Workshop I: Sanitary and regulations on embryo transfer

IETS and HASAC: the genesis of the World Organization for Animal Health (OIE) recommendations for safe trade of embryos

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The International Society for Embryo Technologies (IETS) was created in 1974. To meet the needs for specific regulation in terms of health safety, IETS created an Import & Export committee, chaired by R Mapletoft, in the early 80's. A formal relationship between IETS and the World Organization for Animal Health (OIE) was then set up in 1987. With the development of new embryo technologies and the concern about the safety of animals produced with such technologies entering the food chain, the scope of the committee was expanded in 2000 under the initiative of M Thibier so as to include those issues, resulting in the current IETS Health and Safety Advisory Committee (HASAC, https://www.iets.org/comm_hasac.asp). HASAC functions to advise the IETS Board members, IETS members and OIE. HASAC is composed of IETS members from academic, regulatory and industry sectors, under the direction of a chair nominated by the IETS Board of Governors (BoG) (current chair: Julie Gard, succeeding to F Fieni, P Chavatte-Palmer and M Thibier). Its aims are: - to review regularly and extensively the literature in order to evaluate potential risks, based on scientific evidence, with regard to international trade of embryos and human consumption of animal or animal products derived from embryo transfer and related technologies. - to provide guidelines such as codes of practice, recommendations and any information pertinent to the safe movement of embryos and safe introduction into the food chain of animal or animal products derived from reproductive biotechnologies without unduly restricting technological advances and commerce.- to communicate to IETS members all its achievements and upon acceptance by IETS BoG, to all the relevant International Agencies. Three HASAC subcommittees meet annually but work electronically throughout the year: 1. The Research subcommittee maintains and revises literature relevant to the animal health implications of current and emerging technologies. A large database, including an abstract, HASAC interpretation and conclusions on all publications examined, is updated each year. Based on these yearly evaluations, science-based recommendations are then handed for evaluation to the Regulatory subcommittee. 2. The Regulatory subcommittee examines new evidence provided by the scientific subcommittee and discusses whether current recommendations for the management of the risks potentially associated with embryos in terms of pathogen-embryo interactions should be modified. Any proposed modifications to alter text with regards to regulations and/or OIE recommendations are put forward to the BoG and, if approved, subsequently formally proposed to the OIE for incorporation into the Terrestrial Animal health Code. Commission members of OIE most often support the proposed amendments from IETS/HASAC before finally being voted on, and mostly accepted, by the OIE General Assembly. 3. The Manual, Forms and Certificates subcommittee develops, elaborates and publishes a code of practice providing guidelines to practitioners for managing their operations so that pertinent quality assurance standards will be met. Additionally, this committee creates and maintains recording and identification systems of embryos to ensure traceability.

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Viral emergences and consequences for the risk of disease transmission via *in vivo* derived embryos

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Viruses can emerge unexpectedly in different regions of the world. These can induce negative consequences on reproductive performances. This paper presents an update on emerging diseases that may be of primary concern to ruminants and equids and whose impact should therefore be monitored in the context of the European embryo trade. Development of artificial insemination (AI) together with embryo cryopreservation has led to international trade of cattle germplasm for more than 60 years. Although experimental data show that many animal pathogens can be associated with semen and embryos, risk of disease transmission can be substantially reduced or eliminated by applying sanitary protocols recommended by the International Embryo Transfer Society (IETS) and the World Organization of Animal Health (OIE). The basic principle to ensure such a high level of biosecurity for semen relies on the concept of pathogen-free semen collection center. In the case of embryos, practical guidelines have been published in the manual of IETS in order to provide risk management procedures ensuring the safety of herds using embryo transfer, and embryo washing procedures which are the most effective means of reducing the number of microorganisms associated with germplasm. Although transfer of bovine embryos is much less likely to result in disease transmission than transport of live animal, the sanitary risk associated with bovine embryo transfer remains the subject of scientific investigations and adaptations of national and international legislations (OIE). Concerning transmission risk via ET, the IETS HASAC Committee reviews scientific publications on an annual basis and updates a complete set of more than 400 references, which can be consulted on their website (www.iets.org). All diseases and pathogenic agents have been placed into one of four categories (category 1 to 4) based on the amount of research indicating the likelihood of disease control through the use of embryo transfer. For category 1 diseases, risk of transmission of a given disease from donor to recipient via an embryo is negligible, providing biosecurity measures described for handling embryos, material disinfection, and animal health requirements (semen, donor, and recipients). For category 4, no conclusions are yet possible with regard to the level of transmission risk, or the risk of transmission via embryo transfer might not be negligible even if the embryos are properly handled according to the IETS Manual between collection and transfer. This paper will present the epidemiological situation in Europe of (re)emerging viral diseases affecting ruminants and belonging to the different categories: Bluetongue (cat 1, 2, 4), Schmallenberg (cat 4), Lumpy Skin Disease (cat 4) and Foot-and-Mouth Disease (cat 1, 3) but also on some diseases affecting the equids: West Nile and Equine infectious anemia.

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The constrains for a registered Embryo Transfer Team concerning bovine embryo importation and exportation

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The goal of international embryo trading is to allow safe exchanges of genes. That's why they are only performed between registered Embryo Transfer Teams. Their responsibility is to guarantee health authorities and breeders that the embryos don't carry contaminant pathogens and that the filiation of the calves born will be certified. This part of the workshop presents the practical, economic and administrative constrains in a French context as an example of the European one. All these constrains increase the cost of the exchanges, above all with no European Union countries. Consequently they limit their development. Practical constrains are not very difficult as they consist by following IETS recommendations. Administrative constrains are inevitable since they are verified during annual controls for the team's approval. Some other ones could be minimize as, for example, health requirement for export outside European Union. Indeed each country has its own sanitary specifications even for the same disease. Thus, a huge progress will be noticed if all countries could follow the same OIE recommendations! Meanwhile a specific production for each country must be done. It is then more important to select good donors to maximise the chances and having sufficient number of embryos to limit health tests expenses.

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Consequences of sanitary issues (diseases outbreaks) on bovine semen exportations from Europe to third countries: history and current situation

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Today, most of European Members States (MS) involved in bovine genetic or genomic selection are also trading germinal products (GP) all over the world. Exchanging semen and embryos is easier and safer than dealing with live animals and can provide incomes allowing to keep the cost of selection schemes more reasonable and to manage semen stocks. It allows customers to get access to a wider range of sires and provides sanitary guarantees since GP are produced according to high sanitary regulation standards.
However, commercial competition with traditional exporting countries such as USA, Canada is very tough. Main criteria taken into account for buying are genetic merit of the sires, biological quality of the products (fertility) and their sanitary safety brought through the respect of EU Directives (88/407, 43/2003), of OIE recommandations and of IETS procedures. Despite the full respect of the regulation, MS had to face various and unexpected emergent diseases during the last 20 years such as Foot and Mouth Disease (FMD) during 2001, Blue Tongue Virus (BTV 1 and BTV8) in 2006/2007 and then again in 2015, Schmallenberg disease (SBV) in 2012 and for France Blue Tongue again (BTV4) in 2017. These different outbreaks were linked to drops in volumes of semen sold from MS to third countries. (Eurostat: http://epp.eurostat.ec.europa.eu/newxtweb/). Surprisingly, this negative impact was rather moderate and short in time even if some third countries took benefit of the situation to stop importations from EU MS. This is still the case of USA, Canada, China and Mercosur who deny the reliability of the RT-PCR test to detect the presence of viral RNA in semen of seropositive bulls. This could be considered as a technical barrier to trade. The positive impact of such outbreaks was to prompt MS to find common solutions to carry on exporting GP: health certificates were renegotiated with most of third countries and adapted, SBV additional declarations were proposed and new diagnostic tests were developped. Cooperation between MS was reinforced and the role of the EU Commission and of OIE was strenghtened. Regarding Blue Tongue, the experience of 2006 was useful to manage and cope with the new outbreaks of 2015 and 2017 in France. Today, new sanitary threats are surrounding EU 28 MS such as Lumpy skin disease in eastern Europe and Peste des Petits Ruminants in Bulgaria. This means that we have to remain vigilant all the time and to anticipate such negative situations. To do so, MS have to take benefit of their previous experiences and to carry on working in a joint and constructive way.