HEALTH AND SAFETY ADVISORY COMMITTEE
REPORT

Professeur Michel THIBIER
Chairman of the Committee
Paris, le 31 Janvier 2004
SUMMARY OF THE MAIN CONCLUSIONS

The IETS Board of Governors has approved the HASAC suggestion at its meeting of January 2001 to present a summary of the discussions held in these meetings on the IETS web site. Below, follows a compendium of the summaries of each of the 5 meetings held in Portland Or. (USA), 10 – 12 January 2004.

1. The IETS HASAC Parent committee met from 19.45 to 21.25 hrs. 12 January 2004 – Portland, OR, USA. There were 42 attendees.

The minutes of the meeting held in San Diego (USA) (October 2003) were reviewed and adopted and the following items arising from the minutes were discussed:

- Publication of full articles in refereed scientific journals is critically important for consideration by the HASAC.
- Categorization of pathogens on the basis of embryo-pathogen interactions with in vivo-derived embryos was published in the OIE bulletin and also in the OIE Code (for the first time included in the Code) to the great satisfaction of HASAC.
- The Research Update has grown to be a large document – most recent update should now be posted on the IETS website.
- The practicality and safety of OPS are under investigation.
- Disinfection protocols for dry shippers are under study.
- Progress on the risk assessment respecting IVF embryos from abattoir derived ovaries was considered and it was decided to assign the project to someone with risk assessment mathematical skills under the direction of one member of the Committee in order to develop a risk model regarding IBR and BVD and possibly one or two other diseases.
- Work on the draft appendix on embryos of wild felids was postponed indefinitely because of lack of information.
- Some further diseases have been categorized (or re-categorized) as indicated at the previous meeting.
- Relationship with OIE and IETS remains strong and the consolidated Appendix on livestock in vivo derived embryos is now complete.
- Each issue of the IETS Embryo Transfer Newsletter will contain updates from HASAC Subcommittees.

In the course of the meeting, a question was raised related to animals used to produce pituitary hormone products. The fact that some such animals may have been fed with animal products, in a matter of potential concern due to the fear of TSE’s. The research subcommittee will consider the matter at its next meeting.

Among the recommendations to the Board, two resolutions were approved by respectively the forms and certification and the food safety subcommittees and were passed on to the Board for approval1.

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1 and have since then (i.e. on 13 January 2004) been approved by the Board.
They read as follows:

1°: "Whereas taking into consideration International Embryo Transfer Society's (IETS) involvement for nearly 30 years in developing forms and certification resulting in worldwide acceptance of embryo identification and codified in the IETS Manual, therefore The International Embryo Transfer Society's Board of Governors respectfully requests that the Board of directors of International Committee for Animal Recording accept the embryo identification system recommended by IETS;"

2°: "Because the IETS feels that the risk associated with offspring of clones is likely to be less than the SCNT (somatic cell nuclear transfer) clones as supported by data from cloned animals and extensive findings in mouse clones, the IETS recommends that the regulatory agencies consider separately the issue of SCNT clones and progeny of clones"

The next meeting will take place in association with the USAHA conference in Greensboro (USA) in October 2004.

2. The IETS HASAC Regulatory Subcommittee met from 09.10 to 12.30 hrs. 10 January 2004 – Portland, OR, USA -ten members in attendance.

Ten members attending representing research, commercial and regulatory sectors of Australia, Canada, France, India, the Netherlands, United Kingdom and the United States. The absence of members from Brazil and China was noted and regretted.

Issues discussed were:

- **The risk assessment respecting IVF embryos from abattoir derived ovaries** has been stalled, partially due to work pressure of the main author and partly due to the lack of data in particular, disease incidence, viral titers in follicular fluid and cumulus cells, replication rates in culture and maturation phases and infective dose via uterus at eight days post estrus. It was decided to assign the project to someone with risk assessment mathematical skills under the direction of A. Wrathall to develop a risk model regarding IBR and BVD. Large markets are interested in such embryos if they can be produced safely.

- On this topic, a letter prompted discussion of disease transmission in slaughterhouse derived IVF embryos. It is recommended that ovaries be selected from veterinary inspected establishments in which tuberculosis infected carcasses are condemned and destroyed. For other disease risks the OIE guidelines respecting IVF embryos be followed but that disease control programs and their efficacy be considered respecting other diseases such as brucellosis. In the failure of confidence in those programs then testing of washing fluids and degenerate embryos and unfertilized ova is recommended.

Queries such as these are welcomed by the committee.

**OPS labeling and safety issues** will be discussed at the next meeting.

**The following OIE disease appendices** were discussed.

- Maedi-Visna: The OIE recommendations for rams entering semen collection centres is to obtain them from flocks free of clinical and serological evidence of disease for five years. The proposed wording for donor ewes is two years residency in such a flock. It was considered superfluous to require such a residency since no animals may be added except from other flocks of equal status. To accommodate collection of embryos from flocks not free for five years that one year of clinical freedom plus PCR testing of sonicated degenerate embryos and unfertilized ova be undertaken.
Caprine Arthritis Encephalitis: The same as for MV.
Contagious Caprine pleuropneumonia and Rift Valley fever were tabled pending consultation with experts in the disease.
Enzootic abortion of Ewes: this can only be detected reliably by sonification and testing of degenerate embryos and unfertilized ova.
Rinderpest: generated much discussion but due to its placement in Category 3 it was felt that the guidelines for live animals could be adopted for embryos.

Succession planning. It was decided to continue to attempt to broaden the membership of the committee.

3. The IETS HASAC Research Subcommittee met from 14.00 to 17.00 hrs. 10 January 2004 – Portland, OR, USA. Major items of discussion were:

South American FMD project in sheep and goats. A paper in the proceedings of the 106th Annual Meeting of the USAHA on assessing the disease-free transfer of ovine and caprine embryos from FMDV-seropositive or convalescent donors was discussed in some detail. It was concluded that a peer reviewed publication of the results of this study could have an impact in the Categorization of this agent in these species.

Disinfection in dry shippers. In progress evaluation of methods for disinfection of dry shippers was presented by A. Bielanski. He provided original information that some disinfectants could be used effectively to disinfect dry shippers from selected producers of these containers.

Guidelines for disease categorization. The subcommittee initiated a re-evaluation of WCD Hare’s document entitled “Criteria and methodology used by the Research Sub-committee when categorizing infectious diseases with regard to the risk of their transmission through embryo transfer”.

Appearance of research update on IETS homepage. Finally, there was discussion of the need to insert the latest Research Update (2003) on the newly designed IETS Website.

4. The IETS HASAC Forms and Certification Subcommittee met on 10 January 2004 at the Doubletree Hotel, Portland, Ore (USA). The Subcommittee:

- Reviewed modifications to forms made at its last meeting which included adding a place to indicate if sexed semen was used and to indicate if an embryo had been biopsied to determine the sex. No revisions were made to these forms or to the forms to accommodate cloning.

- Reviewed modifications made at its last meeting to the labeling of straws which included codes to show when an embryo was biopsied to determine the sex. Based on feedback, the Subcommittee recommends as an alternative, that straws with biopsied embryos can be labeled DTB (Direct Transfer Biopsied).

- Discussed briefly the possible need to recommend that country codes be shown preceding registration numbers on forms and straws. This will be discussed at the next meeting.
- Discussed preliminary first step toward developing a **record system for transgenics**. Draft forms and possible coding on the straw were reviewed.

- Reviewed the relationship between IETS and National Organizations relating to participation at meetings by representatives of national organizations such as CETA, AETA, etc.

- Received an update on the direction being taken following a recommendation by the Regulatory Subcommittee to establish the practicality of and biosecurity issues relating to the OPS straws.

- **Approved a recommendation** that the IETS Board of Governors send a resolution to the Board of Directors of the International Committee on Animal Recording (ICAR). The resolution requests ICAR to accept the embryo identification system recommended by IETS.

The next meeting will take place at Copenhagen (DK) in January 2005 in association with the IETS annual conference.

5. **The IETS HASAC Food Safety Sub-committee** met in Pettygrove meeting room on January 11, 2004. The sub-committee had the following deliberations:

- A report was presented on the **OECD - INRA sponsored workshop** on “Risk assessment of foods derived from cloned animals” held in Versailles, France in November 2003. Discussions focused on the need to separate clones and their progeny for safety assessments and also to separate the transgenic clones from unmodified clones.

- A Report from **FAO- WHO joint consultation** on Foods derived from GM animals and fish held in Rome, from November 17-21, 2003 was presented. The objective of the consultation was to provide scientific advice to member states on safety assessment of food derived from GM animals. The meeting concluded that there are potential benefits of GM animals but also recognized hazards in form of disease transmission, zoonosis, contamination of food supply with unapproved GM animals, environmental impacts (specifically with transgenic fish), and challenges of post-release detection of transgene. The workshop also recognized the need to adopt the safety criteria set for the GM plants as the basis for evaluation of GM animals and need for post-market surveillance.

- **US FDAs position** on “Food consumption risks associated with animal clones” was presented. The general discussion on harms, hazard and risks was followed by the general principles of risk assessment, risk management and risk communication. Among the highlights of the risk assessment document being developed by Center for Veterinary Medicine (CVM of FDA) are: Foods derived from the clones of different animal species e.g. cattle, goat, swine and sheep were “likely to be as safe as” their conventional comparators, however, more data is needed to substantiate that.

It was mentioned that the risk assessment document will be posted on the web for comments (for 60 days) by mid May (tentatively) and then become a final document after incorporating views by fall of 2004.

- **An update on “Regulation of Biotechnology-derived animals in Canada”** was provided. The acts and regulations guiding the regulations of cloned and transgenic animals were mentioned and the integrated approach by various departments of Government of Canada was highlighted as well as : the definition of Novel Foods and the examples of different categories of novel food; safety assessment criteria set by Health Canada for evaluation of novel foods (e.g.
food derived from cloned animals), based on the WHO, FAO recommendations; the safety evaluation based on molecular characterization, toxicological analysis and nutritional equivalence; an example of novel food evaluation in form of “Enviropigs” evaluation was presented; a traceability tool based on DNA analysis was discussed.

- Categorization of cloned animals and progeny of clones as separate entity was discussed and the recommendation was made to carry forward a resolution through IETS to regulatory agencies as following:

“Because the IETS feels that the risk associated with offspring of clones is likely to be less than the SCNT (Somatic Cell Nuclear Transfer) clones as supported by data from cloned animals and extensive data in mouse clones, the IETS recommends that the regulatory agencies consider separately the issue of SCNT clones and progeny of clones”.

The next meeting will be held in association with IETS annual meeting in Copenhagen in January 2005.