Fera Science Ltd (Fera)

Protocol for Proficiency Testing Schemes

Version 6, January 2023

Part 4 – Fapas® GM scheme (GeMMA)

PREFACE

This Protocol is a series of inter-related documents. This document, Part 4, sets out specific details for the Fapas® Genetically Modified Materials (GeMMA) Scheme. Although this document duplicates some of the text in Part 1 – Common Principles, it cannot be used in isolation. Part 4 must always be read in conjunction with Part 1 and vice versa.

VERSION HISTORY

This Protocol was completely revised in 2009, superseding all proficiency testing scheme Protocols previously published by Fera in any of its incarnations.

Version 6 of January 2023, this version, supersedes Version 5 of April 2017. The changes are as follows;

3.2. Update to sample shipment

4.1. Clarification of qualitative assessments

4.2. new reference

5 References updated

Contact information

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1. INTRODUCTION

1.1 Fera, PTG, Fapas® and GeMMA

Fera was vested on 1 April 2015. Fera provides a wide range of proficiency testing (PT) schemes under the brand name of Fapas®. The management of these PT schemes is the sole task of one team within Fera, known internally as the Proficiency Testing Group (PTG).

For the purpose of this Protocol we use Fapas® to mean Fera PTG. Part 4 of this Protocol, i.e. this document, specifies details relating only to the Fapas® GM scheme (GeMMA).

1.2. Accreditation

Fera is a UKAS accredited Proficiency Testing Provider, No. 0009. Accreditation is conferred upon Fapas® GM scheme (GeMMA) in accordance with ISO/IEC 17043:2010 [1].

The formal schedule of the accreditation can be obtained from the United Kingdom Accreditation Service (UKAS) web site (Adobe PDF format) [2].

Unless otherwise specified in the detailed programme or brochure, all Fapas® GM scheme (GeMMA) PTs can be considered to be within scope of accreditation. Details of the PTs and scope can be inferred from the published brochure and schedule of accreditation.

2. ORGANISATION OF GM SCHEME (GeMMA)

2.1. Management System

The accredited management system covers all aspects of the PTs organised by Fapas® GM scheme (GeMMA), i.e. the same system applies whether a particular PT is within scope of accreditation or not.

The management system covers all aspects of the PTs organised by Fapas® GM scheme (GeMMA):

- Qualitative assessments
- Quantitative assessments
- Assessment on w/w basis
- Event-specific (e.g. Roundup Ready® soya (40-3-2)) and genetic elements (e.g. p35S)
- DNA test materials
- Processed and unprocessed matrices

3. PARTICIPATION IN SCHEMES

3.1. Test Material Preparation and Homogeneity

All Fapas® GM scheme (GeMMA) test material preparation, homogeneity and stability testing is carried out by subcontracting laboratories. Details of test material preparation and homogeneity results are retained by Fapas® but no longer published in the reports. Homogeneity testing may be qualitative (to confirm absence of an event or detection of contamination) or fully quantitative depending on the presence of a GM event, where relevant.

Participants may contact Fapas® to request details of test material preparation and homogeneity testing, where it is pertinent to their assessment. Such details may be released on request, except where this compromises data which is commercial in confidence or where such knowledge is scientifically invalid in the interpretation of assessments.

3.2. Dispatch and Receipt of Test Materials

All Fapas® GM scheme (GeMMA) test materials are sent by standard post or courier. Fapas® cannot be held responsible for delays arising from Customs or local postal delivery difficulties.

3.3. Analysis of Test Materials

It is the responsibility of participants to read the instructions (provided electronically via email or downloaded from the Fapas® website, www.fapas.com) and to follow them exactly prior to conducting the actual analysis of the test material. Fapas® cannot be held responsible for any problems arising from failure to comply with these instructions.

Example instructions are available on request from Fapas®.

3.4. Follow-Up Services

After a PT has been completed and values for analyte concentrations assigned, surplus PT materials may be available to purchase for use as quality control (QC) materials or reference materials (RM). These materials are not Certified Reference Materials (CRM). Certified Reference Materials for the food analysis sector, however, are not numerous and surplus Fapas® test materials may be the only source of a suitable quality control material.

A list of surplus test materials (both QC and RM) that can be purchased is available from the website, www.fapas.com. For Fapas® GM scheme (GeMMA) Scheme PTs, surplus test materials may be extremely limited or not available.

Most Fapas® GM scheme (GeMMA) reports issued since 2001 are available for purchase. Prices are available on request. Participants in all the Fapas® schemes have free access to an electronic copy of reports for those tests for which they have registered. Electronic copies of reports are available on request and a charge will be made for these.

If a participant wishes to obtain advice on any aspect of their performance they should contact Fapas® by email (info@fapas.com) in the first instance. Participants must note that Fapas® may offer assistance in the form of a broker service whereby Fapas® will either anonymously or, subsequent to all parties agreeing to waive their confidentiality, pass on the participant's inquiry to an expert laboratory/external advisor.

4. PERFORMANCE ASSESSMENT

4.1. Qualitative assessment

Sourcing uncontaminated material for GM testing is often difficult. It is only for GM events knowingly added to the matrix during test material preparation that it can confidently be assumed that the participants' consensus will be 'detected'. For all other events the possibility of trace contamination means that the expected result will be 'not known'. Qualitative results are therefore evaluated against the consensus and then may be expressed as either Agreeing or Disagreeing with the consensus, where such assessments are provided for information only. In addition, where a test material is known to be positive with respect to GM contamination, results may be performance assessed as Satisfactory or Not Satisfactory.

4.2. Quantitative assessment

Quantitative results for Fapas® GM scheme (GeMMA) Scheme PTs are usually expressed as z-scores. The standard deviations for proficiency assessment are derived from fitness-for-purpose values [3] and expert opinion (usually the Fapas® GM scheme (GeMMA) Advisory Committee).

Quantitative GM results are log transformed. The rationale for this approach is documented [3, 4, 5, 6] and, hence, the formula for calculation of z-scores is;

$$z = \frac{(x - x_a)}{\sigma_p}$$

where x is the participant's reported result, after $\log_{10}$ transformation

x_a is the assigned value, on $\log_{10}$ transformed values

and σ_p is the standard deviation for the proficiency test, in the $\log_{10}$ domain.

The value of σ_p used is dependent on the GM event being analysed and the values applied are detailed in each PT report.

Quantitative results have historically been submitted on a percentage weight-for-weight (% w/w) basis. Under EU Commission Recommendation No. 2004/787/EC [7], the percentage of GM-DNA has been defined under section II DEFINITIONS, item (h), as: the percentage of GM-DNA copy numbers in relation to target taxon specific copy numbers calculated in terms of haploid genomes. This EU Commission Recommendation is for guidance purposes only, therefore, the submission of results expressed in a percentage (%) on a haploid genome basis is optional and not mandatory. In practice, few participants in the Fapas® GM scheme (GeMMA) submitted results on % haploid genome basis and it is no longer practical to assess these data.

5. REFERENCES

1 ISO/IEC 17043:2010, Conformity assessment – General requirements for proficiency testing.

2 http://www.ukas.com, accessed 09/12/2022

3 Powell, J. and Owen, L., 2002, Reliability of Food Measurements: The Application of Proficiency Testing to GMO Analysis, *Accred. Qual. Assur.*, **7**, 392-402.

4 Analytical Methods Committee, 2004, GMO Proficiency Testing: Interpreting z-scores derived from log-transformed data, RSC, AMC Technical Brief, No.18, December 2004.

5 Thompson, M., et al, 2006, Scoring in GMO Proficiency Tests based on log-transformed results, *J. AOAC Int.*, **89** (1), 232-239.

6 Sykes, M., Macarthur R., (2020) Letter to the Editor regarding: Log transformation of proficiency testing data on the content of genetically modified organisms in food and feed samples: is it justified? Analytical and Bioanalytical Chemistry. 412, (16), p. 3947

7 Commission Recommendation No. 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003, *Official Journal,* **L 348**, 24/11/2004, 0018-0026.

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