



## Accreditation of diagnostic tests for animal diseases

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The project aims to build the capacities of laboratories in the Central American and Caribbean region by accrediting laboratory diagnostic tests for both terrestrial and aquatic transboundary diseases that are also of commercial and social significance, selected by the beneficiary countries.

### **STDF/PG/495**

#### **Status**

Completed

#### **Start Date**

01/03/2016

#### **End Date**

31/12/2022

#### **Project Value (US\$)**

\$1,238,118

#### **STDF Contribution (US\$)**

\$840,898

#### **Beneficiaries**

Belize  
Costa Rica  
Dominican Republic  
El Salvador  
Guatemala  
Honduras  
Nicaragua  
Panama

#### **Implementing Entities**

Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA)

#### **Partners**

Food and Agriculture Organization of the United Nations (FAO)  
Ministries/Secretariats of Agriculture and Livestock of the beneficiary countries  
Pan American Health Organization (PAHO)  
World Organization for Animal Health (OIE)

#### **Background**

The livestock sector is economically, socially and strategically important in the OIRSA region and even accounts for as much as 50% of agricultural GDP in some countries. Consumption of livestock products in the region is varied and a substantial portion

of the output is meant for self-consumption, while some products must be imported to meet domestic demand. Some regional livestock production chains export appreciable amounts, as in the cases of beef, milk and milk by-products, as well as fishery and aquaculture products, among others. Foreign trade could expand significantly, which could increase the risk of introducing diseases – of the kinds that limit the productivity and lifespan of animals, and also pose a human health risk. The support of laboratories with accredited tests is required for diagnosing these diseases in order to ensure that such diagnoses are accurate and reliable.

Intraregional trade in animals and animal products has often been affected by the imposition of sanitary measures with no scientific basis. Markets have even been closed for various reasons, including the application of "retaliatory" measures such as the banning of milk imports from a country because it has prohibited exports of eggs. There is also a lack of trust among partners regarding sanitary conditions in a country or territory and the manner in which they may be verified.

One of the aims of OIRSA is to support its member countries in ensuring the effective implementation of their disease prevention, control and eradication programmes. For several decades now, OIRSA member countries have prioritized the strengthening of their analytical laboratories, and significant OIRSA-supported projects have been managed and implemented to that end. However, although the region's laboratories have been strengthened thanks to improved infrastructure, equipment and technical staff training, no quality management systems have been developed and established on a permanent basis to guarantee the credibility of the tests conducted by these laboratories, basically owing to budgetary constraints. The need for accurate and safe diagnostics is now a priority for the countries, and this has been expressed through the resolutions issued by their Ministers of Agriculture and Livestock, who together make up the highest authority of OIRSA.

Regional trade, and more specifically international trade in animals, animal products and by products, is generating an ever greater need for quality management systems in processes and laboratory assays that meet tried and tested technical standards and can be accredited. Working with accredited laboratory diagnostic tests will enable beneficiary countries to streamline the trade in animals and animal products, in compliance with the sanitary requirements established in the OIE terrestrial and aquatic animal health codes, as well as those set by destination markets, based on reliable laboratory results and the established levels of protection. The accreditation of laboratory tests under the ISO/IEC 17025 technical standard will ensure their technical competence and the validity of the results issued.

#### **Expected Results**

##### ***Accreditation of the following laboratory tests selected by each beneficiary country***

- Rose Bengal and ELISA tests to detect bovine brucellosis antibodies and lateral flow immunochromatographic testing for bovine spongiform encephalopathy (BSE), accredited under the ISO 17025 standard in Guatemala.
- Real-time polymerase chain reaction (PCR) assay for the diagnosis of white spot disease in shrimp, accredited under the ISO 17025 standard in Belize.
- Real-time polymerase chain reaction (PCR) assays for the diagnosis of necrotizing hepatopancreatitis (NHP), infectious hypodermal and hematopoietic necrosis (IHHNV) in shrimp, and haemagglutination inhibition (HI) assays for the detection of the Newcastle disease virus, accredited under the ISO 17025 standard in El Salvador.
- Real-time polymerase chain reaction (PCR) assays for the diagnosis of Newcastle disease, and polymerase chain reaction (RT-PCR) assays for the detection of the avian influenza virus, and diagnosis of Mycobacterium bovis through bacterial isolation, accredited under the ISO 17025 standard in Honduras.
- Real-time polymerase chain reaction (PCR) assays for the diagnosis of white spot disease in shrimp, Rose Bengal and Rivanol tests for the detection of antibodies against bovine brucellosis and immunohistochemical testing to detect bovine spongiform encephalopathy (BSE), accredited under the ISO 17025 standard in Nicaragua.
- Conventional polymerase chain reaction (PCR) assays for the diagnosis of white spot disease in shrimp, diagnosis of brucellosis, using the Rose Bengal and ELISA technique accredited under the ISO 17025 standard in Panama.
- Real-time polymerase chain reaction (PCR) assays for the detection of the classical swine fever virus, the avian influenza virus and the Newcastle disease virus, accredited under the ISO 17025 standard in the Dominican Republic.
- Assay for the detection of bovine brucellosis by bacterial isolation and conventional polymerase chain reaction (PCR) assay, under the ISO 17025 standard in Costa Rica.

To achieve these results, the current status of the quality management system of participating laboratories is to be analysed and assessed, and an action plan is to be drawn up for the accreditation of each assay in accordance with the standard, including each laboratory's quality policy. A protocol will be developed for taking, handling and sending samples, using the OIE Manual as reference. An induction programme will be devised and implemented for the technical staff of the official veterinary service. The production sector will be encouraged to participate in the laboratory management process. A performance assessment programme will be implemented by means of inter-laboratory assays, external audits will be conducted and an internationally recognized accreditation agency will be contracted for each assay.

### ***Twining of at least one laboratory in the subregion with an OIE Reference Laboratory***

Under the project, at least one laboratory in the subregion will be twinned with an OIE Reference Laboratory so as to provide services to the subregion and promote the establishment of a subregional laboratory network. This will be done in coordination with the existing Network of National Laboratories of the Veterinary Services of the Americas in order to share information and exchange experiences and technical skills among the laboratories involved.

The selection requirements for the country and the laboratory are: (1) reports on the OIE PVS assessments of laboratories that meet the specifications of biosafety levels 2 (BSL-2) or 3 (BSL-3), depending on the disease selected for the twinning; (2) the country where the laboratory is established agrees to receive samples from the other countries; (3) there are enough flights from the other countries to facilitate the arrival of samples; and (4) the authorities must request an OIE PVS assessment of the laboratory (if this has not been done).

### ***Sustainability mechanism implemented for the accreditation of tests***

To achieve this result, a specialist firm will be retained to prepare the financial sustainability study for the accreditation of the tests selected. A procedural guide will also be drawn up for implementing a quality management and documentation system, identifying the lessons learned throughout the project.

### ***Implementation of national reference laboratory system***

To achieve this, a country-by-country analysis will be conducted so as to identify the options for developing a national reference laboratory system, in which official laboratories and private laboratories recognized and accredited by the State would participate. Moreover, in pursuit of this objective, all countries benefiting under the project will be invited to request the OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS tool).