

04 October 2016

Terms of Reference (STDF/PPG/539)
Elaboration of a project proposal for the development of a system for the import
of laboratory samples into Guatemala

Background

Guatemala, the largest economy in Central America, has developed its conformity assessment infrastructure over the last 15 years. During this time, the Guatemalan Accreditation Office (OGA) and the Laboratories Commission of the Guatemalan Exporters Associations (AGEXPORT) were established; proficiency tests for laboratories, training courses and laboratory business plans were developed. With the support of international projects and technical assistance received, government and private laboratories were equipped and accredited to serve the local market.

Today Guatemala is a member of the main international accreditation organizations and has signed mutual recognition agreements with the International Laboratory Accreditation Cooperation (ILAC) and the Inter American Accreditation Cooperation (IAAC).

However, to continue on this path of development and growth of the national laboratory capacity, a system that facilitates the import of laboratory samples into the country is needed. Laboratory samples are imported into the country for various reasons, including proficiency tests, instrument calibration, testing confirmation procedures, registration procedures, as well as for commercial services for neighbouring countries. Fresh or processed foodstuff, as well as vegetable, biological or mineral material are among the samples that come into Guatemala.

Samples that are imported by laboratories are often rejected, lost, or confiscated by Customs due to misinterpretation of the risk assessments or the technical information sheets. At present, a single sample coming into Guatemala is treated as a consignment, dismissing the fact that the product is being imported only for lab testing purposes and will not be used by general consumers.

The existing system requires the importer to request permission to import a single sample, as if it were a whole consignment of the product. Depending on the relevant competent authority, a "risk analysis" is done by a technical committee, or by an office clerk, and permission is either granted or denied. There is no documented criteria for the risk analysis being performed nor are there records of past risk analyses that have been done.

In March 2016, the STDF Working Group approved a project preparation grant (PPG) aiming at supporting Guatemala to elaborate a project proposal for the development of a new approach for the way laboratory samples are handled by national authorities when entering into the country (STDF/PPG/539). A system similar to ones that exist in Australia, the United States or the Netherlands, in which laboratories are classified and registered by biosecurity levels and can import samples without assessing the risk of each one of them, could be envisaged. These types of systems lead to increased biosecurity, simplification of importing procedures, facilitation in terms

of accreditation for labs and methods, and increased competitiveness for agriculture and food production which require rapid test results.

This document sets out the Terms of Reference (ToRs) for implementation of this PPG by the Laboratories commission of the Guatemalan Exporters Association (AGEXPORT), with support of a suitable international consultant. It addresses the recommendations of the STDF Working Group, and clarifies the scope of work to be carried out under the PPG.

The STDF Working Group recommended that during implementation of the PPG: (i) the participation of national authorities as well as the involvement of official laboratories should be ensured; (ii) the possible regional impact and possibilities of replicating the approach in other countries should be assessed; and (iii) possible linkages and synergies with other national and regional projects in the field of laboratories should be further explored.

Objective

To elaborate a project proposal for the development of a biosecurity-based import system of laboratory samples into Guatemala to be submitted for funding to any interested funding source (internal or external) or to the STDF.

Implementation modalities

The Guatemalan Exporters Association (AGEXPORT), through its Laboratories Commission, will be responsible for the implementation of this PPG and will sub-contract the services of an international consultant.

The international consultant will be selected by AGEXPORT, in consultation with the STDF Secretariat.

Description of tasks

Over the course of the project preparation period the Guatemalan Exporters Association (AGEXPORT), with the support of the international consultant, will carry out the following tasks:

1. Hold in-depth consultations with all relevant stakeholders involved in the process of import of laboratory samples (including government authorities, private sector actors and academia) in order to fully understand how the system of import of laboratory samples currently operates. These consultations should also seek to ensure key stakeholders' full commitment to the resulting project, including agreement on the specific role of each one of them.
2. Identify and assess the types and scope of laboratory samples that are or need to be imported into the country.
3. Review the current status and identify the training needs of laboratories (private and public) and regulators regarding biosecurity practices.
 - 3.1. Include in the project proposal a training component, which will include training programmes for competent authorities and for laboratory staff in charge of biosecurity.

4. Evaluate the existing laboratory infrastructure and identify the possible criteria to be used to classify them into biosecurity levels according to the services offered.
 - 4.1. Include in the project document a component on the development of the technical criteria for laboratory classification according to biosecurity levels and determine technical assistance needs.
 - 4.2. Include in the project document a technical assistance plan to support laboratories and the competent authorities to implement the new criteria for biosecurity classification to be implemented by the project.
5. Review the current legal framework for the import of laboratory samples.
 - 5.1. Include in the project document a component on the update of the regulatory framework and a technical assistance plan for the enforcement of the new regulations for the implementation of a biosecurity-based import system of laboratory samples.
6. Take account of and build on what has been done in the field of laboratories by other national and regional projects and programmes and explore the possibilities of replicating the system in other countries in the region.
7. Consult national authorities, bilateral donors and development partners to explore opportunities to leverage funds for the implementation of the project to be developed through this PPG. Based on the outcomes of these discussions, and the likelihood to secure donor-funding, the project proposal produced may be written in the format/template of one of these potential donors (rather than the STDF project template).
8. Develop a project proposal, based on the assessment conducted and consultations with concerned stakeholders. This will include preparation of a draft of the project proposal for presentation and discussion at a project validation workshop. The validation workshop should be attended by all concerned projects stakeholders. Based on the discussions and comments received, the project proposal will be finalized.
9. Elaborate a short written report on the implementation and outcomes of the PPG and submitted it to the STDF Secretariat. This report should describe the activities implemented, the results achieved, and the key stakeholders who were actively involved and/or consulted.

Time frame

60 working days

Budget

The STDF will cover expenses related to the implementation of this PPG up to a maximum amount of US\$49,812, as estimated in the table below.

Activity	Responsible	Estimated Budget (US\$)
International expertise: Biosecurity expert (60 working days, rate US\$500 per day)	AGEXPORT	30,000.00
Stakeholder meetings / workshops	AGEXPORT	1,940.00
Travel and DSA of international consultant: - Plane ticket - Hotel & DSA (60 days)	AGEXPORT	3,000.00 11,400.00
Workshop materials	AGEXPORT	1,100.00
Unforeseen expenses 5%	AGEXPORT	2,372.00
TOTAL		49,812.00

Duty station and logistics

Project preparation activities will mainly take place in Guatemala City, Guatemala, with possible travel outside the capital as required. Logistical arrangements for this travel will be organized by AGEXPORT, as necessary.

The international consultant might undertake preparatory and follow-up work at his/her home station prior to and/or after the missions to Guatemala.

Qualifications of the international consultant

- Expertise in laboratory biosecurity
- Knowledge of risk analysis
- Experience in laboratory biosecurity criteria in different fields
- Handling of different types of samples for international transportation
- Knowledge of samples handling procedures currently used in Australia, the United States, the Netherlands or similar systems.
- Experience in laboratory assessments for biosecurity
- Knowledge of the ISO 17025 standard.
- Expertise in project development