The Food and Environment Research Agency

Protocol for Proficiency Testing Schemes

Version 2, January 2012

Part 4 – GeMMA Scheme

PREFACE

This Protocol is a series of inter-related documents. This document, Part 4, sets out specific details for the Genetically Modified Materials Analysis (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 the Food and Environment Research Agency (previously, Central Science Laboratory), i.e. all previous editions of the separate FAPAS and FEPAS Protocols.

Version 2 of January 2012, this version, supersedes Version 1 of November 2009. The changes are as follows;

1.2 Amendments to reflect publication of standard ISO/IEC 17043 and compliance with its requirements

3.1 Addition of text with regard to test material and homogeneity details in Reports

3.3 and 3.4, change to electronic instructions and reports, not hardcopy

4.2 Addition of text regarding use of Q-scores

CONTENTS

1. INTRODUCTION

1.1 Fera, Defra, PTG and FAPAS

The Food and Environment Research Agency (Fera) is an Executive Agency of the UK Government Department for Environment, Food and Rural Affairs (Defra). Fera provides a wide range of proficiency testing (PT) schemes.

The management of these PT schemes is the sole task of one of many teams within Fera. Known internally at Fera as the Proficiency Testing Group (PTG), this team provides Fera's PT schemes globally under the brand name of FAPAS PT. The Genetically Modified Materials Analysis (GeMMA) Scheme is one of these PT schemes.

For the purpose of this Protocol we use FAPAS PT to mean Fera PTG.

1.2. Accreditation

GeMMA Scheme is accredited by the United Kingdom Accreditation Service (UKAS). Accreditation is conferred upon GeMMA Scheme 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].

2. ORGANISATION OF GeMMA

2.1. Management System

The scope of accreditation covers all aspects of the PTs organised by GeMMA:

- Qualitative assessments
- Quantitative assessments
- Assessment on w/w basis and haploid genome 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

Subcontracted laboratories are used for test material preparation and homogeneity testing. Raw homogeneity results are submitted to FAPAS® for statistical evaluation. 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. In either case, homogeneity testing is performed on ten randomly selected distribution units, in duplicate.

Participants may contact FAPAS PT 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 GeMMA test materials are sent by standard post. FAPAS® cannot be held responsible for delays arising from Customs or local postal delivery difficulties.

If GeMMA PTs are subject to delays or cancellations, this is usually due to availability of suitable test materials or reference materials for testing. Cancellations may also be due to insufficient numbers of participants registering for a test. Participants will be notified by email at the earliest opportunity in the event of delay or cancellation. Participants registered for a cancelled PT will have the option to change their registration to another test.

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 PT website, www.fapas.com) and to follow them exactly prior to conducting the actual analysis of the test material. GeMMA Scheme cannot be held responsible for any problems arising from failure to comply with these instructions.

Example instructions are available on request from GeMMA Scheme.

3.4. Follow-Up Services

After a PT has been completed and values for analyte concentrations assigned, surplus PT test materials can be used as "quasi-reference" quality control materials. It must be stressed that test materials are *not* Certified Reference Materials. However, certified reference materials for the food analysis sector are not numerous and surplus FAPAS PT test materials may be the only source of a suitable quality control material.

A list of surplus test materials that can be purchased after the test closing date is available from the FAPAS PT website, www.fapas.com. For GeMMA Scheme PTs, surplus test materials may be extremely limited or not available.

Most GeMMA reports issued since 2001 are available for purchase. Prices are available on request. Participants in all the FAPAS PT 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 PT by email (info@fapas.com) in the first instance. Participants must note that GeMMA Scheme may offer assistance in the form of a broker service whereby GeMMA Scheme 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 becoming increasingly 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. In addition, where a test material is known to be positive with respect to GM contamination, results may be expressed as Satisfactory or Not Satisfactory.

4.2. Quantitative assessment

Quantitative results for GeMMA Scheme PTs are usually expressed as z-scores. The standard deviations for proficiency assessment are derived from fitness-for-purpose values [4] and expert opinion (usually the GeMMA Advisory Committee). Occasionally, Q-scores may be issued instead, where a fitness-for-purpose RSD_R is not available. See Part 1 of this Protocol and the International Harmonised Protocol for a description of the use of Q-scores [3]. Q-scores present the bias of reported results taking no account of the standard deviation for proficiency. Since bias cannot be predicted, no satisfactory range can be given. Q-scores should NOT be interpreted in the same way as z-scores. Q-scores would be given purely for presentational purposes and for information only.

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

$$z = \frac{(\log_{10} x - \log_{10} x_a)}{\sigma_p}$$

where x is the participant's reported result

x_a is the assigned value

and σ_p is the standard deviation for the proficiency test.

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. GeMMA Scheme therefore accepts results on either % w/w or % haploid genome basis and treats these results separately.

5. REFERENCES

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

2 http://www.ukas.com/about-accreditation/accredited-bodies/proficiency-testing-organisations.asp

3 Thompson, M., Ellison, S.L.R. and Wood R., 2006, The International Harmonised Protocol for the Proficiency Testing of Analytical Chemistry Laboratories, *Pure Appl. Chem.*, **78** (1)**,** 145-196.

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

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

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

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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