EUROPEAN COMMISSION
DIRECTORATE-GENERAL
JOINT RESEARCH CENTRE
Directorate F - Health, Consumers and Reference Materials
Food & Feed Compliance

Description of the EURL GMFF Validation Process

1. Introduction

The European Union Reference Laboratory for GM Food and Feed (EURL GMFF) has been established by Regulation (EC) No 1829/2003[1]. The objectives and tasks of the EURL GMFF are outlined in the Annex of the same Regulation. The operations of the EURL GMFF are carried out in line with Annex III to Regulation (EU) No 503/2013[2], for the validation of methods for detection, identification and quantification of genetically modified plants for food or feed uses, food or feed containing or consisting of genetically modified plants and food produced from or containing ingredients produced from genetically modified plants or feed produced from genetically modified plants. The operations are carried out in line with Annex I to Reg. (EC) No 641/2004[3] for all other cases.

The validation process (detailed in § 2) is conceived in a complete step-wise approach: it starts with the reception of the documentation and data on the method and the samples (step 1); it moves through the scientific assessment (step 2) of such information; the method performance against acceptance criteria are then experimentally verified in-house at the EURL GMFF facilities (step 3, experimental testing of the method and samples); a full method validation follows through a collaborative trial (step 4) with the participation of National Reference Laboratories of the EU Member States; the validation process ends with the reporting (step 5) to the European Food Safety Authority (EFSA). The report is published on the EURL GMFF website (http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx). The validation process follows the time limit of six months as established for EFSA to release its opinion in accordance with the provisions of Reg. (EC) No 1829/2003.

2. Overview of steps in validation process

The validation process consists of the following steps:

Step 1. Reception of the documentation and data on the method and the samples;
Step 2. Scientific assessment of documentation and data;
Step 3. Experimental testing of the samples and methods;
Step 4. Collaborative trial;
Step 5. Reporting to Authority (EFSA).

Step 1: Reception of documentation and data of the samples
A complete submission consists of four elements: a) the method(s) for detection, identification and quantification of the GMO(s) subject of the application and the corresponding data fulfilling the method acceptance criteria[4,6]; b) the control samples[7] and the samples of food and feed[1,6]; c) the annotated sequences of the GM-insert(s) and the flanking sequences in electronic format[8]; d) the proof of payment of the flat-rate contribution in accordance with Reg. (EU) No 120/2014[5].

Step2: Scientificassessment of documentation and data
The second step involves the scientific assessment of the documentation and data related to

the method(s) and samples. Based on the scientific evidence provided by the applicant the EURL GMFF verifies that the method(s) and samples provided fulfil the requirements of the method acceptance criteria set by the European Network of GMO Laboratories (ENGL)[4].

Step 3: E*xperimental testing of the samples and methods*
The third step in the process is the experimental testing of the method(s), using the samples provided. During the experimental testing, the EURL GMFF performs the following steps:

- Design of the collaborative study, if the method(s) shall undergo a full validation process, or of the method verification if the method(s) has(have) been already fully validated;
- Check of the quantity and quality of the control samples received from the applicant according to the requirements of the method validation;
- Preparation of samples and reagents for the in-house method verification or for the full validation;
- Test of the detection method(s) provided by the applicant;
- Test of the extraction method(s) provided by the applicant, if not already validated.

The results of the experimental testing aim at verifying that the method(s) fulfil(s) the method acceptance criteria as defined by the ENGL and that the method(s) and the control samples are suitable to undergo the full validation process, through a collaborative study (in case of a full validation process). If the method submitted has been already validated through a collaborative study on a single line GMO and it is submitted in the context of a stacked GMO, the method is subject to a single laboratory verification aimed at assessing its performance on the stacked GMO sample (§ Annex 2 to the 'Definition of minimum performance requirements for analytical methods of GMO testing'[4]).

Step 4: Collaborative trial
The inter-laboratory study, called collaborative trial, for method validation is organised by the EURL GMFF according to the requirements defined in the 'IUPAC Protocol for the Design, Conduct and Interpretation of Method-performance Studies'[9] and in the International Standard (ISO) 5725[10]. The experimental work is carried out by twelve National Reference Laboratories among those nominated under Annex II to Reg. (EU) No 120/2014[5]. The process involves a random selection step of those laboratories responding to a call for expression of interest in participating to the ring-trial.

Step 5: Reporting to the European Food Safety Authority (EFSA)
The EURL GMFF performs the statistical treatment of all data collected during the collaborative trial, and reports the results to EFSA; the EURL GMFF publishes the results together with the validated protocols on the EURL GMFF website.
In particular, the following documents are published:

1. Validation report, reporting the results of the validation study which includes the validated protocol in Annex;

2. Validated protocols, containing the detailed description of the validated method(s) as a stand-alone document;

3. Report of the in-house validation of the DNA extraction process.

In addition, the EURL GMFF compiles a technical report which includes all information recorded during the experimental testing (step 3) of samples and methods.

The EURL GMFF carries out its operations under accreditation according to ISO 17025:2005.

3. References

1. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Official Journal of the European Union, L 268/1.

2. Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006. Official Journal of the European Union, L157/1.

3. Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. Official Journal of the European Union, L102/14.

4. Definition of minimum performance requirements for analytical methods of GMO testing (20/04/2015), http://gmo-crl.jrc.ec.europa.eu/doc/MPR%20Report%20Application%2020_10_2015.pdf

5. Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms. Official Journal of the European Union, L39/46.

6. Explanatory notes to applicants (Reg. (EU) No. 503/2013), http://gmo-crl.jrc.ec.europa.eu/guidancedocs.htm

7. Note to the applicants on the type and nature of control samples according to Reg. (EC) No 1829/2003, http://gmo-crl.jrc.ec.europa.eu/guidancedocs.htm

8. Guideline for the submission of DNA sequences derived from genetically modified plants and associated annotations within the framework of Directive 2001/18/EC and Regulation (EC) No 1829/2003, Section 5 'Final Sequence format'. http://gmo-crl.jrc.ec.europa.eu/doc/Guideline%20for%20the%20submission%20of%20DNA%20sequences.pdf

9. Horwitz, W. 1995. Pure and Appl. Chem, 67, 331-343

10. Accuracy (trueness and precision) of measurement methods and results. ISO, 5725, 1994