



EUROPEAN NETWORK OF GMO LABORATORIES (ENGL)

Working Group on Method Performance Requirements (WG-MPR)

MANDATE

Background

The document "Definition of minimum performance requirements for analytical methods of GMO testing", jointly developed by the EURL GMFF and the ENGL, provides guidance to applicants seeking authorisation for GMOs under Regulation (EC) No 1829/2013, as well as to National Reference Laboratories (NRL), or any other institution, wishing to develop methods for GMO analysis and to propose them to the EURL GMFF for validation.

The current version of the document (in force since October 2015) applies to polymerase chain reaction (PCR)-based methods for the detection, identification and/or quantification of GMOs, in combination with methods for DNA extraction.

The document states that "*if novel methods (e.g. those using technologies other than PCR) are subsequently developed that fulfil legal requirements, then this document will be amended accordingly*".

Similarly, the recent interpretation of the European Court of Justice that food and feed products obtained by new mutagenesis techniques, i.e. genome editing, are to be considered as GMOs, means that this guidance document also needs to be applicable to this new type of GMOs.

Considering the developments in analytical methodologies (e.g. digital PCR,) and the need for clarification of the requirements in the light of genome-edited plant products, the ENGL Steering Committee is of the opinion that the document needs to be reviewed and, where appropriate, to be amended.

Tasks

The group should work in subsequent steps; as step 1 the WG should:

1. Review the current version of the method acceptance criteria and performance requirements document for its applicability to digital PCR methods for detection, identification and quantification of food and feed; and if necessary, establish dPCR-specific criteria. In doing so, the document produced by the WG on digital PCR should be taken into account.

and

2. Review, and if necessary amend, the current version of the method acceptance criteria and performance requirements document for its applicability to PCR methods for detection, identification and quantification of food and feed products obtained by new mutagenesis techniques.

As step 2 the WG should:

3. Review, and if necessary amend, the current version of the method acceptance criteria and performance requirements document for its applicability to PCR methods for detection, identification and quantification of food and feed products derived from GM animals.

Timeline

At the first meeting a work plan will be established. The first meeting should take place in 2019.