



European Medicines Agency
Veterinary Medicines and Inspections

London, 17 March 2008
Doc. Ref. EMEA/123421/2008

**OVERVIEW OF COMMENTS RECEIVED ON
DRAFT GUIDELINE ON THE PROCEDURE TO BE FOLLOWED WHEN A BATCH IS
SUSPECTED TO BE CONTAMINATED WITH BOVINE VIRAL DIARRHOEA (BVD) VIRUS**

Table 1: Organisations that commented on the draft Guideline as released for consultation

	Name of Organisation or individual	Country
1	IFAH-Europe	EU
2	Association of Veterinary Consultants	EU

Table 2: Discussion of comments

GENERAL COMMENTS – OVERVIEW
IFAH Europe: We would like to express our appreciation that so many of the IFAH-Europe remarks to the previous draft version of this guideline (then still proposed as an Annex to Guideline EMEA/CVMP/743/00/Rev.1) have been taken into account. Nevertheless, given the thoroughness of the measurements required by the ‘bovine serum guideline’ (EMA/CVMP/743/00) and bovine serum being the major potential source of BVDV contamination of vaccines, we maintain our opinion that a guideline for a very exceptional case like the one regarded here is not justified and we would have found it more logical if the scope of this guideline had been extended to all cases where a vaccine is suspected to contain a viral or bacterial contaminant. If the guideline is maintained, we propose that the list of references is updated with and the text is adapted to take account of a publication directly relevant to the (non-)significance of the presence of inactivated BVDV in vaccines: <i>Makoschey B, van Gelder PT, Keijsers V, Goovaerts D.</i> <i>Bovine viral diarrhoea virus antigen in foetal calf serum batches and consequences of such contamination for vaccine production.</i> <i>Biologicals.2003 Sep;31(3):203-8.</i> A copy of the article is attached. No further specific comment on the text. The CVMP confirmed its position that it is important to agree on an approach to the confirmation of BVDV contamination, which can be followed and mutual recognised by all the Competent Authorities that are the target audience for this guideline. AVC: The Association of Veterinary Consultants has studied the draft guideline and is of the opinion that it will provide useful guidance. No further comments are thought necessary.