



Mandate for an ENGL Standing Working Group on Update of Methods (SWG-UpMeth)

Approved by the ENGL Steering Committee on 11th February 2015

Background

According to Regulation (EC) No 1829/2003, the authorisation of GMO for food and feed use is granted for ten years. The applicant has the possibility to apply for a renewal of such authorisation for another ten years.

The legal text does not clearly specify the requirements for the methods of detection in case of renewals, thus leaving room for interpretation.

The first requests for renewal will be submitted soon; potentially, about 10-15 applications for renewal will be submitted in 2015.

Technological advances may allow the identification of issues with the original validated methods which, at the time of first validation, could not be identified, e.g. reference gene copy number, sub-optimal reference gene assays, commercial unavailability of some reagents, real-time PCR machines not anymore on the market, delta-Ct methods not anymore implementable due to the lack of CRMs, etc.

Regardless the specific case of a renewal, the authorisation owner holds the responsibility of ensuring that at any time the detection method remains fit for purpose; thus the identification of flaws in the method should trigger a corrective action not only at the point of renewal but at any time during the authorisation.

Tasks

The standing WG should:

- Establish general criteria based on which for any issue identified with a validated method a specified action is recommended (e.g. in-house verification of some method parameters by the EURL GMFF, by a volunteering control laboratory)
- Review on a regular basis the methods of detection of GMOs for which a renewal is foreseen and provide advice to the EURL GMFF on their status (e.g. still fit-for-purpose, need for verification, need for re-validation etc.)

Timeline

The group is expected to meet at least once a year. The first meeting should take place within the first half of 2015. At this meeting a work plan for the coming 12 month will be established.