# ASEAN GUIDELINES ON GENETICALLY MODIFIED ORGANISMS (GMO) PROFICIENCY TESTING (PT)

## TABLE OF CONTENT

## 1. INTRODUCTION

PT can serve as a tool or method to demonstrate the competency and capability of a laboratory in performing a specific analytical test regarding the samples given. It is also commonly used as a method to validate and demonstrate a laboratory's measurement process by comparing the testing results from a particular laboratory to the results of a reference laboratory (PT provider) as well as other participant laboratories.

PT is an essential element for laboratory quality assurance and continuous improvement as it is one of the criteria in ISO/IEC 17025:2017. Thus, it is very important for the laboratory to take part in PT.

## 2. TERMINOLOGY

The terms and definitions given in ISO/IEC 17043:2010 Conformity assessment – General requirements for PT international standard is used for this document, as follows below:

a) **Proficiency Testing (PT)** : the evaluation of participant performance against the pre-established criteria by means of inter-laboratory comparisons
b) **PT item** : sample, product, reference material, piece of equipment, measurement standard, data set or other information used for proficiency testing
c) **PT scheme** : proficiency testing designed and operated in one or more rounds for a specific area of testing, measurement, calibration of inspection
d) **PT provider** : organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme
e) **Subcontractor** : organization or individual engaged by the proficiency testing provider to perform activities specified in this standard and that affect the quality f proficiency testing scheme

## 3. SCOPE

This guideline provides the general requirements for laboratories to conduct/participate in PT for Genetically Modified Organism (GMO) analysis. This document follows the ISO/IEC 17043:2010 Conformity assessment – General requirements for PT.

This document does not cover the specific methods used in performing PT. The laboratories shall practice their own standard operating procedures (SOPs) and methods during the analysis of PT items.

## 4. PARTICIPATION IN PT SCHEME

### 3.1 Selection of PT Scheme

Usually, the PT schemes provided by the PT providers are not method specific. It is the responsibility of participating laboratory to check and ensure that the selected PT scheme is suitable and able to fulfil the laboratory's purpose.

The participant should subscribe to participate in PT scheme provided by competent and/or accredited PT providers. The PT providers or their subcontractors shall be competent to conduct interlaboratory comparisons and have expertise with the particular type of PT item and the capability to analyse the determined properties. The guidelines/standards in ISO/IEC17025 and ISO/IEC17043 can be used to demonstrate the competency of PT providers' laboratories or their subcontractors' laboratories.

### 3.2 PT Scheme Subscription

In general, the PT providers have their own systems for the participants to subscribe to participate in their PT schemes. The participant shall follow

the instructions given by the PT provider. The PT provider will provide the programme details such as dispatch date, closing date, price, payment method and other relevant details for each particular PT scheme. The information of PT scheme can be accessed via the PT provider's website or provided documents.

## 4. PT SCHEMES

### 4.1 Instructions for participants

The PT samples normally come with documented instruction for participants. The participants shall follow the instructions given by the PT provider. The instructions of PT programmes may vary according to different PT providers.

### 4.2 Handling and storage of PT items

The PT item received shall be stored appropriately according to the PT provider's instructions or in appropriate conditions depending on the type of items to avoid cross-contamination or sample degradation.

## 5 TECHNICAL REQUIREMENTS

### 5.1 Personnel

5.1.1 The laboratory shall appoint their own employee (permanent or contract) as analyst or personnel to handle the PT sample received.

5.1.2 The assigned personnel shall be qualified and competent and follow the laboratory management system during the process of handling PT samples.

5.1.3 The management of the laboratory shall plan how to handle the PT scheme and communicate to personnel about their respective

duties and responsibilities throughout the process of analysing the PT sample.

5.1.4 The assigned personnel shall have adequate knowledge, educational and professional qualifications, training, and skills relevant to the PT sample received.

5.1.5 The laboratory management may delegate authority to assigned personnel to select an appropriate PT scheme.

5.1.6 The assigned personnel shall plan and carry out appropriate testing on the PT sample received using the appropriate test method and instruments.

5.1.7 The assigned personnel shall have capability in expressing opinions and interpretation of the results.

5.1.8 The assigned personnel shall evaluate the obtained results and perform statistical analysis on the collected data prior to results submission.

## 5.2 Facilities, environment and equipment

5.2.1 The participant shall ensure that the laboratory has appropriate facilities which include the laboratory facilities and suitable equipment for handling and analysis of PT samples.

5.2.2 The participant shall ensure that the laboratory environmental conditions such as temperature, humidity, and cleanliness of work areas do not adversely affect the PT sample analysis process.

5.2.3 The participant shall ensure segregation of work areas to minimise cross-contamination.

5.2.4 The PT sample shall be stored separately from standards, reference materials and reagents to avoid cross-contamination.

5.2.5 The analysis of PT sample shall be carried out in correct order and work flow in order to ensure testing accuracy.

5.2.6 The access to and use of working areas shall be monitored and restricted to designated staff only in order to minimise the source of contamination on PT sample during analysis.

5.2.7 The PT sample shall be analysed separately from other samples to avoid cross-contamination.

5.2.8 The participant shall ensure and note that non-expired reagents are to be used, all equipments used for analysing PT sample are well maintained, and calibrations were carried out according to schedules.

## 5.3 Analysis method or procedure

5.3.1 The participants shall use the test method, calibration or measurement procedure of their choice, which should be consistent with their routine procedures.

5.3.2 The participants shall ensure that the results obtained after analysing the PT sample are valid and reliable. Some good practices are:

a) Use reference materials (RM) or certified reference materials (CRM) for quality controls that are not expired
b) Ensure the instruments used for analysis have been calibrated according to the maintenance schedule
c) Test sample in replicates (duplicate or triplicate) following laboratory analysis standard operating procedures (SOPs)
d) Conduct testing using different methods or different instruments to ensure the results obtained are consistent and precise
e) Review the results before submitting to the PT provider

## 5.4 Result submission or result reporting

The results of PT shall be submitted to the PT Provider within the stipulated time given (deadline) according to the format or instructions given. The results can be expressed as copy numbers or percentage weight-for-weight (% w/w) or as a statement e.g. “Detected” or “Not Detected” depending on the PT provider’s result

format. After results submission, the PT Provider will issue the final evaluation report to all participants. Performance of participants in the PT shall be evaluated as “Satisfactory” or “Not Satisfactory” depending on the issuance of PT evaluation result. The participant shall review the issued final evaluation report and address any need for corrective action.

### 5.5 Documentation

The process and results obtained from the analysis of PT samples shall be recorded appropriately. This includes the associated worksheets, operators, instrument print out of results, final evaluation report from the PT provider and any related documents such as test methods, work instruction (WI) or laboratory standard operating procedures (SOPs).

## REFERENCES

1. ISO/IEC 17043:2010: Conformity assessment – General requirements for proficiency testing.
2. ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories.
3. Protocol for Proficiency Testing Schemes, Version 5, September 2016.Fapas, Fera Science Ltd (Fera), Part 1- Common Principles.
4. Protocol for Proficiency Testing Schemes, Version 5, April 2017. Fapas, Fera Science Ltd (Fera), Part 4 – Fapas® GM Scheme (GeMMA).