Brussels, 26 June 2017

Minutes
of the meeting of the expert group on germinal products

24 April 2017, Brussels

1. Approval of the agenda

2. Nature of the meeting

The meeting was non-public. The Member States' representatives from the competent authorities and the representatives of the Rep Vet Group - veterinarians from European Artificial Insemination companies in the cattle and pig sectors - were participating in the meeting, the latter on an ad-hoc basis due to the need for specific expertise.

3. List of points discussed

1. 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 the EU Animal Health Law (AHL)[1] 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.

        The opinion of some Member States and of the Rep Vet Group is that 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, should be preserved in a future delegated act to AHL, despite the fact that such semen is mainly used at the holding where it was collected. The other Member States were of the opinion that semen intended to be moved to other Member States should only be collected at the approved semen collection centre. The Commission will draft provisions in a future delegated act to AHL for movement to other Member State of semen collected from ovine and caprine animals at their holdings, as derogation from the standard rule and with special conditions for such movement (targeted movement, under the agreement of the Member State of destination).

        As regards approval of semen collection centres for equidae, the Member States and the Rep Vet Group were in favour of keeping in the future legislation all 3 types of residency of stallions at semen collection centres, as foreseen in the current legislation. However, they also pointed out a need to be more specific as regards period of time for which stallions falling under programme 2 (point 1.6(b) of Chapter II(I) of Annex D to Council Directive 92/65/EEC - donors which may leave the semen collection centre occasionally) are present at the semen collection centre. Also the conditions for the

[1] 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)

programme 2 and programme 3 (point 1.6(c) of Chapter II(I) of Annex D to Council Directive 92/65/EEC - "walk-on stallions") should be improved and strengthened.

There was also suggested by the Commission to take under consideration if a biosecurity plan to be developed by semen centres and embryo teams should also be approved during the official approval of semen centres and embryo teams, and provisions on that incorporated into a future delegated act to AHL.

– Semen storage centres for semen of porcine animals.

The Commission informed representatives of the Member States and of the Rep Vet Group of its plans to include provisions on semen storage centres for semen of porcine animals in a delegated act to AHL, what is new comparing to the current legislation. Such draft delegated act will be then consulted during the further expert group meetings on germinal products.

In addition, representatives of the Rep Vet Group asked for provisions in future delegated act to AHL on semen storage centres where fresh/chilled semen is stored (not only for frozen semen).

Moreover, the Member States and the Rep Vet Group suggested that there is no need to separate storage centres per species or even per type of germinal product and they would welcome sets of provisions in a future delegated act to AHL for a germinal products storage centre storing any germinal product, which would be given only one approval number. Information on types and species of stored germinal products would be provided in the approval documentation and in the list of approved germinal products storage centres publicly available.

Finally, the Member States and the Rep Vet Group requested for clarification and further consideration as regards future delegated act to AHL 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 will look into this issue in detail and the outcome will be presented during the next expert group meeting.

– An option for a germinal product establishment:

- to form a compartment;

  One Member State informed about a possibility for semen collection centres for porcine animals to be considered as compartments. In that Member State pathogen free holdings for pigs already exist. Other Member States were positive as regards this idea but posing a question how to implement it in practice. It was pointed out that compartmentalisation could be very difficult for vector borne diseases and FMD.

  The Rep Vet Group was in favour of such compartmentalisation with an interest of particular diseases such as: bluetongue, LSD and bovine tuberculosis.

  One Member State highlighted that this idea should be implemented on voluntary basis, with respect of equal treatment of Member States and non-EU countries, foreseeing increased monitoring and strict biosecurity measures in place, based on the risk and always linked to a particular disease.

The Commission reminded that Article 37 of the AHL lays down provisions for recognitions of the disease-free status of compartments and informed that separate expert group meetings are planned to discuss this area in detail.

- 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.

  The Commission informed about its intention 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). These requirements are essentially limited to the minimum that the germinal product comes from a confined establishment but no specific requirements exist.

  Four Member States taking the floor were of the opinion that at the moment there is no need to lay down specific provisions for a germinal product establishment being a part of a confined establishment. Requirements for genetic material exchanged between zoos should be left to zoos in a framework of their collaboration. However, the Member States requested for provisions on movement of genetic material obtained from bees. The Commission questioned the need for that as it was aware that inseminated queens are moved, but bees' semen normally not. It has agreed to examine this issue and come back with the outcome during the next expert group meetings.

– 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).

  The Member States 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. The Member States and the Rep Vet Group were in favour of flexible approach allowing semen sexing units to be a part of approved semen collection centres as well as to function independently. The Commission will prepare draft text for the future delegated act to AHL containing detailed provisions on approval of semen sexing units and rules for transport of semen to and from such units, which will be consulted during the next expert group meetings.

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

  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 will look into the practicality of those solutions and consider how to legally phrase these suggestions into provisions for the future delegated act to AHL.

– Should the conditions for approval of quarantine premises used for animals before addition to a semen collection centre be laid down?

The representatives of the Rep Vet Group were of the opinion that such quarantine premises (i.e. for pigs) should be registered or be a part of semen collection centre approved by the competent authority.

One Member State said that the term 'quarantine units' is reserved for legislation on entry into the Union (so far they exist only for birds) and suggested that this area should be left for national legislation.

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.

The Commission informed delegations about a process of assessing animal diseases for their listing in Annex II to AHL. The outcome of this assessment will be presented later during future dedicated expert group meetings. Once the list of diseases is finally established and categorisation of those diseases is completed, further work on animal health requirements for movement within the Union and for entry into the Union of germinal products should continue.

Delegations mentioned the following diseases as of particular importance for germinal products sector:

- Aujeszky's disease;
- IBR/IPV;
- ASF and bluetongue – a need to establish requirements in relation to introduction of semen donors into the semen collection centre;
- Bovine tuberculosis – a need to re-asses importance of this disease in relation to possible transmission via embryo transfer;
- Porcine brucellosis;
- PRRS – in relation to a risk for introduction of this disease via porcine semen to countries free of this disease [comment sent via e-mail after the meeting].

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

The Commission informed representatives of the Member States and of the Rep Vet Group about its plans to include provisions on movement within the Union and entry into the Union of bovine oocytes (and ovaries) in a delegated act to AHL, what is new comparing to the current legislation. Such draft delegated act will be then consulted during the further expert group meetings on germinal products.

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

The Member States and the Rep Vet Group were in favour of provisions in a delegated act to AHL on movement of mixed/ pooled semen of porcine, bovine and ovine animals. They were also of the opinion that mixing of semen should be restricted only to a semen collection centre where the semen was collected.

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

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.

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

The Member States informed that the current system of marking of straws and other packages with germinal products has been working well and they could not report on any problems in this area. Some of them would see a need for more data (UELN/ microchip number of a donor horse, in vivo/ in vitro embryos, ect.) included in the code placed on the straw. Some Member States and the Rep Vet Group requested for standardisation of that code.

The Rep Vet Group informed that the item relating to straws' marking would be discussed during the International Committee for Animal Recording (ICAR) conference in Edinburgh (UK) on 14-16 June 2017. The Rep Vet Group will report to the Commission on the outcome of this discussion which then will be presented and discussed during the next expert group meeting to be held in the second half of 2017.

Two Member States would also welcome standardisation of marking of straws containing dog's semen.

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.

This point of the agenda was not discussed and postponed for the next meeting.

h. Official controls of germinal product establishments (including clarification of links with the new EU Official Controls Regulation (OCR)[2]).

The Commission explained that new OCR provides that competent authorities shall perform official controls on all operators regularly, on a risk basis and with appropriate frequency ("risk-based controls"). Specific rules for establishments such as germinal products establishments can be however laid down in a delegated act under Article 20 of the OCR. The participants of the meeting, 3 Member States and the Rep Vet Group, expressed their opinion that there is a need to lay down provisions based on Article 20(2) of OCR specifying that official veterinarians, not any competent authorities, are responsible for official controls of germinal product establishments. The complexity and technicality of this

[2] 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)

particular sector require from the controlling competent authority specialised knowledge and allowing an efficient and professional performance of the checks of the germinal product establishments. One Member State explained its experience with controls by non-veterinary CA-officials.

2. Miscellaneous.

4. Conclusions/recommendations/opinions

The Commission obtained required information on the current situation in the Union in relation to germinal products' sector, as well as expectations of particular Members States for the future legislation.

A follow up expert group meeting is required to discuss a draft legal text including the presented views.

5. Next steps

The outcome of the discussion and opinions provided by the participants of this expert group will be used by the Commission in the context of the Animal Health and Welfare Section of the Standing Committee on Plants, Animals, Food and Feed (PAFF)[3] and during further Commission work towards delegated acts under AHL.

6. Next meeting

The date for the further meeting will be established in the second half of 2017.

[3] http://ec.europa.eu/food/animals/health/regulatory_committee_en

7. List of participants

LIST OF PRESENCE TO MEETING - LISTE DE PRESENCE

15 demands

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