



STANDARD OPERATING PROCEDURE FOR THE SUBMISSION OF WOAH-APPROVED REFERENCE REAGENTS

Background

According to the [Terms of Reference](#) for WOA Reference Laboratories: “[Reference Laboratories should] store and distribute to national laboratories biological reference products and any other reagents used in the diagnosis and control of the designated pathogens or diseases.”

In fulfilment of this mandate, [WOAH-approved reference reagents](#) play a critical role in ensuring the availability of high-quality diagnostic materials to WOA Members. These reagents provide a standardised platform that enables Reference Laboratories to share validated biological materials, thereby fostering global cooperation and enhancing laboratory diagnostic capacities worldwide.

Furthermore, as outlined in WOA *Terrestrial Manual* [Chapter 1.1.6. Validation of diagnostic assays for infectious diseases of terrestrial animals](#), Sections B.1.4 and B.4.4 — reference reagents are essential for quality control, proficiency testing, and harmonisation purposes.

The guidelines for the preparation, validation and distribution of WOA approved reference reagents can be found [here](#).

Scope	<p>This procedure describes the process to be followed for WOA-approved reference reagents for diagnosis of infectious animal diseases for decisions regarding inclusion to the list of currently available WOA-approved International Standard Reagents.</p> <p>The procedure has three steps:</p> <ol style="list-style-type: none">1. Submission of a request for inclusion of a referent reagent on the list;2. Decision on acceptance on the list of WOA-approved International Standard Reagents;3. Ongoing maintenance of the reagent’s status on the list.
Related documents	<ol style="list-style-type: none">1. Template for requesting inclusion of a reagent into the WOA approved International Standard Reagent2. Assessment template for the BSC/AAC.3. Chapter 1.1.6. of the <i>Terrestrial Manual</i>4. Guidelines - Reference Reagents - WOA
Documents to be submitted	<p>Data Sheet (Template): A technical summary describing the reagent, its intended use, validation data,</p>

	and confirmation that testing was conducted in accordance with WOAH guidance and relevant international standards. Request Letter: A brief cover letter indicating the laboratory’s intent to submit the reagent for WOAH approval – Letter need to be addressed to bsc.secretariat@woah.org (terrestrial animals); aac.secretariat@woah.org (aquatic animals)
List of acronyms	BSC: Biological Standard Commission DDG: Deputy Director General - International Standards and Science HQ: Headquarters SCAD: Scientific Commission for Animal Diseases TAHSC: Terrestrial Animal Health Standard Commission

Standard operating procedure

This SOP applies to WOAH Reference Laboratories wishing to submit diagnostic reference reagents for evaluation and official endorsement into the WOAH-approved International Standard Reagents.

1. RECEPTION OF A REQUEST FOR INCLUSION OF A REFERENCE REAGENT				
Step	Time Reference	Responsible person/entity	Action	Reference Document
1.1.	45 days before the following Commission meeting (July–Dec)	Candidate (WOAH Reference Centre)	Laboratory submits all required documentation to the BSC/AAC Secretariat. To the bsc.secretariat@woah.org (terrestrial animals); aac.secretariat@woah.org (aquatic animals)	1. Template data sheet 2. Letter request from the Ref Lab expert to the BSC Secretariat
1.2.	–	BSC/AAC Secretariat	The BSC/AAC Secretariat verifies completeness and may request additional information or clarification	–
1.3.	–	BSC/AAC Secretariat	Acknowledges receipt of the request and includes the request in the agenda of the following BSC meeting	–

2. EVALUATION OF THE CANDIDATE FOR REFERENCE REAGENT

Step	Time Reference	Responsible person/entity	Action	Reference Document
2.1.	During the meeting BSC/AAC	BSC/AAC	The BSC/AAC evaluate the submitted dossier	Template assessment
2.2.	1 month after the BSC/AAC meeting	BSC/AAC Secretariat	<p>The Secretariat will include in the Commission meeting report:</p> <ul style="list-style-type: none"> i. Accepted ii. Rejected <ul style="list-style-type: none"> a. Send letter to the candidate with rationale <p>The Secretariat might request further information, and the application will be postponed for decision in the next meeting following the same process 1.1.</p>	
2.3.1		BSC/AAC Secretariat	Approved reagents are published on the WOAHP website.	Veterinary products - WOAHP - World Organisation for Animal Health
2.3.2.			And update the of standard reagents on the CC&RL Annual Report questionnaire	

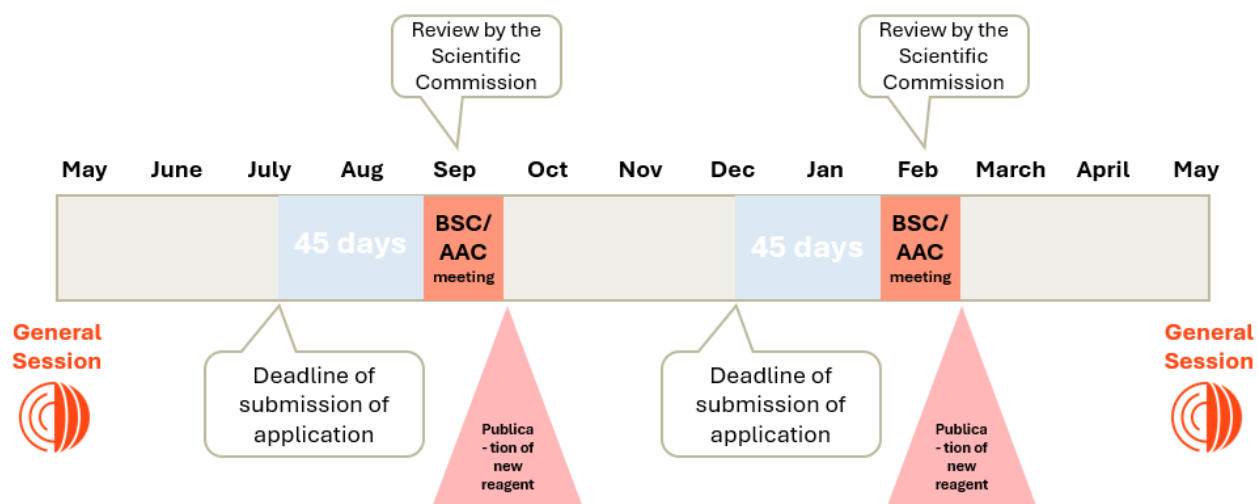
3. MAINTENANCE: ANNUAL ASSESSMENT OF THE LISTED REAGENTS

Step	Time Reference	Responsible person/entity	Action	Reference Document
3.1.	July	BSC/AAC Secretariat	Prior to the September meeting of the BSC/AAC, the Secretariat will consult with designated experts to confirm that each reagent remains available and that all associated information is current. Those no longer available will be removed from the list of WOAHP Reference Reagents.	–
3.2.	Anytime	Candidate (WOAHP Reference Centre)	New batches – Laboratories producing new batches of an already approved WOAHP standard reagent must keep records of studies undertaken to verify batch consistency.	–

3. MAINTENANCE: ANNUAL ASSESSMENT OF THE LISTED REAGENTS

Step	Time Reference	Responsible person/entity	Action	Reference Document
			Supporting data demonstrating equivalence between batches must be available upon request.	

Timeline



For more information, kindly contact:

bsc.secretariat@woah.org

aac.secretariat@woah.org