



Proposal: EVALUATION MECHANISM OF BIOSAFETY CONDITIONS IN LABORATORIES HANDLING THE FOOT-AND-MOUTH DISEASE VIRUS AND/OR ITS DERIVATIVES

(Following Resolution No I of COSALFA 41, presented to COSALFA 42, reviewed and submitted to COSALFA 43. Discussed and agreed at the expert meeting of July 6 -7, 2016)

1. OBJECTIVE

This document proposes to set up a *Regional Commission for the Management of Biological Risk and Biosafety* (hereinafter, Regional Commission) as an evaluation mechanism of the biosafety conditions of laboratories handling the foot-and-mouth disease virus and/or its derivatives in COSALFA member countries.

This Regional Commission shall be coordinated by PANAFTOSA PAHO/WHO and will be responsible of providing Technical Cooperation, promoting biological risk management at country level, and evaluating biosafety conditions in antigen/vaccine/reagent manufacturing laboratories, diagnostic laboratories, quality control laboratories, and research laboratories handling the foot-and-mouth disease virus or its derivative fragments. The Regional Commission shall carry out its mandate in coordination with national biosafety commissions.

2. STRUCTURE

The Regional Commission will be formed by a representative of the public sector and a representative of the private sector, with their respective alternates, from countries with an active industry of foot-and-mouth disease virus vaccines. The representatives shall be experts in the areas of laboratory biosafety and biological risk management. PANAFTOSA PAHO/WHO shall act as coordinator contributing to proper operation and development of the functions and terms of reference of the Commission.

3. TERMS OF REFERENCE OF THE COMMISSION'S ACTIVITIES

- a) To elaborate the detailed version of the document Minimum Biosafety Requirements for Laboratories Handling the Foot-and-Mouth Disease Virus or its Derivatives and keep it updated, based on the general guidelines prepared by BANVACO Technical Group submitted for the approval of COSALFA 42 and 43, compliant to international regulations and standards.



- b) To provide technical cooperation and evaluate biosafety conditions in laboratories handling the foot-and-mouth disease virus and/or its derivatives in COSALFA member countries, compliant to the document Minimum Biosafety Requirements for Laboratories Handling the Foot-And-Mouth Disease Virus or its Derivatives and other international regulations and standards, and elaborate the relevant evaluation reports.
- c) Evaluation of laboratories by the Regional Commission shall only be performed by experts of the official sector ensuring the absence of conflicts of interest.
- d) To deliver technical judgment on aspects of biological risk in laboratories and update the information for the knowledge of the Steering Committee and BANVACO Management, National Biosafety Commissions and COSALFA.
- e) To provide advice when required by the official service regarding the analysis of projects for building and/or adapting the physical structure of manufacturing, diagnosis, and research and development laboratories.

PARAGRAPH 1: The reports of laboratory assessments will be presented by PANAFTOSA PAHO/WHO director to the Veterinary Service Head of the pertinent COSALFA member country, to BANVACO Steering Committee and other instances, when appropriate, depending of the cooperation area requested.

PARAGRAPH 2: A program for monitoring antigen/vaccine/reagent manufacturing laboratories, diagnostic laboratories, vaccine quality control laboratories, and research laboratories will be elaborated and the activities will be carried out according to an annual agenda elaborated by PANAFTOSA PAHO/WHO together with the Regional Commission, in consultation with laboratories and the country Veterinary Authority.

4. RESPONSIBILITIES OF THE REGIONAL COMMISSION

The Regional Commission is responsible of:

- a) Complying with the reference terms of the activities
- b) Providing Technical Cooperation through the official service to antigen/vaccine/reagent manufacturing laboratories, diagnostic laboratories, vaccine quality control laboratories, and research laboratories in the area of Biosafety, Biosecurity and Biological Risk Management.
- c) Elaborating evaluation reports and developing the relevant recommendations.
- d) Advising BANVACO Steering Committee and COSALFA on topics connected to its area of expertise.



PAHO



WHO

PANAFTOSA

Pan American Foot-and-Mouth Disease Center

Veterinary Public Health

- e) Promoting the establishment of National Biosafety Commissions in COSALFA member countries and keeping a permanent channel of communication with them.
- f) Identifying the need and establish consulting contacts with experts/institutions outside the scope of the Regional Commission.

5. FUNDING

Usual regulatory and operational activities of the Regional Commission should count on funding provided by COSALFA member countries and, when requested by a country or laboratory, should count on additional ad-hoc funding.

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