



ANNOTATED AGENDA

**Expert Group on Regulation (EU) 2016/429 –
to discuss Delegated Acts on germinal products - E00930
24 November 2017, 10.00-17.00**

Conference Centre Albert Borschette – Rue Froissart 36 – Bruxelles, CCAB-4D

I. DRAFT AGENDA

1. Introduction, opening: DG 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:
 - 2.1. Approval of germinal product establishments:
 - i. Germinal product storage centres;
 - ii. Semen sexing units [germinal product processing establishment] and rules for transport of semen to and from such units (in the Member State of semen collection or in a different Member State);
 - iii. Rules for storage and movement of germinal products collected by germinal product establishment which ceases its activity;
 - 2.2. Rules on movement within and entry into the Union of germinal products:
 - i. Sealing of the containers;
 - ii. Rules for transport.
 - 2.3. Movement within the Union of mixed/pooled semen (porcine/ bovine/ovine animals).
 - 2.4. Rules on marking of straws (traceability of germinal products).
 - 2.5. Samples for testing:
 - i. Samples for official examination for bacterial and viral contamination resulting from activities of an embryo team;
 - ii. Rules for sampling;
 - iii. Rules for sending to another Member State the samples for testing (free service market) and recommended methods for testing.
3. Miscellaneous.

Annex: Working document SANCO/5490/2009 rev.4 "Characteristics and form of marking bovine semen straws in EU Member States, Norway and Switzerland".

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. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

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. It will provide also feedback to the Commission on the perceived state of play of the EU policy (and beyond) in this area. As such, it will facilitate its improvement via further dedicated work.

In particular, outcomes from the discussions will 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/ implementing acts under the EU Animal Health Law (AHL)². This meeting is also meant to cater for more thorough and technical discussions by experienced representatives of the MS on a variety of issues related to germinal products.

This annotated agenda intends to provide background information on the current situation, on what has been done or is planned at EU level concerning this area and to ask relevant questions to MS representatives to explore their various aspects. This document also includes input drafted by the Commission of particular pieces of the text which may be at the later stage used in the delegated acts under the AHL, reflecting the conclusions from the previous meeting of the Expert Group of 24 April 2017. 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.

The annotated agenda intends to frame discussions during the meeting. They are not all-inclusive though. If the participants of the meeting feel that important element(s) have been omitted, feel free to raise those either during the meeting, before or after. Similarly, if you have any questions or want to send written comments, either before or after the meeting, please e-mail to SANTE-CONSULT-G2@ec.europa.eu (DG SANTE Unit G2, Animal Health and Welfare).

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)

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

2.1. Approval of germinal product establishments.

Current legal base:

- Directive 88/407/EEC³

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.

- Directive 89/556/EEC⁴

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 <i>in vitro</i> 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 <i>mutatis mutandis</i> .

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)

- Directive 90/429/EEC⁵

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.

- Directive 92/65/EEC⁶

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.

New legal base - Regulation (EU) 2016/429 (AHL)

Article 4 Definitions
(28) 'germinal products' means: (a) semen, oocytes and embryos intended for artificial reproduction; (b) hatching eggs;
(46) 'germinal product establishment' means: (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

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)

<p>(c) oocytes and embryos; in relation to hatching eggs, a hatchery;</p>
<p>Article 84 <i>Obligation of operators to register establishments</i></p>
<p>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:</p> <ul style="list-style-type: none"> (a) inform the competent authority of any such establishment under their responsibility; (b) provide the competent authority with the following information: <ul style="list-style-type: none"> (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. <p>2. Operators of establishments referred to in paragraph 1 shall inform the competent authority of:</p> <ul style="list-style-type: none"> (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.
<p>Article 93 <i>Obligation of the competent authority concerning registration</i></p>
<p>A competent authority shall register:</p> <ul style="list-style-type: none"> (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); <p>The competent authority shall assign each establishment with a unique registration number.</p>
<p>Article 94 <i>Approval of certain establishments and delegated acts</i></p>
<p>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):</p> <ul style="list-style-type: none"> (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; <p>3. The Commission shall be empowered to adopt delegated acts in accordance with Article 264 concerning:</p> <ul style="list-style-type: none"> (c) special rules for the cessation of activities for germinal product establishments as referred to in point (b) of paragraph 1. [<i>germinal product establishments for bovine, porcine, ovine, caprine and equine animals from which germinal products of those animals are moved to another Member State</i>]
<p>Article 96 <i>Obligation of operators to provide information with a view to obtaining approval and implementing acts</i></p>
<p>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:</p> <ul style="list-style-type: none"> (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.
<p>Article 97 <i>Granting of, and conditions for, approval of establishments and delegated acts</i></p>
<p>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:</p> <ul style="list-style-type: none"> (a) comply with the following requirements, where appropriate, in relation to: <ul style="list-style-type: none"> (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.

i Germinal product storage centres.

The outcome of the previous meeting of the Expert Group of 24 April 2017 was the following:

- the participants suggested that there is no need to separate storage centres per species or even per type of germinal product and requested sets of provisions in a future delegated act to AHL for a germinal product storage centre storing germinal products of any type and originating from more than one species, under one approval number. Information on types and species of stored germinal products should be provided in the approval of a germinal product establishment and in the publicly available list of germinal product storage centres;
- the invited technical experts asked for provisions in future delegated act to AHL on semen storage centres where fresh/chilled semen is stored (not only for frozen semen).

The Commission would like to propose the following recital, Articles and Annex in a delegated act:

Recital	
(x)	Provisions for a germinal product storage centre storing germinal products of any type and originating from more than one species, under one approval number and subject to appropriate traceability ensured, should be possible as there are no health reasons that would require separate storage centres per type of germinal product or per species. Information on types and species of stored germinal products should be specified in the approval of such establishment and in the publicly available list of approved germinal product establishments. There is also a need to lay down in this Delegated Regulation separate provisions on storage of fresh, chilled and frozen semen.

Article 2

Definitions

‘germinal product storage centre’ means a germinal product establishment approved and supervised by the competent authority of a Member State or third country or territory for the storage of semen, oocytes or embryos of one or more species, or any combination of those germinal products, intended for artificial reproduction.

[Empowerment - Article 97(2) of the AHL

(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;

(e) the necessary supervision by the competent authority of germinal products establishments.]

Article 3

Conditions for the approval of germinal product establishments for bovine, porcine, ovine, caprine and equine animals

1. In order to move germinal products of bovine, porcine, ovine, caprine or equine animals to another Member State, an application for approval as germinal product establishment shall be made to the competent authority by the following operators:
 - (a) the operator of an establishment where semen of bovine, porcine, ovine, caprine or equine animals is collected, processed or stored; or
 - (b) the group of professionals or the structure supervised by a team veterinarian competent to perform the collection, production, processing and storage of oocytes and embryos of bovine, porcine, ovine, caprine or equine animals; or
 - (c) the operator of an establishment where fresh, chilled or frozen semen, oocytes or embryos of bovine, porcine, ovine, caprine or equine animals are stored.
2. In the application referred to in paragraph 1, the operator shall specify:
 - (a) the type of germinal products to be collected, processed and stored, i.e. collection of semen, oocytes or embryos, embryo production or storage of germinal products;
 - (b) the species of donor animals, i.e. bovine, porcine, ovine, caprine or equine animals;
 - (c) the conditions of storage of germinal products, i.e. fresh, chilled or frozen;
 - (d) the name and contact details of the germinal product processing establishment referred to in Article 5(1)(c), in the case where all or part of the processing is carried out at a germinal products processing establishment.
3. The operator shall only apply for approval in accordance with paragraph 1 where the following conditions have been fulfilled:
 - (a) the operator had appointed
 - (i) a centre veterinarian responsible in accordance with point 1 of Part 1 of Annex I for the activities of the semen collection centre, or in accordance with point 1 of Part 4 of Annex I for the activities of the germinal product storage centre;
 - (ii) a team veterinarian responsible in accordance with point 1 of Part 2 of Annex I for the activities of the embryo collection team, or in accordance with point 1 of Part 3 of Annex I for the activities of the embryo production team;
 - (b) the facilities, equipment and operational procedures for the activity in question that comply with the requirements set out in:
 - (i) point 2 of Part 1 of Annex I, in respect of the collection, processing, storage and transport of semen of bovine, porcine, ovine, caprine or equine animals;
 - (ii) point 2 of Part 2 of Annex I, in respect of the collection, processing, storage and transport of oocytes and embryos of bovine, porcine, ovine, caprine or equine animals;
 - (iii) point 2 of Part 3 of Annex I, in respect of the production, processing, storage and transport of embryos of bovine, porcine, ovine, caprine or equine animals, including the processing and storage of semen and oocytes used for the embryo production;
 - (iv) point 2 of Part 4 of Annex I, in respect of the storage and transport of fresh, chilled or frozen semen, oocytes or embryos of bovine, porcine, ovine, caprine or equine animals.

Article 4

Competent authorities obligations for the approval of germinal product establishments for bovine, porcine, ovine, caprine and equine animals

1. On the application referred to in Article 3(1) and (2), the competent authority shall grant approval of a germinal product establishment and assign it with a unique approval number provided the following conditions are complied with:
 - (a) in the case of a semen collection centre, the conditions laid down in paragraph 3(a)(i) and (b)(i) of Article 3;
 - (b) in the case of an embryo collection team, the conditions laid down in paragraph 3(a)(ii) and (b)(ii) of Article 3;
 - (c) in the case of an embryo production team, the conditions laid down in paragraph 3(a)(ii) and (b)(iii) of Article 3;
 - (d) in the case of a germinal product storage centre, the condition laid down in paragraph 3(a)(i) and b(iv).

2. The competent authority shall expressly specify in the approval of one of the germinal product establishments granted pursuant to points (a) to (c) of paragraph 1 the following:
 - (a) the type of germinal products to be collected, produced, processed and stored;
 - (b) the species of donor animals, i.e. bovine, porcine, ovine, caprine or equine animals;
 - (c) the name of the centre veterinarian or the team veterinarian appointed by the operator in accordance with Article 3(3)(a);
 - (d) the unique approval number assigned to the semen collection centre, the embryo collection team, the embryo production team or the embryo collection and production team;
 - (e) the name and contact details of the germinal product processing establishment referred to in Article 5(1)(c), in the case where the operator intends to have the processing of germinal products carried out at a germinal products processing establishment.

3. The competent authority shall expressly specify in the approval of a germinal product storage centre granted pursuant to point (d) of paragraph 1 the following:
 - (a) the type of germinal products to be stored;
 - (b) the species of donor animals, i.e. bovine, porcine, ovine, caprine or equine animals;
 - (c) the name of the centre veterinarian appointed by the operator in accordance with Article 3(3)(a)(i);
 - (d) the unique approval number assigned to the germinal product storage centre.

*[Empowerment - Article 160(1) of the AHL: the animal health requirements for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species to other Member States, specifying:
(d) animal health requirements for the collection, production, processing, storage or other procedures and transport].*

ANNEX III

ANIMAL HEALTH REQUIREMENTS FOR THE COLLECTION, PRODUCTION, PROCESSING AND STORAGE OF GERMINAL PRODUCTS OF KEPT ANIMALS OF THE BOVINE, OVINE, CAPRINE, PORCINE AND EQUINE SPECIES, AND FOR TRANSPORT OF THOSE GERMINAL PRODUCTS AS REFERRED TO IN ARTICLE X

Part 1

Animal health requirements for the collection, processing and storage of semen of kept animals of the bovine, ovine, caprine, porcine and equine species, and for transport of that semen

1. All instruments used for the collection, processing, preservation or freezing of semen shall be either disinfected or sterilised as appropriate before use, except for single-use instruments.

2. Frozen semen shall:
 - (a) be placed and stored in storage containers:
 - (i) which have been cleansed and disinfected or sterilised before use, or are single-use containers;
 - (ii) with a cryogenic agent, which shall not be previously used for other products of animal origin;

<p>(b) prior to dispatch or use, be stored in approved conditions for a minimum period of 30 days from the date of collection.</p> <p>3. Where antibiotics or a mixture of antibiotics are added, with a bactericidal activity at least equivalent to that of the following mixtures in each ml of semen: (...), the names of the antibiotics added and their concentration shall be stated in the animal health certificate referred to in Article x.</p> <p>Those antibiotics shall be added to the semen after final dilution or to the diluent.</p> <p>In the case of frozen semen, antibiotics must be added before the semen is frozen.</p> <p>Immediately after the addition of the antibiotics, the diluted semen must be kept at a temperature of at least 5°C for a period of not less than 45 minutes, except the case of semen of kept animals of the porcine species at a temperature of at least 15°C.</p>
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Follow up: The Commission welcomes any comments to the proposed text of the recital, Articles and Annex.

ii Semen sexing units [germinal product processing establishments] and rules for transport of semen to and from such units (in the Member State of semen collection or in a different Member State).

During the previous meeting of the Expert Group of 24 April 2017, the participants expressed their opinion that this area must be fully regulated. Also an option for transport of semen for sexing to the Union from non-EU countries should be foreseen with clear conditions. Moreover, they were in favour of a flexible approach allowing semen sexing units to be a part of approved semen collection centres as well as to function independently.

The Commission would like to propose the following recital and Articles in a delegated act as regards germinal product processing establishments and rules for transport of semen to and from such establishments:

<p>Recital</p> <p>(x) The continuous progress in germinal products processing techniques results in establishing of specialised units for that purpose. However, the equipment of those units is very often expensive. Therefore companies dealing with germinal products very often use services of other operators to process germinal products, including sexing of semen. Thus, it is considered necessary that the processing of germinal products, taking account role of the specialised processing units, and rules for transport of germinal products to be processed and after being processed should be regulated. Therefore, it is appropriate to lay down in this Delegated Regulation rules for processing of germinal products, including a possibility of their processing at a germinal product processing establishment which is not necessarily forming part of a germinal product establishment, as well as detailed rules for transport of semen and other germinal products to and from such germinal product processing establishments.</p> <p style="text-align: center;">Article 2</p> <p style="text-align: center;">Definitions</p> <p>‘germinal product processing establishment’ means a germinal product establishment approved in accordance with Article 4(1), not necessarily forming part of or being situated on the same side of a germinal product establishment approved in accordance with Article 4(1), which carries out part or all of the processing of semen, oocytes or embryos, including semen sexing, collected at germinal product establishments.</p> <p><i>[Empowerment - Article 97(2) of the AHL</i></p> <p><i>(a) quarantine, isolation and other biosecurity measures as referred to in point (a)(i) of paragraph 1;</i></p> <p><i>(b) surveillance as referred to in point (a)(ii) of paragraph 1;</i></p> <p><i>(c) facilities and equipment as referred to in point (b) of paragraph 1;</i></p>
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(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;
(e) the necessary supervision by the competent authority of germinal products establishments.]

Article 5

Processing of germinal products of bovine, porcine, ovine, caprine and equine animals

1. The operator of a germinal product establishment approved in accordance with Article 4(1), shall ensure that the processing of germinal products is only carried out:
 - (a) in the case of semen, in a semen processing room of a semen collection centre fulfilling the requirements set out in point 1(b)(v) of Part 1 of Annex I;
 - (b) in the case of oocytes and embryos, in a processing unit of an embryo collection or production team fulfilling the requirements set out in point 4(a(i)) of Part 1 of Annex I and of Part 3 of Annex I;
 - (c) in the case of semen or embryos, at a germinal product processing establishment.

2. Where the operator of a germinal product establishment approved in accordance with Article 4(1) employs the services of a germinal product processing establishment referred to in paragraph 1(c), it shall ensure that the germinal product processing establishment
 - (a) is specified by name and contact details in the scope of the approval of the germinal product establishment;
 - (b) has the facilities and equipment necessary to carry out the processing and temporary storage of germinal products;
 - (c) has suitably qualified personnel that have received adequate training on disinfection and hygiene techniques to prevent the spread of diseases;
 - (d) keeps records as provided for in Article 10;
 - (e) the establishment has procedures in place ensuring that germinal products are processed and stored in the way to prevent the spread of diseases and without coming into contact with germinal products originating from other germinal product establishments.

[Empowerment - Article 106(1) of the AHL: requirements for record-keeping by the operator in addition to those of Article 103(1)]

Article 9

Requirements for record-keeping by the operator of germinal product establishment

(...)

4. The operator processing germinal products at a germinal product processing establishment, shall keep and maintain records of the dates of any movement of those germinal products to and from the germinal product processing establishment with the reference to the commercial documents, referred to in Article x, which accompanied those germinal products.

Article 10

Requirements for record-keeping by the operator of germinal product processing establishment

Operators of germinal product processing establishments, shall keep and maintain records containing at least the following information:

- (a) the type of germinal products processed at the germinal product processing establishment with reference to the species of the donor animal;
- (b) the dates of movement of semen, embryos or oocytes to and from the germinal product processing establishment with the reference to the commercial documents, referred to in Article x, which accompanied those germinal products;
- (c) the identification of semen, embryos or oocytes processed at the germinal product processing establishment, with the dates of that processing;
- (d) the name and address of germinal product establishment of which germinal products are processed.

[Empowerment - Article 122 of the AHL: traceability requirements for germinal products]

Article x

Rules on movement of germinal products of bovine, porcine, ovine, caprine and equine animals to

and from a germinal product processing establishment

1. An operator of a germinal product establishment, approved in accordance with Article 4(1), shall ensure that a commercial document accompanies germinal products during transport to and from a germinal product processing establishment referred to in Article 5(1)(c).
2. An operator of a germinal product establishment, approved in accordance with Article 4(1), shall ensure that the commercial document provided for in paragraph 1 includes at least the following information:
 - (a) the name and address of a germinal product establishment of the collection or production of the germinal products;
 - (b) the name and address of a germinal product processing establishment where the germinal products are moved for processing;
 - (c) the dates of movement of the germinal products to and from a germinal product processing establishment;
 - (d) the type and the quantity of the germinal products;
 - (e) the marking of the germinal products, as required by Article 11.

Follow up: The Commission welcomes any comments to the proposed text of the recital and Articles.

iii Rules for storage and movement of germinal products collected by germinal product establishment which ceases its activity.

During the previous meeting of the Expert Group of 24 April 2017, the participants of the meeting were of the opinion that a germinal product establishment, which ceased its activity should stay in the list of approved germinal product establishments of the particular Member State and a date when the activity was stopped should be indicated in that list. The participants of the meeting assumed that germinal products stored at that germinal product establishment should be eligible for movement to other Member States. They also suggested some solutions for that germinal product establishment, i.e. transformation into a storage centre or transport of germinal products to already approved storage centre.

The Commission would like to propose the following Articles in a delegated act as regards storage and movement of germinal products collected by germinal product establishment which ceases its activity:

[Empowerment - Article 94(3)(c) of the AHL: special rules for the cessation of activities for germinal product establishments as referred to in point (b) of paragraph 1]

Article 6

Special rules for cessation of activities for approved germinal product establishment for bovine, porcine, ovine, caprine and equine animals

1. Where a germinal product establishment, approved in accordance with Article 4(1), ceases its activity, the operator shall ensure that semen, oocytes or embryos collected or produced before the date of cessation of those activities and stored in that germinal product establishment:
 - (a) are removed to a germinal product storage centre for further storage; or
 - (b) are removed to an establishment with the intention to be used before the date it ceases its activity; or
 - (c) are safely disposed of as animal by-products in accordance with Regulation (EU) No 1069/2009.
2. Where semen, oocytes or embryos are not removed from the germinal product establishment referred to in paragraph 1 before the date it ceases its activity, the operator shall not move such semen,

oocytes or embryos to other Member States.

[Empowerment - Article 101(3) of the AHL: detailed information to be included in the registers of approved germinal product establishments kept by the competent authorities, and their availability to the public]

Article 8

Registers of approved germinal product establishments for bovine, porcine, ovine, caprine and equine animals

1. The competent authority shall draw up and keep up to date registers of germinal product establishments that it has approved in accordance with Article 4(1).
2. The competent authority shall include in the registers referred to in paragraph 1, for each type of the germinal product establishment, the following information:
 - (a) the name, contact details and, where available, the website of the germinal product establishment;
 - (b) the address of the germinal product establishment;
 - (c) the type of germinal products and animal species for which the approval has been granted;
 - (d) the approval number assigned by the competent authority and the date of that approval.
3. Where, in accordance with Article 4(3), a germinal product storage centre is approved by the competent authority for the storage of more than one type of germinal product or of more than one animal species, the competent authority shall include in the registers, referred to in paragraph 1, information on the type of the germinal products and on animal species thereof stored at the centre.
4. Where the competent authority has suspended or withdrawn the approval of a germinal product establishment in accordance with Article 100 of Regulation (EU) 2016/429, it shall, without undue delay:
 - (a) indicate that suspension or withdrawal in the register referred to in paragraph 1 of this Article;
 - (b) specify in the case of the suspension the closing and opening date, and in the case of withdrawal the withdrawal date.
5. **Where a germinal product establishment, approved in accordance with Article 4(1), has ceased its activity as referred to in Article 6, the competent authority shall, without undue delay, indicate the date of cessation of those activities in the register referred to in paragraph 1 of this Article.**
6. Member States shall make the information referred to in paragraph 1 available to the public on their websites and notify those websites to the Commission. In case the website of a Member State has been changed that Member State shall notify, without undue delay, of a new website to the Commission.

Follow up: The Commission welcomes any comments to the proposed text of the recital and Articles.

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

i Sealing of the containers;

Current legal base:

- Directive 88/407/EEC

ANNEX C

3. Semen for intra-Community trade must:
 - (b) be transported to the Member State of destination in containers which have been cleaned and disinfected or sterilised before use and which have been sealed and numbered prior to dispatch from the approved storage facilities.

ANNEX D3/ model animal health certificate for semen sent from semen storage centre

I, the undersigned official veterinarian, hereby certify that the semen described above:

¹⁾ either [1.1. was collected, processed and stored for a minimum period of 30 days immediately following collection in a semen collection centre ⁽²⁾ situated in the Member State of origin of the semen and operated and supervised in accordance with Chapter I(1) and Chapter II(1) of Annex A to Directive 88/407/EEC, and from where the semen was accepted into the semen storage centre detailed in Box 1.12. situated in the same Member State of origin of the semen under animal health and veterinary certification conditions at least as strict as those provided for in:

(¹) either [Annex D1 to Directive 88/407/EEC (³);:]

(¹) and/or [Annex D2 to Directive 88/407/EEC (⁴);:]

(¹) and/or [Annex D3 to Directive 88/407/EEC (³) (⁴);:]

(¹) and/or [until 31 October 2011, Annex D3 to Directive 88/407/EEC (³) (⁴) (⁵);:]

[transport of semen from semen collection centre to semen storage centre under animal health and certification conditions at least as strict as those for intra-Union trade]

- Directive 89/556/EEC

ANNEX A, CHAPTER II

3. Transport
Embryos for trade must be transported in satisfactory hygienic conditions in sealed containers from the approved storage premises until their arrival at their destination.
The containers must be marked in such a way that the number coincides with the number on the animal health certificate.

- Directive 90/429/EEC

ANNEX C

3. Semen intended for intra-Union trade must:
(b) be transported to the Member State of destination in flasks which have been cleaned and disinfected or sterilised before use and which have been sealed prior to dispatch from the semen collection centre.

- Directive 92/65/EEC

ANNEX D, Chapter III(I)

1.4. Semen to be subject for trade shall:
(a) be transported to the Member State of destination in transport containers which have been cleansed and disinfected or sterilised before use, or are single-use containers, and which have been sealed and numbered prior to dispatch from the approved semen collection or storage centres;

ANNEX D, Chapter III(II)

6 Transport of embryos
6.1. Embryos to be subject for trade shall be transported to the Member State of destination in containers which have been cleansed and disinfected or sterilised before use, or are single-use containers, and which have been sealed and numbered prior to dispatch from the approved storage premises.

During the previous meeting of the Expert Group of 24 April 2017, in the opinion of the Member States taking the floor, a container containing germinal products should always be sealed while transported, no matter if transport takes place within one Member State, between Member States or between non-EU country and a Member State. Such a seal should be applied by, or under, supervision of a veterinarian responsible for the germinal products establishment.

The Commission would like to propose the following text of an Article to a delegated act as regards sealing of the containers:

*[Empowerment - Article 160(1) of the AHL: the animal health requirements for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species to other Member States, specifying:
(d) animal health requirements for the collection, production, processing, storage or other procedures and transport].*

Article x
Animal health requirements for the collection, production, processing, storage and other procedures, and

transport of germinal products in order to ensure that the germinal products do not spread listed diseases

1. Operators shall only move to other Member States semen, oocytes and embryos which fulfil the animal health requirements for the collection, production, processing, storage and transport set out in Annex III.
2. Where germinal products are transported to another Member State or to a germinal product storage centre within the same Member State, the centre veterinarian or the team veterinarian [*for discussion: the official veterinarian as in OIE*] shall seal and number the transport containers prior to their dispatch from the germinal product establishment approved in accordance with Article 4(1).

Follow up: The Commission welcomes any comments to the proposed text of the Article.

ii Rules for transport.

During the previous meeting of the Expert Group of 24 April 2017, the participants requested a clarification and further consideration as regards future delegated act on the possibilities and rules for a transport in one container of different types, or even collected from different species, of germinal products. In their view such common transport does not pose a risk of contamination.

The Commission would like to propose the following recital in a delegated act as regards transport in one container of different types, or collected from different species, of germinal products:

*[Empowerment - Article 160(1) of the AHL: the animal health requirements for movements of germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species to other Member States, specifying:
(d) animal health requirements for the collection, production, processing, storage or other procedures and transport].*

Recital

- (x) The expert group at the meeting of 24 April 2017 concluded that there is a need of further consideration of the possibilities and rules for a transport of germinal products of different types, or even collected from different species, in one container. Based on the available publications⁷⁸⁹ such common transport does not pose a risk for contamination of germinal products if they are transported under particular conditions, amongst other in securely and hermetically sealed straws or other packages which outer surfaces is sterilised and in disinfected transport containers, in particular dry shippers, or when filled in with sterile liquid nitrogen, and when the germinal products of different species or of different types are separated from each other in secondary protective bags of which the outer surfaces are sterilised [disinfected]. Therefore, it is appropriate to lay down provisions in this Delegated Regulation allowing transport of germinal products of different types or those collected from different species in one container under certain conditions.

Follow up:

- 1) The Commission welcomes any comments to the proposed text of the recital.

⁷ A. Bielanski. A review of the risk of contamination of semen and embryos during cryopreservation and measures to limit cross-contamination during banking to prevent disease transmission in ET practices. *Theriogenology* 77 (2012) 467-482

⁸ B.W.W. Grout, G.J. Morris. Contaminated liquid nitrogen vapour as a risk factor in pathogen transfer. *Theriogenology* 71 (2009) 1079-1082

⁹ A. Bielanski. Non-transmission of bacterial and viral microbes to embryos and semen stored in the vapour phase of liquid nitrogen in dry shippers. *Cryobiology* 50 (2005) 206-210

- 2) The Commission will draft a text of the Annex with additional requirements for transport in one container of different types, or collected from different species, of germinal products.
- 3) The Commission welcomes any comments to the below suggestions for additional requirements for transport of germinal products of different types or those collected from different species in one container.

Suggestion for additional requirements for transport of germinal products of different types or those collected from different species in one container:

- (a) straws or other packages in which germinal products are placed shall be securely and hermetically sealed and their outer surfaces sterilised;
- (b) germinal products are transported in dry shippers or transport containers are filled with [sterile] liquid nitrogen;
- (c) the germinal products of different species or of different types are separated from each other in secondary protective bags of which the outer surfaces are sterilised [disinfected];
- (d) the country of origin of the germinal products is free of FMD and other highly contagious diseases transmissible through fomites.

Note: Standard requirements for transport of germinal products in the current legislation:

- (a) germinal products shall be placed in sterile straws or other packages which shall be sealed immediately;
- (b) the cryogenic agent used for transport shall not have been previously used for other products of animal origin;
- (c) transport containers are cleansed and disinfected or sterilised before the commencement of each filling operation, or are single-use containers.

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

Current legal situation using 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
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Assessment of the legal situation:

- From an animal health point of view the likelihood that in case when semen is collected from more than one boar, all these boars meet the same health requirements on the day this particular semen is collected, i.e. the semen which is intended to form part of a pooled semen, was collected is close to 100%.
- 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.
- At this moment in the Directive there is no direct provision on 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 be 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%20UK.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.

According to the opinion of the participants of the previous meeting of the Expert Group of 24 April 2017, provisions on movement of mixed/ pooled semen of porcine, bovine and ovine animals should be laid down in a delegated act to AHL. They were also of the opinion that mixing of semen should be restricted only to a semen collection centre where the semen was collected.

Follow up:

- 1) The Commission will draft an Article for a delegated act to AHL including provisions on movement of mixed/ pooled semen, based on the following criteria:
 - (a) provisions will cover semen of porcine, bovine and ovine animals;
 - (b) mixed semen should be dispatched only from a [single] semen collection centre where the semen was collected;
 - (c) straws or other packages in which mixed semen is placed should be marked with (individual) identification numbers of all donor animals;
 - (d) the operator should have procedures in place as regards processing of mixed semen and should include, in his records, details of movement of such semen from semen collection centre;
 - (e) model animal health certificate will foresee an option of movement of mixed semen.

Question: should storage of mixed semen be foreseen in the legislation?

- 2) The Commission welcomes any comments and suggestions as regards above suggested criteria for the movement of mixed/ pooled semen.

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

Current legal base:

- Directive 88/407/EEC

<i>ANNEX A, CHAPTER II</i>	
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.

- Directive 89/556/EEC

<i>ANNEX A, CHAPTER II</i>	
1.	<i>Collection and processing</i>
(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;

- Directive 90/429/EEC

<i>ANNEX A, CHAPTER II</i>	
The collection centres must:	
6.	<i>be so supervised that:</i>
(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;

- Directive 92/65/EEC

<i>ANNEX D, Chapter I(II)</i>	
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;

Article 121 <i>Traceability requirements for germinal products of kept animals of the bovine, ovine, caprine, porcine and equine species</i>
<ol style="list-style-type: none">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:<ol style="list-style-type: none">(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:<ol style="list-style-type: none">(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 <i>Delegation of powers concerning traceability requirements for germinal products</i>
<ol style="list-style-type: none">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:<ol style="list-style-type: none">(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:<ol style="list-style-type: none">(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.

During the previous meeting of the Expert Group of 24 April 2017 the participants informed that the current system of marking of straws and other packages of germinal products has been working well and they couldn't report on any problems in this area. Some of them requested for more data (UELN/ microchip number of a donor horse, in vivo/ in vitro embryos, ect.) included in the code placed on the straw. They requested for standardisation of that code. Two Member States would also welcome standardisation of marking of straws containing dog's semen.

The Commission would like to propose the following Articles in a delegated act as regards traceability of germinal products:

[Empowerment - Article 122(1) of AHL: traceability requirements for germinal products in addition to those of Article 121(1)]

Article 11
Traceability requirements for germinal products of kept terrestrial animals of the bovine, porcine, ovine,

caprine and equine species

1. An operator collecting, producing, processing or storing germinal products of kept terrestrial animals of the bovine, porcine, ovine, caprine and equine species shall mark each straw or other package in which semen or oocytes, or embryos, whether or not separated into individual doses, are stored and transported in such a way that the following can be readily established, where appropriate, in the form of a code:
 - (a) the date of collection or production,
 - (b) the species, the breed and identification of the donor animal
 - (c) the approval number of the germinal product establishment of collection or production, preceded by the name of the country of origin.
2. An operator shall ensure that marking of straws and other packages, and the traceability of germinal products, in accordance with paragraph 1, comply with the technical requirements, operational requirements and specifications of Article(s) xx of Implementing Regulation (EU) [introduce reference to the Implementing Act based on Article 123 of AHL].

[Empowerment - Article 122(2) of AHL: traceability requirements for germinal products of kept terrestrial animals of species other than those of the bovine, porcine, ovine, caprine and equine species]

Article 12

Traceability requirements for germinal products of kept terrestrial animals of species other than those of the bovine, porcine, ovine, caprine and equine species

An operator collecting, producing, processing or storing germinal products of kept terrestrial animals of species other than those of the bovine, porcine, ovine, caprine and equine species shall mark each straw or other package in which semen or oocytes, or embryos, whether or not separated into individual doses, are stored and transported in such a way that the following can be readily established where appropriate, in the form of a code:

- (a) the date of collection or production,
- (b) the species, the breed and identification of the donor animal, preceded by the name of the country of origin.

Follow up:

- 1) The Commission welcomes any comments to the proposed text of the Articles.
- 2) The Commission will distribute, in order to support the discussion, a working document SANCO/5490/2009 rev.4 "Characteristics and form of marking bovine semen straws in EU Member States, Norway and Switzerland".
- 3) The conclusions based on point 2 will have an impact on the Implementing Act based on Article 123 of AHL.

2.5. Samples for testing.

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

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?

Current legal base:

- 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.

- 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.**

Manual of the International Embryo Transfer Society, 4th Edition, p. 66-68

Submission of Samples

Nonembryocidal methods of directly testing embryos for the presence of infectious agents before their transfer into recipients are not currently available. Options for certification of the health of embryos before transfer include reliance on specific tests conducted on the donor animal, washing or trypsin treatment (trypsin washing), and the testing of samples associated with the embryo collection procedure.

Test samples that have been suggested as indicators of embryonic health include 1) collection (uterine flush) fluid, 2) embryo washes, and 3) unfertilized ova and nontransferable embryos from the same collection. Justification for testing

the collection fluid is that it gives some indication of pathogens to which embryos might have been exposed within the reproductive tract of the donor female. However, it should be noted that pathogens found in the collection fluid can be removed from embryos by proper washing.

Testing of the last few washes has been justified as an indicator of what recipient females might be exposed to when the washed embryos are transferred. If washes are to be used as an indicator of embryonic health, it is important that the entire wash be tested. Thus, if each wash is 2 mL and the last 4 washes are to be tested, then all of the pooled 8 mL should be assayed.

Testing of nonfertile and degenerated ova that were collected from a donor is intended to provide a method for detection of any pathogen to which transferable embryos in the same collection might have been exposed. Also, it may provide an indication of the effectiveness of the washing procedure. The validity of the test is based on the assumption that pathogens can be isolated from unfertilized ova and degenerating embryos as well as from transferable embryos from the same collection. Experiments with bovine embryos and degenerated ova support this assumption. For example, bovine herpesvirus-1 virus appears to stick to the zona pel-

lucida of both regardless of their developmental stage and physical state (15).

Whether the above samples should be tested in lieu of serological or other testing of donor males and females is a decision for the national regulatory authorities; however, the greatest value of testing flush fluid, washing fluid, or embryos/ova might be in a circumstance in which the donor is seropositive for a particular disease. It would be unnecessary to test these samples if donor males and females were shown to be free of disease. If these samples are to be collected, they should be prepared and handled as described below. All samples should be held at 4°C if they are to be tested on the same day. If testing cannot be done on the same day, then the samples should be correctly identified and stored at a temperature of -70°C or lower until testing can be accomplished. The importance of correct identification of samples is emphasized.

Collection Fluids

If a large reservoir is used to recover embryos, the collection (uterine flush) fluid should be allowed to settle

(undisturbed) for a minimum of 30 min in a sterile vessel (e.g., graduated cylinder). After removal of any embryos/ova, a sample of the bottom 100 mL with any settled debris is placed in sterile containers and retained. The volume to be retained and tested will be stipulated by the regulatory authority requesting tests of the sample. Realistically, this should be a volume that is easily stored and that can be subjected to meaningful testing protocols (e.g., viral isolation or polymerase chain reaction assay).

For embryos recovered by filtration, the collection (flushing) fluids should be placed in a sterile container (e.g., graduated cylinder) and allowed to settle for at least 30 min. After embryos that have been washed from the filter are identified and removed, fluid used to wash the filter, collection fluid, and sedimented debris should be placed in sterile containers and retained. The exact volume of each sample will be stipulated by the regulatory authority requesting tests of the samples. Realistically, this should be a volume that is easily stored and that can be subjected to meaningful testing protocols (e.g., viral isolation or PCR assay).

Medium used for the last 4 washes (note: a minimum of 10 washes is required for proper washing) of the embryos should be pooled and retained.

Embryos and Unfertilized or Degenerated Ova

All unfertilized or degenerated ova should be washed according to the standard guidelines described in this chapter. These embryos and ova should be sonicated before assay.

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ii Rules for sampling.

Potential questions to be discussed

- 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

- 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?

Note: In accordance with the current legislation all tests must be carried out in a laboratory approved by the Member State. If testing procedures are 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 Official Controls Regulation lays down provisions on rules for methods used for sampling, analyses, tests and diagnoses.

Regulation (EU) 2017/625 (Official Controls Regulation)¹⁰

Article 34	
Methods used for sampling, analyses, tests and diagnoses	
1.	Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities shall comply with Union rules establishing those methods or the performance criteria for those methods.
2.	In the absence of the Union rules as referred to in paragraph 1, and in the context of official controls and other official activities, official laboratories shall use one of the following methods according to the suitability for their specific analytical, testing and diagnostic needs: <ul style="list-style-type: none">(a) available methods complying with relevant internationally recognised rules or protocols including those that the European Committee for Standardisation (CEN) has accepted; or relevant methods developed or recommended by the European Union reference laboratories and validated in accordance with internationally accepted scientific protocols;(b) in the absence of the suitable rules or protocols, as referred to in point (a), methods which

¹⁰ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1)

	<p>comply with relevant rules established at national level, or, if no such rules exist, relevant methods developed or recommended by national reference laboratories and validated in accordance with internationally accepted scientific protocols; or relevant methods developed and validated with inter or intra-laboratory methods validation studies in accordance with internationally accepted scientific protocols.</p>
3.	Where laboratory analyses, tests or diagnoses are urgently needed and none of the methods referred to in paragraphs 1 and 2 of this Article exists, the relevant national reference laboratory or, if no such national reference laboratory exists, any other laboratory designated in accordance with Article 37(1) may use methods other than those referred to in paragraphs 1 and 2 of this Article until the validation of an appropriate method in accordance with internationally accepted scientific protocols.
4.	Wherever possible, methods used for laboratory analyses shall be characterised by the relevant criteria set out in Annex III.
5.	Samples shall be taken, handled and labelled in such a way as to ensure their legal, scientific and technical validity.
6.	<p>The Commission may, by means of implementing acts, lay down rules on:</p> <p>(a) the methods to be used for sampling and for laboratory analyses, tests and diagnoses;</p> <p>(b) performance criteria, analysis, test or diagnosis parameters, measurement uncertainty and procedures for the validation of those methods;</p> <p>(c) the interpretation of analytical, testing and diagnostic results.</p> <p>Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).</p>

Note: 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.

Regulation (EU) 2016/429 (AHL)

<p>Article 17</p> <p><i>Animal health laboratories</i></p>	
4.	<p>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:</p> <p>(a) immediately of any results indicating the suspicion or detection of a listed disease as referred to in point (a) of Article 9(1);</p> <p>(b) without undue delay of any results indicating the suspicion or detection of a listed disease as referred to in point (e) of Article 9(1) other than those referred to in point (a) of Article 9(1).</p>