in the case of animals vaccinated with a gE deleted vaccine, an ELISA for detecting antibodies to Aujeszky's disease virus glycoprotein E (ADV-gE).
    If, during quarantine, any of the animals proves positive in the tests for Aujeszky's disease, those animals must be removed immediately from the quarantine accommodation;
  - as regards **classical swine fever**, an antibody ELISA or a serum neutralisation test (within 30 days preceding the period of quarantine before admission to a semen collection centre and routine testing at semen collection centre).

Legal base in Directive 92/65/EEC

For semen of animals of the equine species, animals:

- shall be subjected to the following tests
  - an agar-gel immuno-diffusion test (Coggins test) or an ELISA for **equine infectious**

anaemia with negative result;

- a test for the isolation of the **equine arteritis virus** or the detection of its genome by polymerase chain reaction (PCR) or real-time PCR carried out with negative result on an aliquot of the entire semen of the donor stallion, unless the donor stallion has reacted with negative result at a serum dilution of one in four in a serum neutralisation test for equine viral arteritis;
- an agent identification test for **contagious equine metritis**, carried out with negative result in each case on three specimens (swabs) taken from the donor stallion on two occasions with an interval of not less than seven days, and in no case earlier than seven days (systemic treatment) or 21 days (local treatment) after possible antimicrobial treatment of the donor stallion, from at least the following sites:
  — the penile sheath (prepuce),
  — the urethra,
  — the fossa glandis.
  The specimens shall be placed in transport medium with activated charcoal, such as Amies medium, before dispatch to the laboratory.
  The specimens shall be subjected to at least one of the following tests:
  — culture under microaerophilic conditions for at least 7 days for the isolation of Taylorella equigenitalis, set up within 24 hours after taking the specimens from the donor animal, or 48 hours where the specimens are kept cool during transport; or
  — polymerase chain reaction (PCR) or real-time PCR for the detection of genome of Taylorella equigenitalis, carried out within 48 hours after taking the specimens from the donor animal.

For semen of animals of the ovine and caprine species, animals:

- have belonged to an officially **brucellosis-free** ovine or caprine holding and they shall not be previously kept in a holding of a lower health status as regards brucellosis
- come from a holding where during the 60 days prior to their stay in the quarantine accommodation they have undergone a serological test for **contagious epididymitis (*B. ovis*)**;
- have undergone the following tests (within the 28 days preceding the commencement of the period of quarantine; during the period of quarantine and at least once every calendar year) with negative results in each case, except for the test for Border disease:
  - for **brucellosis (*B. melitensis*)**, a serological test (the Rose Bengal test or the complement-fixation test [or any other test with an equivalent documented sensitivity and specificity for pre-quarantine period]);
  - for **contagious epididymitis (*B. ovis*)**, a serological test (the complement-fixation test or any other test with an equivalent documented sensitivity and specificity);
  - for **Border disease**:
    — a virus isolation test or a test for virus antigen; and
    — a serological test to determine the presence or absence of antibodies (antibody test).
    Any animal (seronegative or seropositive) shall only be allowed entry to the semen collection centre if no sero-conversion occurs in animals which tested seronegative before the day of entry into the quarantine accommodation.
    If sero-conversion occurs, all animals that remain seronegative shall be kept in quarantine over a prolonged time, until there is no more sero-conversion in the group for a period of three weeks from the day the sero-conversion occurred.
    Serologically positive animals shall be allowed entry into the semen collection centre subject to a negative result in a virus isolation test or a test for virus antigen.

For ova embryos of animals of the porcine species:

In addition to the requirements laid down in Directive 64/432/EEC, donor females of porcine species shall, except *in vivo* derived embryos subject to a trypsin treatment, comply with the requirements for **Aujeszky's disease** laid down in accordance with Article 9 or 10 of that Directive.

For ova and embryos of animals of the equine species, animals:

- must not come from a holding which has been the subject of one of the following prohibition orders:
  - if all the animals of species susceptible to the disease located on the holding have not been slaughtered, the period of prohibition concerning the holding of origin must be at least:
    (i) six months in the case of equidae suspected of having contracted dourine, beginning on the date of the last actual or possible contact with a sick animal.

(ii) six months in the case of glanders or equine encephalomyelitis, beginning on the day on which the equidae suffering from the disease in question are slaughtered;
(iii) in the case of infectious anaemia, until the date on which, the infected animals having been slaughtered, the remaining animals have shown a negative reaction to two Coggins tests carried out three months apart;
(iv) six months from the last recorded case, in the case of vesicular stomatitis;
(v) one month from the last recorded case, in the case of rabies;
(vi) 15 days from the last recorded case, in the case of anthrax;

- if all the animals of species susceptible to the disease located on the holding have been slaughtered and the premises disinfected, the period of prohibition shall be 30 days, beginning on the day on which the animals were destroyed and the premises disinfected, except in the case of anthrax, where the period of prohibition is 15 days.

(provisions of Directive 2009/156/EC)

- have undergone the following tests with negative result:
  - an agar-gel immuno-diffusion test (Coggins test) or an ELISA for **equine infectious anaemia** carried out on a blood sample taken not less than 14 days following the date of the commencement of the period of at least 30 days prior to the date of collection of ova or embryos and not more than 90 days prior to the collection of ova or embryos for trade;
  - an agent identification test for **contagious equine metritis**, carried out on at least two specimens (swabs) taken from the donor mare in no case earlier than seven days (systemic treatment) or 21 days (local treatment) after possible antimicrobial treatment of the donor mare, from at least the following sites:
    (i) the mucosal surfaces of the clitoral fossa,
    (ii) the clitoral sinuses.
    The specimens shall be taken during the period of at least 30 days prior to the date of collection of ova or embryos on two occasions with an interval of not less than seven days in the case of the test referred to in point (i), or on one occasion in the case of the test referred to in point (ii).
    The specimens shall be placed in transport medium with activated charcoal, such as Amies medium, before dispatch to the laboratory.
    The specimens shall be subjected to at least one of the following tests:
    (i) culture under microaerophilic conditions for at least seven days for the isolation of Taylorella equigenitalis, set up within 24 hours after taking the specimens from the donor animal, or 48 hours where the specimens are kept cool during transport; or
    (ii) polymerase chain reaction (PCR) or real-time PCR for the detection of genome of Taylorella equigenitalis, carried out within 48 hours after taking the specimens from the donor animal.

For embryos of animals of the ovine and caprine species:

- must come from herds or holdings:
  - which are officially brucellosis-free or brucellosis-free;
  - in which the following diseases have not been clinically diagnosed:
    — in the previous six months, **contagious agalactia of sheep** (Mycoplasma agalactiae) or **contagious agalactia of goats** (Mycoplasma agalactiae, M. capricolum, M. Mycoïdes var. mycoïdes‘large colony’),
    — in the previous 12 months, **paratuberculosis** or **caseous lymphadenitis**,
    — in the previous three years, **pulmonary adenomatosis, Maedi Visna or caprine viral arthritis/encephalitis**. However, this period shall be reduced to 12 months if the animals infected with Maedi Visna or caprine viral arthritis/encephalitis have been slaughtered and the remaining animals have reacted negatively to two tests.

(provisions of Directive 91/68/EEC)

For trade in semen, ova or embryos of animals from bodies, institutes or centres:
Article 13

1. Trade in animals of species susceptible to the diseases listed in Annex A or to the diseases listed in Annex B, where the Member State of destination applies the guarantee provided for in Articles 14 and 15, and trade in semen, ova or embryos of such animals consigned to and from bodies, institutes or centres approved in accordance with Annex C shall be subject to production of a transport document corresponding to the specimen in Annex E. This document, which must be completed by the veterinarian responsible for the body, institute or centre of origin, must specify that the animals,

semen, ova or embryos come from a body, institute or centre approved in accordance with Annex C and must accompany them during transport.

Legal base in Regulation (EC) No 1266/2007[7] ***(Bluetongue)***

Article 8   ***Conditions for exemption from the exit ban provided for in Directive 2000/75/EC***   6. For the animals, their semen, ova and embryos referred to in paragraphs 1, 4 and 5a of this Article, the following additional wording shall be added to the corresponding health certificates laid down in Directives 64/432/EEC, 91/68/EEC and 92/65/EEC, or referred to in Decision 93/444/EEC: '… (Animals semen, ova and embryos indicate as appropriate) in compliance with … (Articles 8(1)(a) or 8(1)(b) or 8(4) or 8(5a), indicate as appropriate) of Regulation (EC) No 1266/2007'.
Annex III   B. Semen of animals   Semen must have been obtained from donor animals which comply with at least one of the following conditions: (a) they have been kept outside a restricted zone for a period of at least 60 days before commencement of, and during, collection of the semen;   (b) they have been protected against attacks by vectors in a vector protected establishment in accordance with the criteria set out in Annex II for a period of at least 60 days before commencement of, and during, collection of the semen;   (c) they were kept during the seasonally vector-free period in a bluetongue seasonally-free zone, defined in accordance with Annex V, for a period of at least 60 days before commencement of, and during, collection of the semen and were subjected to an agent identification test according to the OIE Terrestrial Manual, with negative results, carried out not earlier than seven days before the date of commencement of collection of the semen.   However, that agent identification test shall not be necessary in Member States or regions of a Member State where sufficient epidemiological data, obtained following the implementation of a monitoring programme during a period of not less than three years, substantiate the determination of the seasonally vector-free period, as defined in Annex V.   The Member States making use of that possibility shall inform the Commission and the Member States in the framework of the Standing Committee on the Food Chain and Animal Health;   (d) they have been subjected to a serological test according to the OIE Terrestrial Manual to detect antibodies to the bluetongue virus group, with negative results, at least every 60 days during the collection period and between 21 and 60 days following the final collection of the semen to be consigned;   (e) they have been subjected, with negative results, to an agent identification test according to the OIE Terrestrial Manual carried out on blood samples collected: (i) at commencement and final collection of the semen to be consigned; and   (ii) during the period of semen collection: — at least every seven days, in the case of a virus isolation test, or   — at least every 28 days, in the case of a polymerase chain reaction test.   Where the semen referred to in this Section is intended for intra-Community trade or export to a third country, the following additional wording shall be added to the corresponding health certificates laid down in Council Directive 88/407/EEC and Commission Decision 95/388/EC, or referred to in Decision 93/444/EEC: 'Semen obtained from donor animals which comply with … (point (a), (b), (c), (d) or (e), indicate as appropriate) of Annex III.B to Regulation (EC) No 1266/2007'.   C. Ova and embryos of animals   1. In vivo derived embryos and ova of bovine animals must have been obtained from donor animals which do not show any clinical signs of bluetongue on the day of collection.   2. Embryos and ova of animals other than bovine animals and in vitro produced bovine embryos must have been obtained from donor animals which comply with at least one of the following conditions: (a) they have been kept outside a restricted zone for at least 60 days before commencement of, and during, collection of the embryos/ova;   (b) they have been protected against attacks by vectors in a vector protected establishment in

[7] Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue (OJ L 283, 27.10.2007, p.37)

accordance with the criteria set out in Annex II for at least 60 days before commencement of, and during, collection of the embryos/ova;

(c) they have been subjected to a serological test according to the OIE Terrestrial Manual to detect antibodies to the bluetongue virus group, between 21 and 60 days following collection of the embryos/ova, with negative results;

(d) they have been subjected to an agent identification test according to the OIE Terrestrial Manual on a blood sample taken on the day of collection of the embryos/ova, with negative results.

3. Where the ova and embryos referred to in points 1 and 2 are intended for intra-Community trade or export to a third country, the following additional wording shall be added to the corresponding health certificates laid down in Council Directive 89/556/EEC (18) and Decision 95/388/EC, or referred to in Decision 93/444/EEC:

'Embryos/ova obtained from donor animals which comply with … (point 1; point 2(a), point 2(b), point 2(c) or point 2(d), indicate as appropriate) of Annex III.C to Regulation (EC) No 1266/2007'.

Point 2(a) of Annex B to Directive 89/556/EEC shall not apply to ova and embryos collected from donor animals kept in holdings subject to veterinary prohibition or quarantine measures pertaining to bluetongue.

Legal base in AHL

Article 5
Listing of diseases

1. The disease-specific rules for the prevention and control of diseases provided for in this Regulation shall apply to:
   (a) the following listed diseases:
      (i) foot and mouth disease;
      (ii) classical swine fever;
      (iii) African swine fever;
      (iv) highly pathogenic avian influenza;
      (v) African horse sickness; and;
   (b) the listed diseases set out in the list in Annex II *[Bluetongue, Bovine tuberculosis, Bovine brucellosis (B. abortus), Ovine and caprine brucellosis (B. melitensis), Campylobacteriosis]*.
2. The Commission shall adopt delegated acts in accordance with Article 264 concerning amendments to the list referred to in point (b) of paragraph 1 of this Article.

Potential questions to be discussed

- In what way the current approach as regards animal diseases relevant for movement within the Union and for entry into the Union of germinal products should be changed, if needed?

  Note: The Commission is now in a process of assessing the list of animal diseases in Annex II to Animal Health Law. The state of play of that process will be explained at the meeting. Member States and the industry will have an opportunity to present their views on the impacts and importance of different diseases for which rules exist at present to this particular sector.

- Is a negative serology (whole virus) necessary for IBR or should semen from vaccinated bulls be allowed if vaccine is DIVA? In particular if used for the production of embryos which are then imported into EU?

c. Movement within the Union and entry into the Union of bovine oocytes (and ovaries).

Explanation and/or potential questions to be discussed

– What additional animal health requirements and/ or other conditions, to those foreseen for embryos, should be fulfilled in order to allow movement between the Member States and entry into the Union of oocytes of animals of the bovine species?

Note: Directive 89/556/EEC does not provide provisions for intra-Union trade in and imports of ova (oocytes) of animals of the bovine species. AHL gives the possibility to lay down requirements for collection, processing, storage and movement of ova (oocytes) of animals of the bovine species between Member States and into the Union from third countries. The Commission is considering to lay down such provisions.

Note: It must be taken into account that the final list of diseases under AHL is not yet established.

d. Movement within the Union of mixed/pooled semen (porcine/ bovine animals).

Current legal situation taking porcine semen as an example

Article 2 of Directive 90/429/EEC provides:

For the purposes of this Directive, the definitions contained in Article 2 of Directives 64/432/EEC, 72/462/EEC, 80/407/EEC and 90/425/EEC shall apply as necessary.

Moreover, 'semen' means the ejaculate of a domestic animal [singular] of the porcine species, in the unaltered state or prepared or diluted.

(g) each collection of semen, whether or not it is separated into individual doses, is clearly marked in such a way that the date of collection of the semen and the breed and identification of the donor animal [singular], as well as the name and the registration number of the centre, preceded by the name of the country of origin, where appropriate, in the form of a code, can be readily established; the characteristics and form of this marking will be established under the procedure laid down in Article 19.

The certificate assigns to each donor a certain quantity of straws or bags or containers

I.31. Identification of the commodities

Species (Scientific name)	Breed	Donor identity	Date of collection	Approval number of the centre	Quantity

Assessment of the legal situation:

- From an animal health point of view the likelihood that all these boars meet the same health requirements on the day this particular semen, i.e. the semen which is intended to form part of a pooled semen, was collected is close to 100%. If something happens it would be the economic risk of the operator to destroy possibly larger amounts of semen.
- Mixed semen was involved in the spread of CSF from an AI centre in 1997 in the NL, but this AI centre was not approved for intra-Union trade and supplied semen only to Dutch producers.
- If TRACES allows to enter more than one boar identity behind a particular quantity of bags or straws of pooled semen, then this is not necessarily available to third countries not operating TRACES and strictly following the model of certificate from which the above picture was snipped. The immediate question would be, do we want such pooled semen also from third countries that may request such a possibility when they learn about its acceptance for European producers of porcine semen.
- This is an issue which needs to be discussed with Member States in the PAFF Committee and then the rules can possibly be adapted accordingly. At this moment our understanding of the Directive sticks to the text and there we cannot find anything about pooled semen, but we tend to see indications (see the annotated quotes above) that this legislation was meant to establish a close link between a dose of semen and the identity of the individual donor male.
- However, there is this EU co-funded study and it can understood that 0.3 piglets more in the litter has some merits for pig producers. http://www.pigresearchcentre.dk/~/media/Files/PDF%20-%20UK/Meddelelse%20969_UK.ashx

Conclusion of the study:

This trial demonstrated that semen doses containing sperm from several boars affected fertility positively compared with doses containing sperm from just one boar.

When a semen dose contained sperm from three or six boars, litter size – measured as total born piglets – increased by 0.3 piglets compared with doses containing sperm from one boar only.

The outcome of this trial has led to the decision that commercial semen doses from Danish DanAvl AI stations will in the future always consist of sperm from minimum three boars.

FUNDING

The trial was financially supported by the Pig Levy Fund and the EU and the Rural District Programme under the Ministry of Food, Agriculture and Fisheries of Denmark. Activity no. 50-351900. File no: 3663-D-10-00461.

Potential questions to be discussed

- Do we want to move between Member States and/or enter into the Union pooled semen? If yes, of which species?
- What additional animal health or other conditions, including for marking of such semen, to those for semen of one donor should be required?
- Should pooling be restricted to the semen collection centre where the semen was collected or the pooling of semen is taking place i.e. in a processing unit placed aside of the main semen collection centre facilities and/or from more than one semen collection centre?

e. Rules on movement within and entry into the Union of germinal products.

Potential questions to be discussed

- What should be requirements for checks before certifying germinal products consignment to other Member State (physical and identification checks; check on emptying, cleaning and disinfection of container prior to use, ect.)?
- Should we require sealing of containers?

f. Rules on marking of straws (traceability of germinal products).

Legal base in Directive 88/407/EEC

ANNEX A, *CHAPTER II*

1. Collection centres must:
   (f) be so supervised that:
      (vii) each individual dose of semen is clearly marked in such a way that the date of collection of the semen, the breed and identification of the donor animal and the approval number of the centre can be readily established; each Member State shall communicate to the Commission and other Member States the characteristics and form of the marking used in its territory;
2. Storage centres must:
   (e) be so supervised that:
      (vi) each individual dose of semen is clearly marked in such a way that the date of collection of the semen, the breed and identification of the donor animal and the approval number of the collection centre can be readily established; each Member State shall communicate to the Commission and other Member States the characteristics and form of the marking used in its territory.

Legal base in Directive 89/556/EEC

ANNEX A, *CHAPTER II*

1. *Collection and processing*
   (h) Each embryo container and the containers in which they are stored and transported shall be clearly code-marked in such a way that the date of collection of the embryos and the breed and identification of the donor sire and donor dam, as well as the registration number of the team can be readily established. The characteristics and form of this code-marking shall be established in accordance with the procedure laid down in Article 18;

Legal base in Directive 90/429/EEC

ANNEX A, *CHAPTER II*

The collection centres must:

6. *be so supervised that:*
   (g) Each embryo container and the containers in which they are stored and transported shall be clearly code-marked in such a way that the date of collection of the embryos and the breed and identification of the donor sire and donor dam, as well as the registration number of the team can be readily established. The characteristics and form of this code-marking shall be established in accordance with the procedure laid down in Article 18;

Legal base in Directive 92/65/EEC

ANNEX D, Chapter I(II)

1. Semen collection centres shall:
1.2. be monitored to ensure that:
   (h) each individual dose of semen or each ejaculate of fresh semen intended for further processing is clearly marked in such a way that the date of collection of the semen, the species, the breed and identification of the donor animal and the approval number of the semen collection centre can be readily established;
2. Semen storage centres shall:
2.2. be monitored to ensure that:
   (f) each individual dose of semen is clearly marked in such a way that the date of collection of the semen, the species, the breed and identification of the donor animal, the approval number of the semen collection centre can be readily established; each Member State shall communicate to the Commission and other Member States the characteristics and form of the marking used in its territory;

Legal base in AHL

Article 121
Traceability requirements for germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species

1. Operators producing, processing or storing germinal products shall mark germinal products of kept animals of the bovine, caprine, ovine, porcine and equine species in such a way that they can be clearly traced to:
   (a) the donor animals;
   (b) the date of collection; and
   (c) the germinal product establishments where they were collected, produced, processed and stored.
2. The marking provided for in paragraph 1 shall be designed in such a way as to ensure:
   (a) the efficient application of the disease prevention and control measures provided for in this Regulation;
   (b) the traceability of the germinal products, their movements within and between Member States and their entry into the Union.

Article 122

Delegation of powers concerning traceability requirements for germinal products

1. The Commission shall adopt delegated acts in accordance with Article 264 concerning traceability requirements for germinal products of kept terrestrial animals of the bovine, caprine, ovine, porcine and equine species supplementing the rules laid down in Article 121.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning traceability requirements for germinal products of kept terrestrial animals of species other than of the bovine, caprine, ovine, porcine and equine species, where necessary for:
   (a) the efficient application of the disease prevention and control measures provided for in this Regulation;
   (b) the traceability of those germinal products, their movements within and between Member States and their entry into the Union.
3. When adopting the delegated acts provided for in paragraph 1, the Commission shall base those acts on the following matters:
   (a) the species of kept terrestrial animals from which the germinal products originate;
   (b) the health status of donor animals;
   (c) the risk involved with such germinal products;
   (d) the type of germinal products;
   (e) the type of collection, production, processing or storage of germinal products;
   (f) the movement patterns for the relevant species and categories of kept terrestrial animals and their germinal products;
   (g) considerations concerning the protection and conservation of species of kept terrestrial animals;
   (h) other elements that may contribute to the traceability of germinal products.

Potential questions to be discussed

- What is the system of marking straws and other packages containing germinal products currently in place in particular Member States?
- Has any Member State faced so far any problem with tracing back the germinal products it received from a different Member State or a third country? If yes, what kind of problems and how can they be solved to avoid such problems in the future?
- Should there be a standardised code placed on the straws and other packages containing germinal products?
- Should we focus only on germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species, or also other species?

g. Samples for testing.

i Samples for official examination for bacterial and viral contamination resulting from activities of an embryo team

Legal base in Directive 89/556/EEC

ANNEX A, Chapter II	
1.	Collection and processing
(n)	Each collection team must submit routine samples of flushing fluids, washing fluids, disintegrated embryos, non-fertilized ova etc., resulting from its activities for official examination for bacterial and viral contamination. The procedure for collecting of samples, conducting such examinations, together with the standards to be achieved shall be decided in accordance with the procedure laid down in Article 18. If the standards laid down are not achieved the competent authority which granted the official approval to the team shall withdraw that approval.

Legal base in Directive 92/65/EEC

ANNEX D, Chapter III(II)	
1.	Collection and processing of in vivo derived embryos
1.13.	Each embryo collection team shall submit for official examination for bacterial and viral contamination routine samples of non-viable embryos or ova, flushing fluids or washing fluids resulting from its activities according to the IETS Manual.

Potential questions to be discussed

- How this procedure is currently implemented by embryo collection/ production teams?
- What should be done in this area in the future legislation?

ii Rules for sampling:

- Is there a need to specify who can take samples from animals (routine official testing, re-testing in case of positive result), and how to identify samples (given name vs official identification number)?

iii Rules for sending to another Member State the samples for testing (free service market) and recommended methods for testing;

Potential questions to be discussed

Note: In accordance with the current legislation all test must be carried out in a laboratory approved by the Member State. Testing procedures, if not specified in the Union legislation (Directives on germinal products or "trade" Directives: 64/432/EEC, 91/68/EEC, 2009/156/EC), then those described in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the OIE should be followed.

Note: Article 34 of the new Official Controls Regulation lays down provisions on rules for methods used for sampling, analyses, tests and diagnoses.

In accordance with Article 17(4) of AHL, in the event that an official laboratory in one Member State conducts diagnostic analyses on samples from animals originating in another Member State, that official laboratory shall notify the competent authority of the Member State from which the samples originated of any results indicating the suspicion or detection of a listed disease.

- Are currently those tests carried out in laboratories in the same Member State where a semen collection centre is located?
- Under which conditions samples for testing should be sent to another Member States? How to ensure that the competent authorities are notified about the results?
- Are there any remarks from Member States as regards specificity of recommended testing methods?

h. Official controls of germinal product establishments (including clarification on links to the new EU Official Controls Regulation).

Legal base in Directive 88/407/EEC

Article 5
1. The Member State on whose territory the semen collection or storage centre is situated shall ensure that the approval provided for in Article 3(a) is granted only where the provisions of Annex A are observed and where the semen collection or storage centre is able to satisfy the other provisions of this Directive. The Member State shall also ensure that the **official veterinarian supervises** the observance of those provisions and shall withdraw approval when one or more of the provisions is no longer observed.
Article 9
1. Member States shall only authorise imports of semen dispatched from a semen collection or storage centre situated in one of the third countries appearing on the list referred to in Article 8 and for which the competent authority of the third country concerned is able to give the guarantees that the following conditions are met: (d) it is subject to inspections by an official veterinarian of the third country at least twice a year.
ANNEX A, *CHAPTER II*
1. Collection centres must: (c) be regularly inspected by an official veterinarian, at least twice a year, in the context of standing checks on the conditions of approval and supervision; 2. Storage centres must: (b) be regularly inspected by an official veterinarian, at least twice a year, in the context of the standing checks on the conditions of approval and supervision;

Legal base in Directive 89/556/EEC

Article 5
1. Approval of an embryo collection team as provided for in Article 3(c) shall be granted only where the provisions of Annex A, Chapter I are observed and where the embryo collection team is able to satisfy the other provisions of this Directive. Any major change in the organization of the team is to be notified to the competent authority. The approval of the team shall be renewed whenever the team veterinarian is replaced or whenever any major changes are made in its organization or the laboratories or equipment at its disposal. The **official veterinarian shall supervise** observance of the provisions outlined above. Approval shall be withdrawn where one or more of the provisions is no longer observed.
Article 8
1. Member States shall only authorise imports of embryos dispatched from an embryo collection or production team situated in one of the third countries appearing on the list referred to in Article 7 and for which the competent authority of the third country concerned is able to give the guarantees that the following conditions are met: (c) it is subject to inspections by an official veterinarian of the third country at least twice a year.
ANNEX A, *CHAPTER I*
In order to be given approval each embryo collection team must fulfil the following requirements: (b) it must be placed under the general supervision and authority of the official veterinarian;
ANNEX A, *CHAPTER II*
1. *Collection and processing* (h) Each embryo shall, where appropriate, be frozen as soon as possible and stored in a place which is under the control of the team veterinarian and which is subject to **regular inspection by an official veterinarian**.

Legal base in Directive 90/429/EEC

Article 5
1. The Member State on whose territory the semen collection centre is situated shall ensure that the approval provided for in Article 3(a) is granted only if it meets the conditions of Annex A and satisfies the other provisions of this Directive. The Member State shall also ensure that the **official veterinarian supervises** the observance of those provisions. The official veterinarian shall propose that approval be withdrawn when one or more of the provisions is no longer observed.

Article 8
1. Member States shall only authorise imports of semen dispatched from a semen collection centre situated in one of the third countries appearing on the list referred to in Article 7 and for which the competent authority of the third country concerned is able to give the guarantees that the following conditions are met: (d) it is subject to inspections by an official veterinarian of the third country concerned at least twice a year.
ANNEX A, *CHAPTER II*
The collection centres must: 3. be **regularly inspected by an official veterinarian**, at least twice a year, at which time checks on the conditions of approval and supervision shall be carried out;

Legal base in Directive 92/65/EEC

ANNEX D, Chapter I(II)
1. Semen collection centres shall: 1.3. be **inspected by an official veterinarian during the breeding season at least once every calendar year** in the case of animals with seasonal breeding and twice every calendar year in the case of a non-seasonal reproduction in order to consider and verify, where necessary on the base of records, standard operating procedures and internal audits, all matters relating to the conditions of approval, supervision and monitoring.; 2. Semen storage centres shall: 2.4. be **inspected by an official veterinarian at least twice every calendar year** in order to consider and verify, where necessary based on records, standard operating procedures and internal audits, all matters relating to the conditions of approval, supervision and monitoring.
ANNEX D, Chapter I(III)
1. In order to be given approval each embryo collection team shall comply with the following requirements: 1.3. the team shall be placed under the **general supervision of the official veterinarian, who shall inspect it at least once every calendar year** to ensure, where necessary based on records, standard operating procedures and internal audits, compliance with the sanitary conditions regarding collection, processing and storage of embryos and to verify all matters relating to the conditions of approval and supervision; 1.8. the team shall have at its disposal storage premises which shall: (d) have storage containers for ova and embryos which are stored in a place which is under the control of the team veterinarian and which is subject to **regular inspections by an official veterinarian**;

Legal base in AHL

Article 97 ***Granting of, and conditions for, approval of establishments and delegated acts***
2. The Commission shall adopt delegated acts in accordance with Article 264 concerning: (e) the necessary **supervision** by the competent authority of germinal products establishments and establishments for assembly operations of ungulates and poultry.

Explanation and/or potential questions to be discussed

After the adoption of the AHL and the soon to be adopted new EU Official Controls Regulation (OCR)[8] a separation between the basic substantial rules specific for the particular area (i.e. on the operators, products, diseases, etc.) and rules on their official controls (i.e. how competent authorities verify compliance with the substantial rules) largely took place in these, with some exceptions (e.g. controls prior to approval of establishments). As provisions related to official controls are still mixed in current legislation on germinal products mentioned above, separation also must be done in the delegated and implementing acts to AHL and OCR replacing those Directives.

[8] 2013/0140 (COD)

The new OCR already provides for many modalities of official controls. These include transparency, written records, documented procedures, methods and techniques, sampling, official laboratories, delegation of official control tasks to bodies or persons and many more. Its general rules state that competent authorities shall perform official controls on all operators regularly, on a risk basis and with appropriate frequency ("risk-based controls"). Nevertheless, specific delegated rules to address sectorial needs (such as animal health rules or germinal product establishments) can be laid down under its Article 20(2). Similarly, an implementing act for uniform minimum frequency of official controls can be laid down under its Article 20(3).

In practice, certain provisions or sentences above should be split into two to three or even more delegated and implementing acts either under the AHL or under the new OCR. Alternatively, some of them may be considered not necessary, since the new OCR is more comprehensive, and are not to be replaced at all. In that case, official controls in those areas will be done in accordance with the OCR.

In addition, certain terms are defined in the new OCR. These include for example, "under the responsibility of the official veterinarian" or "under the supervision of the official veterinarian". Also, "supervision" is not mentioned among the methods and techniques for official controls, while "inspection" is. Therefore the delegated and implementing acts will have to be clarified from terminology point of view too.

In this whole process, cooperation of officials responsible for germinal product establishments and those responsible for official controls is advisable on national level.

- Is there a need to specify that the competent authority performing the controls must be a veterinarian?
- Is there any other need to lay down specific rules beyond the general ones already laid down by the Regulation?
- Is there a need to deviate from risk-based controls and lay down minimum frequencies?