



## Description of the CRL-GMFF Validation Process

### 1. Introduction

The Community Reference Laboratory for GM Food and Feed (CRL-GMFF) was established by Regulation (EC) No 1829/2003 on genetically modified food and feed. The objectives and tasks of the CRL-GMFF are outlined in the Annex of the same Regulation. The operations of the CRL-GMFF are carried out in line with Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 (implementing measures).

The CRL conducts the scientific assessment of the documentation provided by the applicant for authorisation, for its completeness and compliance to the European legislation. If the information provided about the methods and samples fulfils the method acceptance criteria set by the European Network for GMO Laboratories (ENGL – “Definition of minimum performance requirements for analytical methods of GMO testing”), the CRL initiates the validation process of the detection method, making use of the control samples and the samples of food and feed provided by the applicant.

The validation process is carried out in collaboration with laboratories members of the European Network of GMO Laboratories (ENGL) and must be completed within a period of six months after the European Food and Safety Authority (EFSA) has declared an application as valid.

### 2. Overview of steps in validation process

The validation process consists of the following steps (Figure 1):

- Step 1. Reception of documentation and material provided by the applicant;
- 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 the European Food Safety Authority (EFSA).

#### *Step 1: Reception of documentation and material*

The first step entails the reception, checking and registering of samples and relevant documentation. The items received are checked for completeness and visual integrity, prior to any scientific assessment.

#### *Step 2: Scientific assessment of documentation and data*

The second step involves the scientific assessment of the documentation relating to the method, and to samples. The CRL verifies that the methods and samples provided fulfil the requirements of the implementing measures based on scientific evidence provided by the applicant. If the method submitted has been already validated through a collaborative study, the method may not undergo a full validation process (i.e. method verification replacing steps 3 and 4).



## EUROPEAN COMMISSION

DIRECTORATE GENERAL JOINT RESEARCH CENTRE (JRC)

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BIOTECHNOLOGY & GMOs Unit

COMMUNITY REFERENCE LABORATORY FOR GENETICALLY MODIFIED FOOD AND FEED



### *Step 3: experimental testing of the samples and methods*

The third step in the process is the experimental testing of method(s), using the samples provided. During the experimental testing, the CRL performs the following steps:

- Design of the collaborative study, if the method shall undergo a full validation process;
- 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 full validation or the in-house method verification;
- Testing of the detection method(s) provided by the applicant;
- Testing of the extraction method(s) provided by the applicant.

The results of the experimental testing are aimed at verifying that the method(s) fulfils the method acceptance criteria defined by the European Network of GMO Laboratories (ENGL) and that the method and the control samples are suitable to undergo the full validation process, through a collaborative study (in case of a full validation process). In case of method verification, the experimental testing will be executed by the CRL even if the method has been validated previously – to verify that the method performs in a proper manner together with the samples provided. If the testing results do not fulfil the acceptance criteria, the results are confirmed by a third laboratory member of ENGL prior to any decision.

### *Step 4: Collaborative trial*

The inter-laboratory study, called collaborative trial, for method validation is organised by the CRL-GMFF according to the requirements defined in the 'IUPAC Protocol for the Design, Conduct and Interpretation of Method-performance Studies' (Horwitz, W. 1995. Pure and Appl. Chem, 67, 331-343), and in the international standard (ISO) 5725 on "Accuracy -Trueness and Precision - of Measurements Methods and Results" (ISO, 1994). The experimental work is carried out by e.g. twelve or more European laboratories, members of the ENGL.

### *Step 5: Reporting to the European Food Safety Authority (EFSA)*

Upon proper statistical treatment, performed by the CRL-GMFF, of data collected during the collaborative trial, the results are reported to the European Food Safety Authority (EFSA) and published, together with the validated protocols, on the CRL-GMFF web site.

In particular, the CRL-GMFF prepares the following type of documents:

- 1) Validation report, reporting the results of the validation study;
- 2) Validated protocols, containing the detailed description of the validated method(s).

In addition, the CRL-GMFF compiles a technical report which includes all information recorded during the experimental testing of samples and methods.

The CRL-GMFF carries out the entirety of its operations according to ISO 9001:2000 (certificate number: CH-32232) and ISO 17025:2005 (certificate number: DAC-PL-0459-06-00)



### Overview of CRL-GMFF operations

