



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 September 2021
EMA/CVMP/IWP/408557/2021
Immunologicals Working Party (IWP)

Overview of comments received on 'Reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of immunological veterinary medicinal products' (EMA/CVMP/IWP/251741/2015 Rev.1-Draft)

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

Stakeholder no.	Name of organisation or individual
1	EGGVP – European Group for Generic Veterinary Products



1. General comments – overview

Stakeholder no.	General comment (if any)	Outcome (if applicable)
<i>(See cover page)</i>		
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2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
	<i>(To be completed by the Agency)</i>		<i>(To be completed by the Agency)</i>
Page 12, table Equine	1	Comments: Regarding the suitability of different cell lines in horses, we would like to report that Equine Herpesvirus EHV-1 and EHV-4 infect the cell lines BS-C-1, RK-13 and Vero. Also Equine Arteritis virus can infect BS-C-1 and RK-13. Proposed change: Add this information to the table	Not accepted. The proposal to add cell lines to detect Equine Herpesvirus EHV-1 and EHV-4 and Equine Arteritis virus is not appropriate. The cell lines mentioned in the table are those that were used by the applicants for the tests performed to control the absence of extraneous agents and presented in the corresponding marketing authorisation (MA) dossier. The scientific validity of the proposal is not questioned but the table reflects the content of the MA dossiers that were considered valid by the competent authorities.