

# Guide for WOAH Members and International Organisations on submitting comments during the *Process for the elaboration of WOAH International Standards*

WOAH has developed a Standard Operating Procedure (SOP) for the submission of comments by WOAH Members and International Organisations with a cooperation agreement with WOAH (IOs) during the *Process for the elaboration of WOAH International Standards*. Its purpose is to improve the transparency, documentation, and traceability of the process for receiving and responding to comments submitted by WOAH Members and IOs on the work to develop and review WOAH Standards. The SOP also describes the roles and responsibilities of WOAH Members and International Organisations, Specialist Commissions, subject-matter experts, and WOAH Headquarters, during the process.

This document should be read in conjunction with the SOP and provides guidance for Members and IOs on how to submit and present comments for consideration by WOAH Specialist Commissions.

#### The process for the elaboration of WOAH International Standards

Every year the WOAH World Assembly adopts new or revised International Standards at the General Session. The standards proposed for adoption are the result of comprehensive work undertaken by WOAH Specialist Commissions, with the support of subject-matter experts and the WOAH Secretariat.

Members and IOs play a key role in the process of developing new or revising existing standards.

Members and IOs are also encouraged to submit comments on the work plan of the Specialist Commissions to develop or review standards, which are presented in the meeting reports of the Specialist Commissions.

The Specialist Commission meeting reports include a main section that documents discussions and conclusions reached during a specific Specialist Commission meeting. In addition, the reports also include a series of annexes, each of which presents a proposed new or revised standard that is circulated for comment. The reports are published in the three WOAH official languages (English, French and Spanish) and include links to other relevant reports, such as other Specialist Commissions, Working Groups, and *ad hoc* Groups. The Specialist Commission reports are published on the <u>WOAH website</u> and on the <u>Delegates website</u>. These documents are available in MS Word format (".doc") on the Delegates website to facilitate the commenting process; IOs can request them from the Secretariat (email specified below).

Specialist Commission reports are published twice a year after the Specialist Commission meetings, which are held in February and September.

Proposed new or revised standards are circulated for comment in the respective Specialist Commission reports as follows:

- the Aquatic Animal Health Standards Commission (AAHSC) for the *Aquatic Code* and *Aquatic Manual*;
- the Biological Standards Commission (BSC) for the *Terrestrial Manual*;
- the Terrestrial Animal Health Standards Commission (TAHSC) for the Terrestrial Code.

Members and IOs are encouraged to participate in the WOAH Standards-setting process by submitting comments on the circulated new or revised standards. The responsible Commission's response to comments or proposals considered is documented in the relevant Specialist Commission meeting report.

The reports of the Scientific Commission for Animal Diseases (SCAD) is not intended for comment but usually document elements that should be considered together with the report of the TAHSC.

#### Commenting during the Process for the elaboration of WOAH International Standards

#### What is 'commenting'?

'Commenting' is the specific mechanism for Members and IOs to express their opinions on Specialist Commissions' work to develop new or revise WOAH Standards (as presented in the Specialist Commissions' reports) before they are proposed for adoption at a General Session.

#### Who can comment?

Comments can only be submitted by WOAH Members, through their WOAH Delegate, and IOs with which WOAH has a cooperation agreement.

#### What to comment on?

WOAH Delegates and IOs can comment on all items of interest in a Specialist Commission's report (either in the body of the report or in the annexes) or only on those items deemed relevant to their national context.

#### Members and IOs can:

- request new work to be undertaken;
- support or object to work items in a Specialist Commission work programme;
- comment on the priority of work items in a Specialist Commission work programme;
- raise points of interest for work items in a Specialist Commission work programme and provide information, evidence or expertise that could be taken into consideration for the development of the work (especially for ones that have not yet started or are in preparation);
- review and contribute to the development of proposed texts circulated for comment, by:
  - proposing amendments to incorporate new or additional evidence that supports the proposed amendments; or
  - suggesting additional or alternative science-based provisions to improve or complement a proposed text;
  - proposing amendments to a proposed text to address evidence-based concerns on potential challenges for their implementation under specific conditions or contexts (e.g. Members, regions, species);
  - proposing amendments to address wording issues that could compromise the understanding or the meaning of the texts, in any of the three languages.

#### When to comment?

Members and IOs must submit comments before the deadline indicated in the published report of the AAHSC, the TAHSC or the BSC, respectively.

Delegates are encouraged to involve national experts, as well as the relevant WOAH National Focal Points in the consideration of the Specialist Commissions reports, to support him/her in the preparation of the national comments.

Delegates are also strongly encouraged to undertake a consultation with relevant stakeholders (e.g. private sector, NGOs, and other governmental organisations) relevant to their national context.

#### How to present comments?

WOAH Delegates and IOs should prepare, format, and submit comments as per guidance provided in this document as follows:

- If comments refer to a **work programme** or **items documented in the report that do not include annexes** in a Specialist Commission report, follow guidance provided in <u>Section 1</u>;
- If comments refer to a **proposed new or revised text** that was **circulated** for comment in a Specialist Commission report, follow guidance provided in <u>Section 2</u>.

#### How to submit comments?

Comments should be submitted by email to the Secretariat of the responsible Specialist Commission, as provided in the relevant Specialist Commission report, as follows:

- Aquatic Code and Aquatic Manual (AAHSC) <u>AAC.Secretariat@woah.org</u>
- Terrestrial Code (TAHSC) <u>TCC.Secretariat@woah.org</u>
- Terrestrial Manual (BSC) <u>BSC.Secretariat@woah.org</u>

All comments addressed to one Specialist Commission should be included in a single email containing all relevant files.

Files must be sent in MS Word (.doc) format.

If convenient, files could be grouped into one compressed file (.ZIP).

#### Section 1

### Commenting on the work programme or items documented in the report that do not include annexes

WOAH Delegates and IOs should follow the processes described below and submit comments using Form A to comment on the Specialist Commission work programme or items documented in the report that do not include annexes.

In addition, consider the following:

#### 1) How to prepare to comment

WOAH Delegates and IOs should identify the items of interest either in the body of the report or in the annex on the work programme.

Before preparing comments, it is important to read the details provided in the body of the relevant Specialist Commission report, for topics of interest.

The Specialist Commission reports also include detailed information about previous discussions and other relevant reports (e.g. other Specialist Commissions, WOAH *ad hoc* Groups or Working Groups) that should also be considered when preparing comments, to ensure the relevant context into account and to avoid repeating previous discussions.

#### 2) Preparing the file

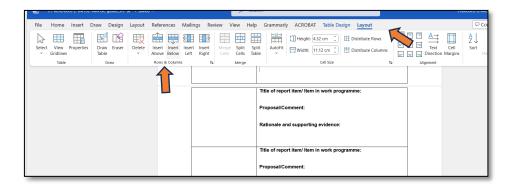
One single file should contain all comments submitted by a Member or IOs.

Before drafting the comments, copy and paste Form A into a MS Word file (.doc).

In the second line of the table, indicate the name of the Member or IO submitting the comments, the Specialist Commission, the report being commented on (February or September), and the year. If the comment is submitted on behalf of several Members, this should be explicitly mentioned for each relevant comment.

Name the file using the following code: [Member/IO name]\_[report: Sept or Feb]\_[year] (e.g. Canada\_Feb\_2023), and save the file.

If the comments are more than three, you may add new rows at the end of the table. For that, click inside the last cell of the table, and, on the 'Layout' tab, click 'Insert Below' in the 'Rows and Columns' group.



#### 3) Presenting the comments

For each comment, the following parts must be provided in the table.

#### a) Title of the Item in the report or Item in the work programme annex

Each comment should specify the specific item (title and number) to which the comment refers:

- if the comments are on a part of the report, for which there is no annex, include the item number and the title of the item as presented in the report;
- if the comments refer to the work programme, include the name of the chapter/title/work as noted in the work programme itself;
- if the comment requests/proposes a new work that is not included in the work programme, it is not necessary to populate this part.

#### b) Proposal or comment

The proposal or comment should be clearly explained in less than 100 words.

These should include a clear suggestion or request to the responsible Specialist Commission.

WOAH Delegates and IOs can use the form A to:

- · request new work to be undertaken;
- support or object to work items in a Specialist Commission work programme;
- comment on the priority of work items in a Specialist Commission work programme;
- raise points of interest for work items in a Specialist Commission work programme and provide information, evidence or expertise that could be taken into consideration for the development of the work (especially for ones that have not yet started or are in preparation);

#### c) <u>Rationale</u>

Members and IOs must explain the rationale to support their proposal/comment.

Each comment should be supported by a brief, but clear, explanation of the reasoning or justification for the proposal being made, in less than 200 words. The rationale should take into consideration the relevant background for the work (e.g. AHG reports, previous SC reports), and include references to documented evidence when relevant.

#### d) Supporting evidence

Where relevant to support the rationale, documented evidence should be provided in the box itself. This could be scientific references, evidenced-based reports, or national and international situation reports.

In all cases, Members and IOs are encouraged to:

- provide accessible links to the documents; or
- insert the documents (PDF files) to this part (i.e. using MS Word, from the ribbon you may find: "Insert>Text>Object>Create from file". Then browse the file of interest, use "Display as an icon" and validate with "ok").

An example of how to present comments can be found in **Appendix I**.

	FORM A	
COMMENTS ON THE WORK PROGRAMME OR ITEMS DOCUMENTED IN THE REPORT THAT DO NOT INCLUDE ANNEXES		
Name of Member or IO:	Commission report and date of report:	
	Title of the item in the report or item in the work programme annex:	
	Proposal/Comment:	
	Rationale:	
	Supporting evidence, if relevant:	
	Title of the item in the report or item in the work programme annex:	
	Proposal/Comment:	
	Rationale:	
	Supporting evidence, if relevant:	
	Title of the item in the report or item in the work programme annex:	
	Proposal/Comment:	
	Rationale:	
	Supporting evidence, if relevant:	
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#### Section 2

#### Commenting on new or revised standards circulated for comment as annexes

WOAH Delegates and IOs should follow the processes described below and use the following form to comment on new or revised standards circulated for comment as annexes.

NOTE: Comments not respecting this guidance may not be taken into consideration by the Specialist Commission.

In addition, consider the following:

#### 1) How to prepare to comment

WOAH Delegates and IOs should identify the subjects of interest in the main body of the Specialist Commission report and the corresponding annexes.

Before preparing specific comments, it is important to read the full body of the report, with a special focus on the specific parts of the topics of interest.

The Specialist Commission reports include detailed information on previous discussions and associated reports that should also be considered when preparing comments, to ensure the relevant context into account and to avoid repeating previous discussions.

#### 2) Preparing the files

Once the items of interest have been selected, WOAH Delegates can download the relevant annexes in Word format from the WOAH Delegates Website. If IOs with a cooperation agreement need the files in this format, please contact the WOAH Secretariat.

One single file per annex should contain all comments from a given Member/IO. If some comments are submitted on behalf of several Members, this should be explicitly mentioned for each relevant comment.

#### 3) Presenting the comments

Comments should be grouped by annex. All comments from a submitter on an annex must be included 'inside' the relevant annex (in MS Word format).

Comments should be submitted in English, French, or Spanish.

Each comment should be made in using a double-column table ('comment table'). <u>Members and IOs must insert each table containing a comment on the text just below the paragraph under consideration.</u> If the comment pertains to an entire chapter or multiple sections within a chapter, it should be positioned at the beginning of the respective annex.

Each 'comment table' must contain the following:

- In the left column, the name of the Member or IOs submitting the comment. If the comment is submitted on behalf of several Members, this should be explicitly mentioned for each relevant comment.
- In the right column, the comment, which should include all the elements described below (comment category, suggested alternative text (or precise suggested deletion), and rationale and supporting evidence).

The "comment table" must follow the format presented below (this table can be copied and pasted into the working file):

Name of Member or IO	Category (addition, deletion, change, editorial, general):
	Proposed amended text (or precise suggested deletion):
	Rationale:
	Supporting evidence, if relevant (e.g. scientific references, national and international reports, tangible experiences in this regard attached to this table)

Comments should <u>only</u> refer to the text proposed in the annex. Comments should not be submitted on comments previously addressed by the Commission unless additional supporting evidence is provided.

Comments must not mention other Members comments and should not name other Member and territories.

For each comment, the table must contain the following elements:

#### a) Comment category

Only the following categories should be used:

- Addition: when proposing to add new content
- **Deletion**: when proposing to remove proposed content;
- **Change**: when proposing to modify the proposed content (meaning);
- **Editorial**: when proposing to address formatting issues and to improve language, including translation without altering the meaning of the proposed content;
- **General Comment:** in this category, the table should be positioned at the beginning of the annex and the comment should be on the whole text, rather than focusing solely on a specific paragraph.

Members and IOs are responsible for categorising each comment submitted to facilitate the Specialist Commission's understanding of the comment.

#### b) Proposed amended text

Members and IOs must suggest an alternative text that would address their concerns. To this end, Members and IOs should include the relevant word or phrase of the original text circulated for comment and use a blue font to show the proposed alternative text.

DO NOT use the automatic 'track-changes' function in MS Word.

Apply strikethrough formatting to indicate suggested deletions.

Apply <u>double underline</u> to proposed additions. Do not use the highlight feature for suggested new text, but instead, use <u>blue font</u>. (NB: these elements are found in MS Word in font settings).

#### c) Rationale

Members and IOs must explain the rationale to support their proposal/comment.

Each comment should be supported by a brief, but clear, explanation of the reasoning or justification for the proposal being made, in less than 200 words. The rationale should take into consideration the relevant background for the work (e.g. AHG reports, previous SC reports), and include references to documented evidence when relevant.

#### d) Supporting evidence

Where relevant to support the rationale, documented evidence should be provided in the "comment table". This could be scientific references, evidenced-based reports, or national and international situation reports.

In all cases, Members and IOs are encouraged to:

- · provide accessible links to the documents; or
- insert the documents (PDF files) into the "<u>Supporting evidence"</u> section. When using MS Word, in "the ribbon" you may find: "Insert>Text>Object>Create from file". Then browse the file of interest, use "Display as an icon" and validate with "ok".

Examples of how to present comments can be found in **Appendix II**.

#### **APPENDIX I**

#### **EXAMPLE: Comments from 'Wonderland'**

FORM A	
COMMENTS ON THE WORK PROGRAMME OR ITEMS DOCUMENTED IN THE REPORT THAT DO NOT INCLUDE ANNEXES	
Wonderland	Code Commission September 2022
	Title of the item in the report or item in the work programme annex:
	Work programme: revision of Chapter 14.8. Scrapie.
	Proposal/Comment:
	Wonderland further encourages WOAH to request that the <i>ad hoc</i> Group of experts further consider the use of genetic resistance and/or live animal testing as valid methods for allowing the safe trade of sheep and goats between countries.
	Rationale:
	The scientific evidence (see references below) supports other methods to mitigate risk and prevent spread of scrapie:
	<ol> <li>González L, Pitarch JL, Martin S, Thurston L, Simmons H, Acín C, Jeffrey M. Influence of polymorphisms in the prion protein gene on the pathogenesis and neuropathological phenotype of sheep scrapie after oral infection. J Comp Pathol. 2014 Jan;150(1):57-70. doi: 10.1016/j.jcpa.2013.10.001. Epub 2013 Oct 10. PMID: 24342584.</li> </ol>
	2. Jeffrey M, Martin S, Chianini F, Eaton S, Dagleish MP, González L. Incidence of infection in Prnp ARR/ARR sheep following experimental inoculation with or natural exposure to classical scrapie. PLoS One. 2014 Mar 10;9(3):e91026.
	3. McIntyre KM, Gubbins S, Goldmann W, Hunter N, Baylis M (2008) Epidemiological characteristics of classical scrapie outbreaks in 30 sheep flocks in the United Kingdom. PLoS One 3(12): e3994.
	4. Dennis MM, Thomsen BV, Marshall KL, Hall SM, Wagner BA, Salman MD, Norden DK, Gaiser C, Sutton DL. Evaluation of immunohistochemical detection of prion protein in rectoanal mucosa-associated lymphoid tissue for diagnosis of scrapie in sheep. Am J Vet Res. 2009 Jan;70(1):63-72.
	Supporting evidence:
	PDF PDF A
	Title of the item in the report or Item in the work programme annex:
	Work programme: revision of Chapter 8.10. Japanese encephalitis.
	Proposal/Comment:
	Wonderland requests that this work item be changed to a Priority 1 for review.

Rationale: considering recent disease events. Supporting evidence: <u>Japanese encephalitis - WOAH - World Organisation for Animal Health</u> Title of the item in the report or Item in the work programme annex: Work programme - New proposal. **Proposal/Comment:** Wonderland request the Code Commission to consider reviewing Chapter 10.2. Avian infectious bronchitis, particularly Article 10.2.3. Rationale: As currently presented, the article is not clear as whether the provisions in the article are alternative or complementary, and consequently it is not clear on how the measures should be applied in the case of vaccinated populations. This lack of clarity is causing problems to agree measures for international trade with trading partners. Supporting evidence: not relevant. Title of the item in the report or Item in the work programme annex: Report – Item 4.2.5. New chapter on Biosecurity **Proposal/Comment:** Wonderland fully supports the decision of the Code Commission to develop a new Chapter on Biosecurity and supports the approach proposed by the AHG. Wonderland would like to emphasise the need for this work to take into consideration the risks posed by arthropod vectors and the importance on ensuring that biosecurity plans take them into consideration. Similarly, the importance of biosecurity to protect the health of personnel and human populations should be duly covered. Rationale: see attached supporting evidence. Supporting evidence: PDF

#### **APPENDIX II**

#### **EXAMPLE A: Comments from 'Wonderland'**

#### CHAPTER 11.4.

#### INFECTION WITH MARTEILIA REFRINGENS

Wonderland	Category: General
	Proposed amended text: not suitable.
	Rationale: Wonderland fully support the proposed changes to this Chapter since were needed.
	Supporting evidence: not relevant

#### Article 11.4.1.

For the purposes of the Aquatic Code, infection with Marteilia refringens means infection with <u>the pathogenic</u> <u>agent M. refringens of the Family Marteiliidae.</u>

Wonderland	Category: Addition
	<b>Proposed amended text:</b> For the purposes of the <i>Aquatic Code</i> , infection with <i>Marteilia refringens</i> means <i>infection</i> with the <i>pathogenic agent</i> M. refringens and M. pararefringens of the Family Marteiliidae.
	<b>Rationale:</b> It needs to be clear that this includes all forms of <i>Marteilia refringens</i> , whether this is the O and M type or other forms such as the more recently proposed new species of <i>M. pararefringens</i> ( <i>Marteilia pararefringens</i> Kerr R <i>et al</i> (2018)), a species that infects the Blue mussel ( <i>Mytilus edulis</i> Kerr <i>et al.</i> , 2018).
	Supporting evidence:
	PDF PDF Kerr 2018 2.pdf Kerr 2018.pdf
	Ken 2010_2,par

 $Information \ on \ methods \ for \ \textit{diagnosis} \ is \ provided \ in \ the \ \textit{Aquatic Manual}.$ 

#### Article 11.4.2.

#### Scope

The recommendations in this chapter apply to: <u>blue mussel (Mytilus edulis)</u>, <u>dwarf oyster (Ostrea stentina)</u>, European flat oyster (Ostrea edulis), <u>European razor clam (Solen marginatus)</u>, <u>golden mussel (Xenostrobus securis)</u>, <u>Australian mud oyster (Ostrea angasi)</u>, <u>Argentinean oyster (Ostrea puelchana)</u>, <u>Chilean flat oyster (Ostrea ehilensis)</u>, <u>blue mussel (Mytilus edulis) and Mediterranean mussel (Mytilus galloprovincialis) and striped venus (Chamelea gallina)</u>. These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

Wonderland	Category: Editorial	
	Proposed amended text: (Ostrea stentina), European flat oyster	
	and striped venus clam (Chamelea gallina).	
	Rationale: Insertion of "clam" is required here as it is part of the common name for Chamelea gallina.	
	Supporting evidence: not relevant	

[...]

#### **EXEMPLE B: Comments from 'Wonderland'**

CAPÍTULO 11.10.

## INFECTION WITH THEILERIA ANNULATA, T. ORIENTALIS AND T. PARVA

Article 11.10.1.

#### **General provisions**

Animals susceptible to infection with Theileria are bovines (Bos indicus, B. taurus and B. grunniens), water buffaloes (Bubalus bubalis), African buffaloes (Syncerus caffer), sheep (Ovis aries), goats (Capra hircus), camels (CamelCamelus dromedarius and C. bactrianus) and some wild ruminants.

Wonderland	Category: Editorial
	Proposed amended text:
	Animals susceptible to infection with Theileria are bovines (Bos indicus, B. taurus and B. grunniens), water buffaloes (Bubalus bubalis), and African buffaloes (Syncerus caffer), sheep (Ovis aries), goats (Capra hircus), camels (Camel dromedarius and C. bactrianus) and some wild ruminants.
	Rationale: Water and African buffaloes are also bovines.

Infection with Theileria can give rise to disease of variable severity and to Theileria transmission. Theileria may persist in ruminants for their lifetime. Such animals are considered carriers.

#### Wonderland

Category: Editorial

#### Proposed amended text:

Animals susceptible to infection with Theileria are Theileriosis is a disease of bovines (Bos indicus, B. taurus and B. grunniens), water buffaloes (Bubalus bubalis), African buffaloes (Syncerus caffer), sheep (Ovis aries), goats (Capra hircus), camels (Camel dromedarius and C. bactrianus) and some wild ruminants.

Infection with Theileria can give rise to disease of variable severity and to Theileria transmissionSome Theileria species are considered highly pathogenic, while others are scarcely or not pathogenic. Theileria may persist in ruminants for their lifetime. Such animals are considered carriers.

**Rationale:** To clarify that the first two paragraphs provide general description of Theileriosis that includes not only sheep and goat diseases but also others, and to avoid to use 'infection with Theileria' in these paragraphs, considering the definition for 'Theileria' described in the fourth paragraph. The proposed text in the second paragraph is extracted from the Terrestrial Manual chapter.

Supporting evidence: not relevant

For the purposes of the Terrestrial Code, infection with Theileria annulata, T. orientalis and T. parva are is defined as a tickborne infection of bovines and water buffaloes with T. annulata, T. orientalis Ikeda, T. orientalis Chitose andor T. parva.

For the purposes of this chapter, Theileria means T. annulata, T. orientalis Ikeda, T. orientalis Chitose and T. parva.

The following defines the occurrence of infection with Theileria:

- 1) Theileria has been identified in a sample from a bovine or water buffalo; or
- 2) antigen or nucleic acid specific to *Theileria* has been identified in a sample from a bovine or water buffalo showing clinical signs consistent with *infection* with *Theileria*, or epidemiologically linked to a suspected or confirmed case, or giving cause for suspicion of previous association with *Theileria*; or
- 3) antibodies specific to *Theileria* have been detected in a sample from a bovine or water buffalo that either shows showing clinical signs consistent with *infection* with *Theileria*, or is epidemiologically linked to a suspected or confirmed case or giving cause for suspicion of previous association with *Theileria*.

# Wonderland Proposed amended text: 3) antibodies specific to Theileria, that are not a consequence of vaccination, have been detected in a sample from a bovine or water buffalo that either shows clinical signs consistent with infection with Theileria, or is epidemiologically linked to a suspected or confirmed case or giving cause for suspicion of previous association with Theileria. Rationale: For consistency with other case definitions in the Code. Supporting evidence: not relevant

For the purposes of the Terrestrial Code, the incubation period for infection with Theileria shall be 35 days.

Standards for diagnostic tests and vaccines are described in the Terrestrial Evidencia documentada:.

[...]