Attachment 2

Stakeholder comments on

***Draft policy review of the bluetongue virus risks associated with the importation of cattle, sheep, goat and deer semen and embryos from the European Union and cattle semen and embryos from Switzerland and Norway,* May 2010**

The Department of Agriculture, Fisheries and Forestry received three submissions from stakeholders on the draft policy review of the biosecurity risks for bluetongue virus (BTV) associated with the importation of cattle, sheep, goat and deer semen and embryos from the European Union (EU), and cattle semen and embryos from Switzerland and Norway, issued on 2 June 2010. These submissions were considered by the department in finalising the policy review.

The Department of Agriculture, Fisheries and Forestry would like to thank those who provided submissions. These were found to be useful and assisted the department in finalising the review.

The issues identified have been included in the following table together with a response on how the issue was considered in the final policy.

Issue 1: Recognition of zoning for BTV	Response
That Australia accepts EU regionalization provisions, by not imposing restrictions related to BTV to semen and embryos from donor animals kept in BTV free countries or zones, for at least 60 days prior to semen or embryos collection, or according to any alternative provision stated on Article 8.3.9 or 8.3.12 of the OIE Terrestrial Animal Health Code. The basis of zoning is a compulsory and transparent monitoring and surveillance program to detect any circulation of any BTV serotype, regardless of the health status of each Member State or Region, as detailed in Annex I of Regulation (EC) No 1266/2007. For example, new serotypes of BTV (1, 6, 11 and Toggenburg Orbivirus) were detected in northern Europe over 2008 and 2009 but in Scandinavian countries those serotypes have not been detected.	The review refers on pages 72-74 to criteria for monitoring and surveillance programs in EC 1266/2007. The Department of Agriculture, Fisheries and Forestry acknowledges developments in monitoring and surveillance required by the EU, as shown by extensive revisions to Annex 1 of this regulation on three occasions (7 November 2008, 10 February 2009 and 28 August 2009). However the review also considers published concerns about the implementation of BT monitoring and surveillance in Europe (pages 28-33 and 43-45). With the exception of Northern Ireland, the EU Member States from which Australia imports the largest quantity of ruminant semen and embryos (the United Kingdom, The Netherlands, France and Germany) are BT restricted zones as defined in EC 2007/1266. Recognition of BT free zones depends on a favourable assessment of a comprehensive dossier by the submitting EU Member State. The department invites submission by EU Member States in accordance with the consensus document SANCO 10157/2005 (Appendix 5 of the review). The 'alternative provision' recommended in Articles 8.3.11 and 8.3.14 of the OIE Terrestrial Animal Health Code, namely that donors were protected from attack from Culicoides for at least 60 days before commencement of, and during, collection are not accepted by the department for the reasons outlined in the review (see below).
Issue 2: Backdating measures	**Response**
Deep frozen semen and embryos are traded sometimes years after collection. With the current proposal it would be impossible to export semen and embryos which have been collected before the BT epidemic.	BTV testing of cattle embryo donors from the EU, Switzerland and Norway is not required for cattle embryos collected prior to 1 May 2006. Prior to 1 May 2006, BTV was identified in several EU Member States around the Mediterranean basin. The Department of Agriculture, Fisheries and Forestry would welcome a submission from individual EU Member States for semen to be eligible for import to Australia if collected prior to 1 May 2006, in accordance with the consensus document SANCO 10157/2005 (Appendix 5 of the review).

Issue 3: Testing for BTV – all serotypes	Response
The EU does not see any justification for the requirement for the whole EU to test for all the 24 serotypes of BTV for donors of semen or embryos to be exported to Australia. In the case of semen, a test proven to be sensitive to the detection the strains circulating in the origin zone should be enough for donors of susceptible species. The same applies for embryo donors other than bovines. In the case of bovine embryos and semen, as Australia is concerned with possible increased risk of BTV8 contamination, a testing method able to detect BTV8 in donor animals should provide enough guarantees.	• The Revised Quarantine Requirements in the review provide an option for group specific BTV tests (pan-reactive PCR assays for BTV). Separate PCRs for each serotype of BTV were not proposed. • The review outlined the reasons for requiring group specific tests which are capable of detecting all 24 serotypes of BTV, namely: the number of BTV serotypes in circulation in EU Member States; uncertainty about the route of introduction of new BTV serotypes into Europe; delays in identification of new serotypes in circulation; the presence of modified live vaccine strains in Europe and their transmission by vectors; evidence of recombination of BTV strains and serotypes in Europe with unknown biological characteristics. The review notes the published recommendations by European researchers to use pan-reactive PCR assays for detection of BTV. • The Department of Agriculture, Fisheries and Forestry agrees that BTV 8 is the serotype of most concern for cattle. However Australia's requirement that cattle semen and embryo donors be tested for all BTV serotypes is retained because of the unexpected emergence and circulation of multiple BTV serotypes, including vaccine strains, in Europe, as outlined in the review. For these reasons pan-reactive PCR assays have been used recently for national surveillance programs by some EU Member States (the United Kingdom and Denmark). • Testing for all BTV serotypes remains for sheep, goat and deer donors of semen and embryos.
Issue 4: Testing for BTV – timing of tests	**Response**
The serological test to detect BTV antibodies after the final semen or embryo collection, can be performed 21 days after collection. Thus, Australia should consider accepting a period for testing between 21 and 60 days, rather than 28 and 60 days, as foreseen on Articles 8.3.11 and 8.3.14 of Chapter 8.3 of the OIE Terrestrial Animal Health Code.	• The review outlined the justification for retaining a period for BT testing between 28 and 60 days (Appendix 6) and includes published data on test sensitivity and specificity on samples collected from the field when BTV is actively spreading.

Issue 5: Vaccines	Response
There is no added value in the reference of vaccines administrated to donors, as either the serological or agent identification testing regime should be enough to provide the necessary guarantees.	• The Department of Agriculture, Fisheries and Forestry will consider evidence demonstrating the safety of vaccines against BTV, including attenuated vaccines, for semen and embryo donors. • Vaccination against BTV, the circulation of vaccine strains in Europe and the safety testing of these vaccines, as detailed in the review, justifies testing semen and embryo donors with serological or agent identification tests that identify all BTV serotypes.
Issue 6: Protection for vector attack	**Response**
There are effective measures able to prevent vector attack to susceptible animals under certain conditions. For example, semen or embryo collection centres often have premises able to provide such guarantees. Thus, Australia should consider as an alternative to testing provisions, donors that are protected from attack from *Culicoides*, likely to be competent BTV vectors, for at least 60 days before commencement of, and during, collection of the semen or embryos, which is in line with the OIE Terrestrial Animal Health Code	• After reviewing the published scientific literature, the review concluded that measures to prevent vector attack were insufficiently effective. • However the Department of Agriculture, Fisheries and Forestry will consider other measures that prevent *Culicoides* vector attack of semen and embryo donors
Issue 7: BTV8 is not a risk for bovine embryos	**Response**
There is no evidence that in-vivo derived, IETS processed, bovine embryos present a risk from BTV-8, even if transplacental transmission is known to occur, none of the BTV8 cases in the EU has so far been traced to embryo transfer…We understand that the OIE is waiting for IETS to opine (hence the safety in relation to BTV-8 is shown as 'under study').	• At the Annual Meeting of the IETS at Cordoba, Argentina in January 2010, the HASAC Research Subcommittee of the Health and Safety Advisory Committee of the IETS reported that 'a further review and a call for further funding and research for BTV8 is desired, even though BTV remains in Category 1' and 'more research is still needed to investigate whether this serotype behaves like other serotypes of BTV in relation to embryos' (Thibier, 2010). The ongoing need for research on this issue was noted at the meeting of the HASAC Research Subcommittee in Orlando, Florida, USA in January 2011. • The Department of Agriculture, Fisheries and Forestry will consider scientific evidence showing that BTV8 should be classed a Category 1 disease. This should include details of transmission trials using embryo transfer with respect to BTV8 in cattle.