



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 March 2017
EMA/CVMP/ERA/8138/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Overview of comments received on 'Guideline on the plant testing strategy for veterinary medicinal products' (EMA/CVMP/ERA/689041/2015)

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

Stakeholder no.	Name of organisation or individual
1.	ECT Oekotoxikologie GmbH
2.	IFAH-Europe



1. General comments – overview

Stakeholder no.	General comment (if any)	Outcome (if applicable)
2.	IFAH-Europe welcomes the opportunity to comment on this draft guideline.	Thank you for your comment.

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Chapter 2.1, Line 68	1.	<p>Comment: Please add the term: ..."including a Brassica species"..... Proposed change (if any):</p> <p>It is highly recommended to use species belonging to six different families of four dicotyledonous including a Brassica species.....</p>	Accepted.
99-102	2.	<p>Comment: Need for clarification. Should the additional study be conducted only with the two new species or should the study be repeated with the two new species and the six species already tested. Proposed change:</p>	Proposed modification: "To better reflect the variety of plant species and to improve the statistical power of the SSD, two additional new species – preferably from two additional plant families- should be tested and used in the SSD calculation in combination with the six species/families tested in Tier B.
Chapter 3.1, Line 119	1.	<p>Comment: Replace the words "three" and "five" by "two" and "six" because two monocotyledonous and nine dicotyledonous species are listed in Annex 2 Proposed change (if any): A minimum number of two monocotyledonous and six dicotyledonous plant species should be included.</p>	Accepted.
122-124	2.	<p>Comment: In cases where EC₁₀ and NOEC are reported as ">" value, the "greater than" can be replaced by "equal to". In doing so, the respective species can be included in the SSD, conservatively overestimating the toxicity. This would be of benefit as the SSD will be more reliable if more species are included. Proposed change:</p>	Partly supported with some amendments: "In general only definite EC ₁₀ or NOEC values (excluding < and > values) should be used in the SSD calculation, with one exception: A < or > value can be included (without < or > sign) in the SSD if it is outside the range of all other available EC ₁₀ /NOEC values for plant species. If < or > values are included in

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177-179	2.	<p>Comment: This statement is not necessarily true: manure will be stored prior to application, and as such, degradation in manure is relevant and should be considered for PEC-refinement.</p> <p>Proposed change: please amend accordingly</p>	<p>an SSD, this should always clearly justified.”</p> <p>Not accepted. Degradation in manure occurs in the test system and is thus factored in in the result of the extended plant test. Therefore, it cannot be additionally considered in the PEC refinement because this would be a duplicate refinement for the same process.</p>
Annex 1, Line 226	1.	<p>Comment: Please replace “Standard operating procedure on test design...” by “Guidance on test design.....”</p> <p>Proposed change (if any): Guidance on test design.....</p>	Accepted.
229	2.	<p>Comment: Cattle manure may not be stored in tanks but in stockpiles. Accordingly, obtaining liquid manure may be challenging and limiting to liquid manure may not represent the manure type usually occurring.</p> <p>Proposed change: please amend accordingly</p>	<p>Not accepted. It is acknowledged that dung is partly stored in stockpiles. However, according to literature research the more relevant storage type is liquid manure (Weinfurtner, 2010). As it is very common, specific difficulties in obtaining manure are not to be expected. Therefore, in this test only liquid manure from tanks above or below ground should be used.</p>