

## **EUROPEAN NETWORK OF GMO LABORATORIES (ENGL)**

### **Working Group on Method Performance Requirements (WG-MPR)**

#### **MANDATE (Revised after 18<sup>th</sup> ENGL SC)**

##### **Working Group Leader(s)**

To be decided

##### **Previous Working Group Members (ENGL Validation Working Group)**<sup>1</sup>

A. Damant, A. Holst-Jensen, E. Laurensse, G. Van den Eede, H. Broll, J. Ciesla, L. Hougs, M. Mazzara, C. Savini, M. Sandberg, P. Corbisier, R. Macarthur, U. Marchesi.

##### **Expected Completion Date**

30 June 2011

##### **Background**

The ENGL-CRL-GMFF method acceptance criteria and performance requirements document<sup>2</sup> underpins work undertaken by the European Union Reference Laboratory for GM Food and Feed (EURL-GMFF) regarding the validation and acceptance of methods of analysis submitted under Regulation EC No 1829/2003<sup>3</sup>.

The ENGL method acceptance criteria and performance requirements document was last revised on 13 October 2008 by the ENGL Validation Working Group (VWG). Important novel elements introduced are acceptance criteria for DNA extraction and purification and method verification criteria, in addition to new provisions concerning the specificity .

The current version states that *“At present this document refers to polymerase chain reaction (PCR) based analytical methods for the determination and quantification of GMOs. However, 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”*.

The current mandate proposed for the WG-MPR is to undertake a further expansion of the current version of the ENGL-CRL-GMFF criteria document, considering developments in the scientific state of the art and broadening of the analytical approaches covered by the document.

---

<sup>1</sup> The persons listed were members of the ENGL Validation Working Group.

<sup>2</sup> [http://gmo-crl.jrc.ec.europa.eu/doc/Min\\_Perf\\_Requirements\\_Analytical\\_methods.pdf](http://gmo-crl.jrc.ec.europa.eu/doc/Min_Perf_Requirements_Analytical_methods.pdf)

<sup>3</sup> Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, 18.10.2003, *Official Journal of the European Union*, L268, 1-23.

## **Detail**

The proposed mandate of the WG-MPR is to:

1. Establish or further improve acceptance criteria and guidance for the assessment and validation of analytical methods that are submitted under Regulation EC 1829/2003<sup>3</sup>, for example:
  - a) Qualitative (real-time PCR) methods
  - b) Taxon specific methods.
  
2. Establish acceptance criteria and guidance for the assessment and validation of analytical methods that are, at the moment, not submitted under Regulation EC 1829/2003<sup>3</sup>, for example:
  - a) Screening methods.
  - b) Non real-time PCR quantification methods.
  - c) Multiplex methods.
  - d) Others.
  
3. Undertake a further review of the current version of the ENGL method acceptance criteria and performance requirements document in light of practical experience and recent developments in the scientific state of the art: for example, additional elaboration and guidance on the definition and acceptance criteria for robustness, standard curves vs delta Ct-curve methods used in simplex in terms of generation of robust data.
  
4. Undertake a review on existing concepts of “Minimum Required Performance Limits” (MRPL) which are in force for food/feed contaminants with “zero-tolerance” in the EU and will evaluate these concepts for their possible transferability and applicability to GMO testing.

It is expected that, rather than modifying the current criteria, the WG-MPR will elaborate on the need for additional criteria, e.g. for target taxon-specific genes, DNA extraction, amplicon size and composition.

## Proposed Timeframe and Deliverables

Activity	Milestone	Deliverable
WG-MPR leader and members to be identified following circulation of the WG-MPR mandate (as revised in the 18 <sup>th</sup> ENGL SC meeting of February 2010)	June 2010	WG-MPR established
WG-MPR to meet, discuss comments raised and make recommendations on how to proceed further.	Q3 2010	Reviewed documents.
ENGL SC and Plenary to discuss the reviewed documents in detail.	October 2010 (for SC) and November 2010 (for Plenary)	ENGL SC/Plenary agreement on: <ul style="list-style-type: none"> <li>– whether, or not, the ENGL method validation criteria document requires expansion and additions in light of the review document; and</li> <li>– whether, or not, to accept the recommendations made by the WG-MPR for the validation/acceptance of methods not covered by the ENGL method validation criteria document.</li> </ul>
If required, a full revision of the ENGL method validation criteria document will be undertaken by the WG-MPR.  This activity will definitely require a meeting of the WG-MPR.	March 2011	The WG-MPR to submit a new revision of the ENGL method validation criteria document to the ENGL SC and ENGL Plenary.  WG-MPR to collect further comments
WG-MPR prepare a final version of the document	June 2011	The ENGL SC and Plenary to approve the final document