TECHNICAL MEETING ON REQUIREMENTS FOR HANDLING FOOT-AND-MOUTH DISEASE VIRUS EXOGENOUS STRAINS TO THE REGION

REPORT OF THE MEETING

Rio de Janeiro, 6 – 7 July 2016

Objectives

1. Review the Comments of the documents on Minimum Requirements for the Management of Biological Risk and Biosafety and their Evaluation Mechanism.
2. Discuss the Standard and Operational aspects for the Management of Biological Risk and Biosafety in Laboratories Handling the Foot-and-Mouth Disease Virus.
3. Elaborate a Recommendation for COSALFA.

Summary

The meeting was opened with a presentation analyzing COHEFA 12's request in Resolution 4, which asked COSALFA to examine the requirements and conditions of biological biosafety necessary to review the restrictions imposed to the handling of FMD virus strains exogenous to the region. These restrictions derive from Resolution IX of COSALFA 28 meeting, which established the inconvenience of introducing/maintaining/handling foot-and-mouth virus strains exogenous to the region due to the potential of viral escape with the resulting consequences for the health of herds and the agricultural economy of the region.

Current options were described and, due to: 1) the significant improvement of countries in their fight against foot-and-mouth disease observed within the framework of the Action Plan 2011-2020 of the Hemispheric Program for the Eradication of the Foot-and-Mouth Disease (PHEFA), with four years free from the disease in the territory and the FMD-free status with and without vaccination, 2) the technological advancement of the vaccine manufacturing industry in terms of biosafety and biological risk management, and 3) COHEFA 12 decision of having an antigen and vaccine bank in order to count on strategic reserves with a view to advance towards free territories without vaccination in the medium term so as to have timely response mechanisms to minimize impacts in the event of potential viral attacks coming from other affected regions, it was recommended to modify the statements of the abovementioned Resolution IX.

Additionally, it was observed that chapter 1.1.3. of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, approved in 2015, indicates that in terms of biosafety and biosecurity, biological risk assessment is the adequate process for detection and characterization of health, safety and security risks, followed by implementation, measurement of effectiveness, and communication of control measures employed to reduce those risks to acceptable levels and, therefore, biological risk management provides the countries with a means to protect both their human and animal populations in the event of inadvertent

escape, intentional release of or exposure to pathogens, based on science, transparency, economic viability and sustainability.

The risk of accidental or intentional escape of an infectious agent from a laboratory is acknowledged as inherent to biological risk management, regardless of the foot-and-mouth disease serotype or strain being handled.

Besides, within the framework of the elaboration of the project to create an Antigen and Vaccine Bank for COSALFA, BANVACO, an expert group worked on the elaboration of the Minimum Requirements for the Management of Biological Risk and Biosafety in Laboratories Providing Services and/or Products for BANVACO as well as an Evaluation Mechanism of Biosafety Conditions in Laboratories Providing Services and/or Products for BANVACO. At COSALFA 43, member countries received these documents and decided to extend their scope to all laboratories handling the foot-and-mouth disease virus and its derivatives. Therefore, based on the international standards recommended by the OIE and the documents drafted by the expert group, the technical elements are provided to modify the decision made by Resolution IX of COSALFA 28.

Next, the following documents were thoroughly reviewed: Evaluation Mechanism of Biosafety Conditions in Laboratories Handling the Foot-And-Mouth Disease Virus and/or its Derivatives and Minimum Requirements for the Management of Biological Risk and Biosafety in Laboratories Handling the Foot-and-Mouth Disease Virus and/or its Derivatives, which were modified to fit the scope defined by COSALFA 43. The representative of ICA Colombia forwarded written comments since he was not able to attend the meeting.

Conclusions

1. The handling of foot-and-mouth disease virus strains by laboratories of COSALFA countries, either for production, diagnosis, or research, where most territory has reached a FMD-free status, is a critical link of risk management that must have a supranational mechanism in place such as a Regional Commission for the Management of Biological Risk and Biosafety to monitor, evaluate and disseminate the biological risk management of those laboratories within the framework of the COSALFA, under PANAFTOSA technical coordination, through the joint work of national authorities and national biosafety bodies of the countries, in order to prevent the inadvertent escape or intentional release of pathogens, or to reduce the exposure to them.

2. Standards related to biosafety management must be aligned and harmonized with international standards and the document Minimum Requirements for the Management of Biological Risk and Biosafety in Laboratories Handling the Foot-and-Mouth Disease Virus and/or its Derivatives, elaborated by the expert group.

3. The countries of the region should promote and reinforce national biosafety commissions so they become national legitimate entities for the enforcement of biosafety standards.

4. The functions and tasks of the Regional Commission for the Management of Biological Risk and Biosafety (Regional Commission) should be supported with the relevant funding provided by COSALFA member countries.

5. The document Minimum Requirements for the Management of Biological Risk and Biosafety in Laboratories Handling the Foot-and-Mouth Disease Virus and/or its Derivatives was elaborated as a preliminary document describing the major aspects that should be addressed for the management of biological risk, but it should be thoroughly reviewed and completed by the Regional Commission to be used as the reference to evaluate the management of biological risk at laboratories.

Recommendations to COSALFA

1. Modify Resolution IX of COSALFA 28, which imposed restrictions to the handling of foot-and-mouth disease virus strains. With that aim, the creation of a regulatory framework within the context of COSALFA is recommended for the handling of virus by its member country laboratories under the assumption that hazards associated with the handling of foot-and-mouth disease virus strains can be effectively managed based on biological risk analysis. In this regard, a Regional Commission for the Management of Biological Risk and Biosafety should be set up to operate as a supranational, impartial and transparent evaluation mechanism coordinated by PANAFTOSA according to the document Evaluation Mechanism of Biosafety Conditions in Laboratories Handling the Foot-and-Mouth Disease Virus and/or its Derivatives (document of July 7, 2016).

2. The countries with laboratories handling the foot-and-mouth disease virus should promote and strengthen national biosafety commissions.

3. The Regional Commission should use the document Minimum Requirements for the Management of Biological Risk and Biosafety in Laboratories Handling the Foot-and-Mouth Disease Virus and/or its Derivatives (document of July 7, 2016) for the elaboration of the definitive document that will become the required standard to align and harmonize the national biosafety standards for laboratories handling the foot-and-mouth disease virus.

4. COSALFA should identify a source of resources for the regular operation of the Regional Commission for the Management of Biological Risk and Biosafety.

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Agenda

(*30/05/2016 Version*)

WEDNESDAY - July 6 2016	
09:00-09:15	Opening of meeting and agenda overview *PANAFTOSA-PAHO/WHO*
09:15-09:30	Update on agreements and resolutions affecting the handling of exogenous foot-and-mouth disease virus strains in the countries of the COSALFA
09:30-10:15	Review of notes to the document *Minimum Requirements for the Management of Biological Risk and Biosafety in Laboratories Handling the foot-and-mouth disease virus and/or its derivatives*
10:15-10:30	Coffee-break
10:30-11:15	Review of notes to the document *Evaluation Mechanism of Biosafety Conditions in Laboratories Handling the Foot-and-Mouth Disease virus and/or its Derivatives*
11:15-12:00	Discussion on whether the documents respond to all the activities involving the foot-and-mouth disease virus
12:00-13:30	Lunch
13:30-15:30	Discussion on Standard and Operational Aspects for the application of *Minimum Requirements for the Management of Biological Risk and Biosafety in Laboratories Handling the foot-and-mouth disease virus and/or its derivatives*
15:30-15:45	Coffee-break
16:45-18:00	Discussion on Standard and Operational Aspects for the application of the *Evaluation Mechanism of Biosafety Conditions in Laboratories Handling the Foot-and-Mouth Disease Virus and/or its Derivatives*
	End of first day
THURSDAY - July 7 2016	
09:00-09:15	Review of the work done on the first day
09:15-10:30	Discussion on the status of National Biosafety Commissions, standards and members
10:30-10:45	Coffee-break
10:45-12:00	Elaboration of a Recommendation for COSALFA. Review of agreements and Meeting Conclusions
12:00-12:30	Lunch

Participants:

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