



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

**VICH draft Guideline: GL21 Efficacy of Anthelmintics: specific
recommendations for chickens (*Gallus gallus*).**

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

Discussion of comments

GENERAL COMMENTS – OVERVIEW		
Comment N°	Comment received	Outcome of consideration
1-1	This guideline lacks the appropriate scientific citations throughout, which should be remedied.	The EWG intends to update references currently in the guideline if they are available by the time of final publication. This includes the updated WAAVP guideline for poultry published in 2022. 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.

SPECIFIC COMMENTS ON THE TEXT OF THE GUIDELINE

SECTION			
Line No.	Comment N°	Comment received and rationale; proposed change	Outcome of consideration
Title	1-2	Comment: "gallus gallus" is wrongly written. Proposed change (if any): Change to "Gallus gallus"	The EWG agreed that this revision is acceptable and made the edit.
75-76	1-3	Comment: The cited guideline is outdated. Proposed change (if any): Change citation to "World Association for the Advancement of Veterinary Parasitology (WAAVP): Second edition of guideline for evaluating the efficacy of anthelmintics in poultry", Vet. Parasitol. 2022; 305, 109711; doi: 10.1016/j.vetpar.2022.109711	The EWG agreed and the citation was updated.

SECTION			
Line No.	Comment N°	Comment received and rationale; proposed change	Outcome of consideration
83	1-4	<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>	<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.</p>
114-115	1-5	<p>Comment:</p> <p>a) The table lacks scientific citations. b) hyphenation (under "range") is inconsistent</p> <p>Proposed change (if any):</p> <p>a) Add relevant scientific citations. b) hyphens should be used with or without space consistently.</p>	<p>Table 1 is outside the scope of the EWG charge and was not reviewed/discussed. There were no citations in the original GL. For comment b, the EWG agreed that spacing on hyphens should be corrected. For consistency with other GLs, EWG added a space before and after the hyphen.</p>
119	1-6	<p>Comment: What is a young bird?</p> <p>Proposed change (if any): Definition of "young bird" needs to be added.</p>	<p>The EWG agreed that factor could be discussed and defined (or revised) as necessary. However, this comment is outside the scope of the EWG tasks/mandate. The EWG recommends that this topic be considered in future reviews of the guideline.</p>

SECTION			
Line No.	Comment N°	Comment received and rationale; proposed change	Outcome of consideration
164	1-7	<p>Comment: 20 <i>A. galli</i> is considered an adequate infection.</p> <p>Proposed change (if any): Revise the number and/or include valid scientific citations to back up this number.</p>	<p>The minimum adequacy of infection numbers are based on combined information from literature and from regulatory studies. The EWG added a footnote applying to the whole section which states that "the recommended minimum numbers are based on a review of published literature and data from studies submitted for regulatory review".</p> <p>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. Finally, the EWG noted that the most recent 2022 version of the WAAVP guideline for poultry did not provide a definition of adequacy of infection for <i>A. galli</i>.</p>
166	1-8	<p>Comment: "within 10 days of treatment" is incorrect..</p> <p>Proposed change (if any): change to "within 10 days after treatment", and specify that this includes the end of treatment over several days.</p>	<p>The statement under consideration is from Section A.4.3 and states, "Necropsies should be conducted within 10 days of treatment." The EWG agreed that a minor editorial change to revise the sentence to read, "Necropsies should be conducted within 10 days after treatment." was acceptable. The EWG determined that an additional statement specifying that this is meant to encompass the end of treatment over several days was not necessary.</p>