

Methods

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ENGL, the European Network of GMO Laboratories

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When the current EU policy on Genetically Modified Organism (GMO) was designed, GMO-specific detection methods were not generally available. Under the leadership of the Joint Research Centre of the European Commission (JRC), a European Network of GMO Laboratories was formed, the ENGL.

ENGL brings together the GMO control laboratories (including national reference laboratories - NRL) of the EU to establish standards, spread good practices, and discuss problems. Its standards are today used throughout the EU and beyond.

ENGL shows how an EU-wide network supports the level playing field that is essential for un-disturbed trade, and how it benefits its members in their daily work.

Introduction and background to ENGL

The European Union authorises genetically modified organisms (GMO) for entering the market only after careful risk assessment by EFSA, the European Food Safety Authority. Respecting the consumer right-to-know, it is also mandatory to label any food or feed product that contains an ingredient of which more than 0.9% of its mass are from an authorised GMO and even if this presence is fortuitous or technically unavoidable.

The EU Regulation (EC) No 1829/2003 on genetically modified food and feed (http://gmo-crl.jrc.ec.europa.eu/legalbasis.htm) makes validated methods for detecting GM food and feed a pre-condition for authorisation and requires that these methods are equally applied throughout the EU.

When this policy was conceived, PCR-based methods for GMO detection just became available and were not yet commonly applied in the food and feed control laboratories in the EU-Member States. In order to support their introduction and their harmonised application, the European Network of GMO-Laboratories (ENGL) was officially set-up in 2002. Since then the network is instrumental for adapting the EU GMO control system to scientific progress.

ENGL - membership, structure, and function

All official GMO control laboratories of the EU Member States, including the NRLs for GMO, are members of ENGL. The ENGL is led by the European Union Reference Laboratory for GM Food and Feed (EU-RL GMFF, http://gmo-crl.jrc.ec.europa. eu/), hosted by the JRC. GMO laboratories from non-EU states are also participating as members (EEA) or observers. See the list of participants at: http://gmo-crl.irc.ec.europa.eu/ENGL/ ENGLmembers.htm

The EU-RL GMFF chairs the network and provides its secretariat. It organises and finances the meetings of the ENGL plenary, the ENGL Steering Committee and the ENGL working groups.

There are 2 ENGL plenary meetings per year, open also to observers. They normally take place in Ispra, north Italy, the seat of the EU-RL GMFF. Their main function is to update the network on new developments and allow for face-to-face networking of the members. They also serve for sharing good practices and discussing common problems, establishing the work plan of the network and exchanging ENGL documents approved by the ENGL Steering Committee.

The ENGL Steering Committee (ENGL-SC) consists primarily of the NRL for GMO. It also meets twice per year to prepare the ENGL - plenary meetings, to establish the ENGL work plan, to decide about the creation and mandate of ENGL working groups and monitor their progress, and to adopt their final results as ENGL products. Currently the ENGL has four active working groups:

WG MPR (Method Performance Requirements)

This WG works on the document "Definition of minimum performance requirements for analytical methods of GMO testing". The aim is to broaden the scope of the current document (http://gmo-crl.jrc.ec.europa.eu/guidancedocs.htm) to qualitative, taxon-specific, DNA extraction and multiplex methods. Criteria for defining false positives, false negatives, and for assessing the performance of gualitative detection methods are discussed, as well as a protocol for testing methods' robustness and general criteria for DNA extraction methods.

WG SPP (Sample Preparation Procedure)

The WG pulls together good sampling practice and is preparing a guidance document on Sample Preparation Procedures. The final draft is at an advanced stage and will inter alia advocate performance tests for the different steps of the sample preparation. Good working procedures will be described.

AG SMV (Advisory Group on Selection of Methods for Validation)

The mandate of this advisory group is, opposite to the WGs, not limited in time. The group identifies detection methods that should be validated for filling gaps in the regulatory GMO detection toolbox. So far taxon-, element-, and constructspecific methods have been suggested by the ENGL members and a priority list will be proposed by the group to the ENGL-SC for adoption. Thereafter the ENGL members will be invited to contribute and participate in their validation, which will be led by the EU-RL GMFF.

WG DIR (Detection Interpretation Reporting)

This WG shall produce / update practical guidance for the detection, identification and quantification of GMOs in food or feed, the interpretation of analytical results, and their reporting.



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It will address authorised GMOs, for which event-specific methods are available, and unauthorised GMOs, for which those methods are normally lacking. To embrace the broad scope of the document, activities were divided in three subgroups:

- G1 Cut-off values and verification of analytical results,
- G2 Matrix approaches and reporting,
- G3 Knowledge-based approaches and new technological developments.

ENGL results

After more than ten years of existence, the importance of ENGL for the harmonisation of GMO detection throughout the EU and beyond cannot be overestimated. Based on its vast hands-on expertise it ensured that its generally accepted method performance criteria, against which the performance of methods can be assessed, are realistic and feasible for practical control situations. By bringing together the entire regulatory GMO analysis expertise of the EU it is highly respected as authority in this field.

The ENGL has also produced a number of guidance documents that are published on the EU-RL GMFF website and therefore globally available (http://gmo-crl.jrc.ec.europa. eu/guidancedocs.htm). Certain of them became a global de facto standard and the ENGL itself serves as example for other regions of the world where similar networks are forming. ENGL members are regularly called upon to provide training on GMO analysis to colleagues from third countries.

Generally speaking, ENGL organisation, practices and documents also served as models in other detection areas such as food microbiology.

ENGL outlook

The number of GMOs (plants and animals) that are reaching and will reach commercialisation is increasing. Their regulatory management will continue to need (cost-) effective, reliable methods for their detection, identification and quantification. ENGL's expertise will remain instrumental for the development and global acceptance of such practically feasible methods, even if the challenges resulting from new breeding techniques and the possible introduction of GM-animals into the food and feed chain should not be underestimated.

These big challenges that lie ahead result from scientific and technological progress. New techniques of genetic engineering challenge current detection methods and require that new analytical techniques must be implemented by the community of the EU GMO-control laboratories. The ENGL will support this implementation while continuing ensuring that proposed methods remain feasible, both in terms of scientific and technical complexity and cost.