



**PUBLIC CONSULTATION AT STEP 4 OF THE VICH
PROCEDURE
OVERVIEW OF COMMENTS RECEIVED**

**VICH draft Guideline: GL20 Efficacy of Anthelmintics: Specific
recommendations for felines.**

VICH EWG: ANTHELMINTICS

Name & Country of individual, organisation, or VICH delegation that commented

Comment n°	Name - Country
1	World Association for the Advancement of Veterinary Parasitology (WAAVP) through EMA
2	New Zealand's Agricultural Compounds and Veterinary Medicines (ACVM)

Discussion of comments

GENERAL COMMENTS – OVERVIEW		
Comment N°	Comment received	Outcome of consideration
1-1	<p>This guideline lacks the appropriate scientific citations throughout, which should be remedied.</p> <p>The list of parasites information is given on varies, e.g. in Table 1 <i>Physaloptera</i> and other nematodes mentioned e.g. line 200 is not mentioned, nor are the tapeworms. Parasite names must be spelled out at first mentioning, and abbreviated later.</p> <p>The guideline should be adapted to show which helminths are under consideration, and if Table 1 is only for roundworms this should be mentioned (line 123, Table header).</p>	<p>For the first point, the EWG intended to update references currently in the guideline if they were available by the time of final publication. This would include the updated WAAVP guideline for dogs and cats. Because the EWG was tasked with updating only certain topics/sections in the guidelines, it would not be possible (and is out of scope for the EWG) to support all sections of the GLs with scientific citations. For the second point, the EWG agrees with only using the abbreviation after first spelling out the full parasite name. Finally, WAAVP is correct that not all parasites discussed in Section 4.4 (Label claims) are addressed in Section A.3, which provides the number of infective parasitic forms recommended for induced infections. Table 1 was outside the scope of the review of the EWG and does not only include roundworms. WAAVP's point is appreciated and the addition of other parasites to Table 1 should be considered in future revisions of the guideline.</p>

SPECIFIC COMMENTS ON THE TEXT OF THE GUIDELINE

SECTION			
Line No.	Comment N°	Comment received and rationale; proposed change	Outcome of consideration
74-75	1-2	<p>Comment: The cited guideline is outdated.</p> <p>Proposed change (if any): Change citation to "World Association for the Advancement of Veterinary Parasitology (WAAVP): Second edition of</p>	<p>Thank you for your comment. The EWG intended to update references if they were available by the time of publication. This citation has been revised to reference the 2022 version of the WAAVP guideline.</p>

SECTION			
Line No.	Comment N°	Comment received and rationale; proposed change	Outcome of consideration
		guideline for evaluating the efficacy of anthelmintics for dogs and cats", Vet. Parasitol. 2022; 312, 109815; doi: 10.1016/j.vetpar.2022.109815.	
80	1-3	<p>Comment: Effectiveness and efficacy are used as synonyms. According to the EMA document "https://www.ema.europa.eu/en/documents/presentation/presentation-efficacy-effectiveness-models_en.pdf" these are two different things. The guidelines are always only concerned with efficacy, not with effectiveness.</p> <p>Proposed change (if any): The term "effectiveness" should be replaced by "efficacy" for consistency throughout.</p>	The EWG acknowledges the differences between effectiveness and efficacy identified by WAAVP and described in the EMA document. During review of the VICH GL, the EWG noted that the previously published guidelines did not use the terminology consistently in the text; and glossary definitions provided in the General Guideline (GL7) may not reflect current thinking. However, this topic was out of scope for the EWG. The EWG discussed the possibility of changing all terms to "efficacy" for consistency throughout the document and did not agree unanimously to this approach. The EWG agrees this topic should be considered in a future revision.
113, 200	1-4	<p>Comment: <i>Capillaria aerophile</i> is wrong; besides, there is a synonym of species now used more frequently in publications than this name.</p> <p>Proposed change (if any): change to "<i>Capillaria aerophila</i>" and mention "(syn. <i>Eucoleus aerophilus</i>)" at first mentioning</p> <p>Comment: The table lacks scientific citations.</p> <p>Proposed change (if any): Add relevant scientific citations.</p>	The EWG believes "aerophile" is a typographical error (specifically due to autocorrect) and agrees to use the appropriate name. However, it would be appropriate to update the name of the species at this time as well. The EWG agrees with the proposed edit.
125-129 (Table 1)	1-5	<p>Comment: The table lacks scientific citations.</p> <p>Proposed change (if any): Add relevant scientific citations.</p>	This is a helpful suggestion; however, the EWG was not tasked with reviewing, updating, or providing clarification on Table 1. There were no citations for this table in the original GL and none were added as this was not part of the EWG mandate.

SECTION			
Line No.	Comment N°	Comment received and rationale; proposed change	Outcome of consideration
Section 4.1	2-1	For the following point. Can you please clarify if this requirement pertains to field effectiveness? “Effectiveness against helminths will be evaluated examining for the presence or absence of parasitic elements in faecal material or blood.”	This comment refers to Section 4.1, d. The EWG did not add this or update this language from the previous version of the GL; however, recognizes the question. The EWG added "In field studies," to the beginning of the sentence to improve clarity.
163-169	1-6	Comment: "several studies... could be pooled to accumulate 12 animals". This statement is very loose and needs precise clarification regarding under which criteria data from different studies can be pooled. How many are "several studies? Therefore, how many could be pooled? What is the rationale for pooling said studies? Locality? Time? Testing official lab? As stated, it might be construed in different, wrong ways. Proposed change (if any): Provide detailed information to answer the questions above.	The EWG agrees that the description of pooling procedures in Section 4.2 is not clear and may be open to various interpretations. However, because this topic/section is not part of the EWG charge, no revision to the guidance were made. We suggest that this topic is considered for revision in the future.
176-177	1-7	Comment: 5 nematodes is considered an adequate infection. Proposed change (if any): Revise the number and/or include valid scientific citations to back up this number.	The minimum adequacy of infection numbers are based on combined information from literature and from regulatory studies. The EWG agreed to add a footnote in Section 4.3 which states that "the recommended minimum numbers are based on a review of published literature and data from studies submitted for regulatory review". The EWG also acknowledges that providing citations could be beneficial and is consistent with good scientific practice; however, published information would not provide complete information in this situation because in most cases, experience from controlled regulatory studies were a primary factor in the determination of the minimum number.
205-207 (Table 2)	1-8	Comment: The table lacks scientific citations. Proposed change (if any): Add relevant scientific citations.	The EWG was not tasked with reviewing, updating, or providing clarification on Table 2. No edits were made to this table in the EWG revision except for minor formatting changes.