10 September 2015
EMA/CVMP/IWP/342158/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Overview of comments received on 'Guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with bovine viral diarrhoea virus' (EMA/CVMP/IWP/205351/2006-Rev.1)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1	International Animal Health Organisation (IFAH)-Europe

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1. General comments – overview

Stakeholder no.	General comment (if any)	Outcome (if applicable)
1	IFAH-Europe welcomes the opportunity to comment on this draft revised guideline. In line with our comment to lines 75-85 we believe that serious consideration should be given to the continued need for this guideline, given the publication of the Ph. Eur. monograph on bovine serum since the original version of this guideline was published.	

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
75-85	1	**Comment:** Are the examples given still valid today? Since the publication of the Ph. Eur. monograph on bovine serum is it still possible for contamination is present in such high levels in various vaccines to trigger an antibody response in animals? **Proposed change:** Consideration should be given to the possible withdrawal of this guideline if it is no longer necessary.	Partly accepted. Proposal: to keep the GL (in the way it is written today does not pose any major problems, whereas it is still useful in case of contamination which is always possible) and to delete the examples from lines 77 to 85.
101-102	1	**Comment:** For clarity please amend as follows **Proposed change:** "inoculated into **cells** sensitive **to** ~~cells~~, but free of BVDV"	Accepted.