



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 March 2022
EMA/CVMP/SWP/10941/2022
Committee for Veterinary Medicinal Products (CVMP)

Overview of comments received on Guideline on determination of withdrawal periods for milk (EMA/CVMP/SWP/10941/2022)

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

Stakeholder no.	Name of organisation or individual
1	AnimalhealthEurope



1. General comments – overview

Stakeholder no.	General comment (if any)	Outcome (if applicable)
1	AnimalhealthEurope welcomes the opportunity to comment on this draft revised guideline and only has minor comments below.	The stakeholder is thanked for their comments.

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Line 132	1	<p>Comment: The consistently used term in the GL is (and should be) "milk withdrawal period" but not "milk discard time"</p> <p>Proposed change: Please replace "milk discard time" by "milk withdrawal period".</p>	Accepted and implemented. See final version.
Line 135-142	1	<p>Comment: Explanation of the difference between tolerance limit and prediction limit is difficult to understand for individuals not experienced in statistics. For example, what is the meaning of 100q % or 100p %?</p> <p>Proposed change: Please provide an explanation that is easier to understand.</p> <ul style="list-style-type: none"> • Tolerance interval covers a proportion of the population distribution. • Prediction interval quantifies the uncertainty for a single predicted value. • Confidence interval quantifies the uncertainty of a population parameter such as a mean. 	Partially accepted. A new wording/explanation is proposed. See final version
Line 179-194	1	<p>Comment: There is an intense statistical elaboration on low and high yielding cattle but specific guidance for the choice of the animals is rather limited.</p> <p>Proposed change: If possible, the CVMP expectations regarding inclusion of low and high yield cattle should be defined more precisely to avoid uncertainties regarding "representative sample of animals".</p>	Not accepted. As this revision is only to update the definition of withdrawal periods according to Regulation (EU) 2019/6, no new scientific content will be included. However, the comment will be taken into account for the next scientific revision of the guideline. Further on, information about study design is given in VICH guideline 48 (EMA/CVMP/VICH/463199/2009)
Line 228-229	1	<p>Comment: "... note for guidance ..." needs to be updated because the present draft is / will be a guideline.</p>	The stakeholder is thanked for their suggestion. See final version.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		Proposed change: Please replace "note for guidance" by "guideline"	
Line 258-260	1	Comment: Please rephrase the sentence because it is a difficult construction for non-native speakers to understand: "... to the time point at and where after 95% of the population ..." Proposed change: -	Accepted. A modified wording is proposed. See final version
Line 260	1	Comment: Please add a full stop (".") after MRL. Proposed change: see above	Accepted. See final version.