

The European Network of GMO Laboratories (ENGL) as a platform for exchange of information

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**International Workshop on Harmonisation of GMO
Detection and Analysis
28-29 October 2010, Nelspruit - South Africa**

Summary

- ENGL – The beginning
- ENGL - The role
- ENGL - Organization
- ENGL – Regulatory context
- ENGL – Work program
- ENGL – Achievements
- ENGL – Information exchange
- ENGL – The future!

ENGL – The beginning

- **November 1999 – Ad-hoc “Novel Foods” meeting on “Methods for the Detection of Genetically Modified Organisms – Derived Foodstuffs, JRC-Ispra**
 - Recommendations from Member States Competent Authorities
 - Establish a network for the laboratories of the Member States
 - The network should be structurally and functionally coordinated by the Commission, through JRC
 - JRC should have a central role for the setting-up and management of this network

ENGL – The beginning

- **November 1999 – Ad-hoc “Novel Foods” meeting on “Methods for the Detection of Genetically Modified Organisms – Derived Foodstuffs”, JRC-Ispra**
- **Needs identified:**
 - Collection and exchange of information
 - Co-ordination of tasks to reduce costs
 - Identification and solutions to technical gaps or needs (reference material, sampling plans, detection methods)
 - On-line access to shared expertise

ENGL – The beginning

- **In 2000, informal presentation of ENGL by JRC-Ispra**
 - kick-off meeting in June 2000.
 - 2nd meeting in February 2001
 - Concrete proposal to formalise the network
 - JRC would draft a proposal for a Consortium Agreement

ENGL – The beginning

- **The official ENGL**

- 4th December 2002 – Brussels – ENGL's official inauguration.
- Signature of Consortium Agreement
 - JRC + 44 member states laboratories



- Represented all 15 EU Member States + Norway
- JRC represented through
 - Institute for Health and Consumer Protection (IHCP)
 - Institute for Reference Materials and Measurements (IRMM)

ENGL – The beginning

- **ENGL enlargement**

- 2004 – laboratories from 10 new Member States join ENGL.
 - Inauguration ceremony in Prague



- 2007 – laboratories from Bulgaria and Romania join ENGL.
- 1st. July 2009 – signature of new Consortium Agreement

ENGL – The role

- Solve the large number of problems that enforcement laboratories face within the field of Genetically Modified Organisms in food, feed, seeds and the environment.
- Scientific support to the environmental and food community policies

ENGL – The role

- To develop, consolidate and improve, at European level, the science-based harmonization and validation of most modern analytical tools for the traceability and authentication of GMOs and their derived products
 - Method development and validation
 - Sampling
 - Establishing databases
 - Technology transfer

ENGL – The role

- Provide support to the Community Reference Laboratory (CRL), as defined on EC Regulations N°1829/2003 and N° 882/2004.
- Act as a network of scientific excellence on detection and traceability of GMOs and related issues
- Provide the best practice information to worldwide stakeholders through international liaisons and set up an active communication policy

ENGL - Organization

● “CONSORTIUM AGREEMENT”

- New Members designated by National Competent Authorities operating under one of the Community Acts or under corresponding equivalent regulations and Directives related to GMO of EEA, EFTA member states. Candidate Countries or Potential Candidate Countries may join the ENGL
- Each contracting party shall designate the necessary professional technical staff
- JRC shall allocate a specific budget for ENGL management
- Day-by-day management shall be handled by a secretariat under JRC coordination

ENGL - Organization

- **“CONSORTIUM AGREEMENT”**

- **Membership definition**

Each member of the ENGL has been designated either by the:

- Competent Authorities operating under Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically Modified Organisms and repealing Council Directive 90/269/EEC, or
- Competent Authorities operating under Regulation (EC) N° 1829/2003, or
- Authorities operating under Regulation (EC) N° 882/2004, or
- Competent Authorities operating under EU legislation on the marketing of seeds of agricultural and vegetable plant species and of forest reproductive material

ENGL - Organization

- **“CONSORTIUM AGREEMENT”**
 - **Steering Committee**
 - One ENGL member per each Member State or states to which EEA or EFTA applies
 - Chaired by JRC, as Committee president
 - Supervise and coordinate the shared work
 - Power to add new party and decide upon termination of the agreement with a party.

ENGL – Regulatory Context

JRC Scientific and Technical Reports

The EU Legislation on GMOs

An overview

Damien Plan, Guy Van den Eede



EUR 24279 EN - 2010



ENGL – Regulatory Context

Annex of Regulation (EC) n° 1829/2003 on GM Food and Feed (amended by Annex III of Regulation (EC) N° 1981/2006):

- The Community Reference Laboratory for FM Food and Feed “shall be assisted by the National Reference laboratories...referred to as the European Network of GMO Laboratories”

ENGL – Regulatory Context

- **Regulation (EC) N° 641/2004 on detailed rules for the implementation of Regulation (EC) N° 1829/2003:**
 - ENGL – acceptance criteria and performance requirements of methods submitted by the applicants according to Regulation (EC) N° 1829/2003

ENGL – Regulatory Context

- **Regulation (EC) N° 882/2004 about Official Control :**
 - Defines CRL, NRLs and Official Laboratories
 - CRL-GMFF is the laboratory referred to in the Annex to Regulation (EC) N° 1829/2003.



ENGL – Regulatory Context

- **Regulation (EC) N° 1981/2006 on Detailed Rules for the implementation of Regulation (EC) N° 1829/2003, concerning CRL-GMFF:**
 - Lists all NRLs/ENGL members that can provide assistance to CRL/GMFF in validation process and that accomplish the specific Quality requirements defined in Annex I.



ENGL – Work Program

- **JRC-IRMM:**
 - Production of Certified Reference Materials to be used in GMO analysis
- **JRC-IHCP/EURL-GMFF:**
 - Reception, preparation, storage and maintenance of control samples
 - Training and capacity building
 - Information and data exchange

ENGL – Work Program

- **Organisation of Plenary Meetings and breakout Working Groups:**
 - 2 Plenary sessions per year since 2002, grouping now more than 120 delegates representing laboratories from 27 Member States and EEA countries
 - 2 meetings per year of the Steering Committee
 - Several Working Group focusing on
 - Sampling
 - Performance criteria for testing methods
 - Control samples and Reference Material
 - Measurement Uncertainty
 - Unit of measurement
 - Unauthorized GMOs

ENGL – Achievements


- **Concepts and rules:**
 - Definition of minimum performance requirements for analytical methods of GMO testing
 - Modular approach validation
 - Relevant International norms



ENGL – Achievements

- **Reference and guideline documents:**
 - Definition of minimum performance requirements for analytical methods of GMO testing
 - ENGL explanatory document on unit of measurement
 - Guidance document on measurement uncertainty for GMO testing laboratories

ENGL – Achievements



Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing
European Network of GMO Laboratories (ENGL)

13 October 2008
Date of application: 13 April 2009

INTRODUCTION

The scope of this European Network of Genetically Modified Organism Laboratories (ENGL) document is to provide recommendations on how methods for genetically modified organism (GMO) analysis shall be evaluated and validated by the Community Reference Laboratory for Genetically Modified Food and Feed (CRL-GMFF) in the context of Commission Regulation (EC) No 1825/2003¹.

There is synergy between recommendations made within this document and those of the Codex Alimentarius Commission².

Reliable analytical methods are required for compliance with national and international regulations in all areas of analysis³. It is internationally recognised that a laboratory must take appropriate measures to ensure that it is capable of providing and does provide data of the required quality. Such measures include:

- using validated methods of analysis;
- using internal quality control procedures;
- participating in proficiency testing schemes; and
- becoming accredited to an international standard, normally ISO/IEC 17025⁴.

Method validation is therefore an essential component of the measures that a laboratory should implement to allow it to produce reliable analytical data. In some sectors, most notably in the analysis of food, the requirement for methods that have been "fully validated" is prescribed by legislation⁵. Full validation for an analytical method is usually taken to comprise an examination of the characteristics of the method in an inter-laboratory method performance study (also known as a collaborative study or collaborative trial). Internationally accepted protocols have been established for the "full" validation of a method of analysis by a collaborative trial, most notably the International Harmonised Protocol⁶ and the ISO procedure⁷. These protocols/standards require a minimum number of laboratories and test materials to be included in the collaborative trial to validate fully the analytical method.



ENGL EXPLANATORY DOCUMENT ON THE USE OF "PERCENTAGE OF GM-DNA COPY NUMBERS IN RELATION TO TARGET TAXON SPECIFIC DNA COPY NUMBERS" CALCULATED IN TERMS OF HAPLOID GENOMES¹ AS A GENERAL UNIT TO EXPRESS THE PERCENTAGE OF GMOs


This document is elaborated by an *ad hoc* working group within the European Network of GMO Laboratories (ENGL) in response to requests for explanatory guidance from the Standing Committee for Food Chain and Animal Health and stakeholders in the EU member states concerning the unit of expression of GM material quantities in agricultural and derived products and in the context of the existing EU regulatory framework. This document, while explaining some of the key scientific elements, is primarily focused on explaining the consequences for expression of GM content.

The document takes account of current scientific knowledge and of the existing technological capabilities. This explanatory document may be revised to take account of progress in science and/or technology.

It has been formally approved for release by the Steering Committee of ENGL on July 5th 2007.


In order to further improve the document comments may be sent to guy.van-olm-seeds@ec.europa.eu

JRC Scientific and Technical Reports




Guidance Document on Measurement Uncertainty for GMO Testing Laboratories

S. Trapman, M. Burns, H. Broll, R. Macarthur, R. Wood, J. Zel



EUR 22798 EN02 - 2008

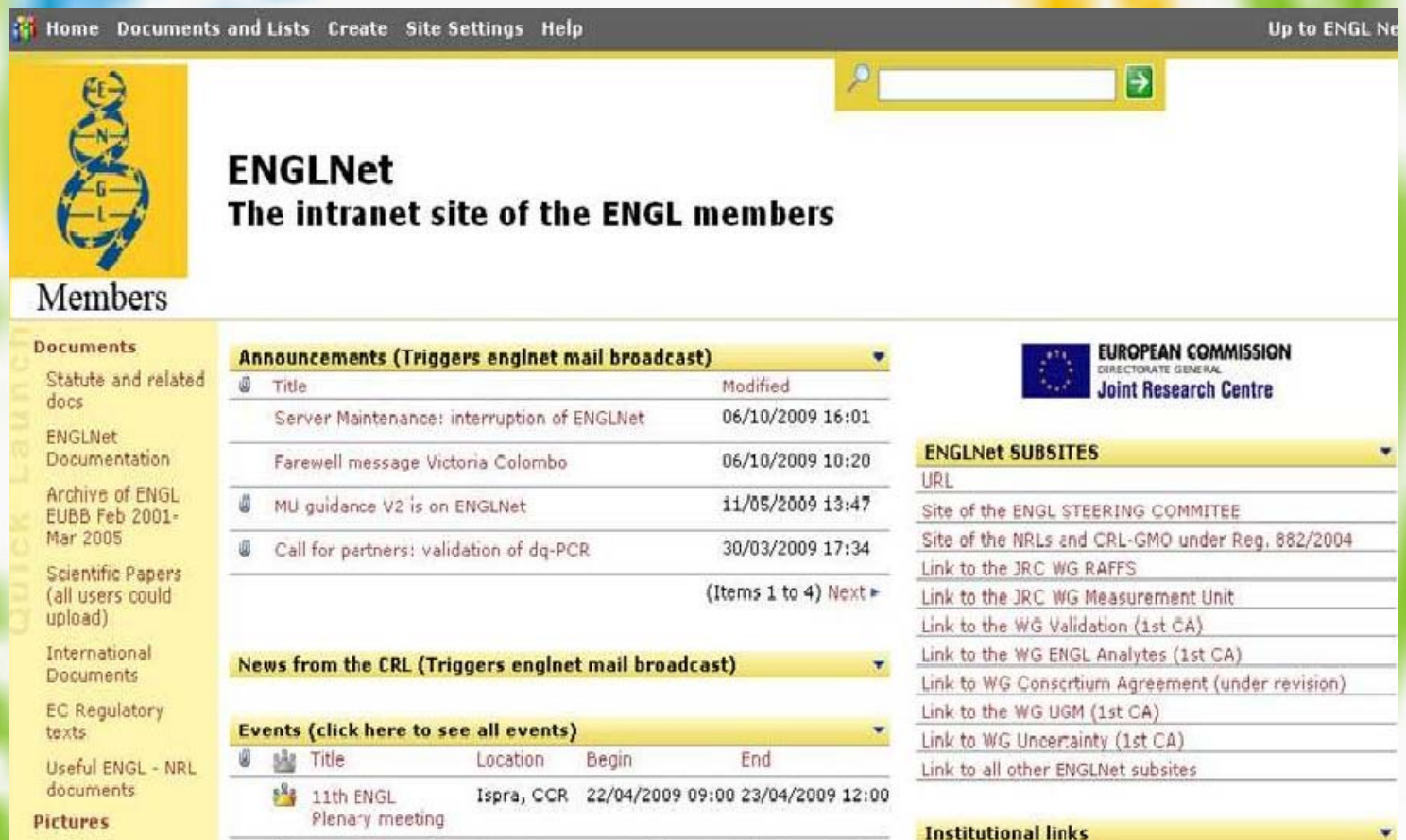


ENGL – Information exchange

- **ENGL Plenary meetings**
 - Technical advices on routine analysis, research activities, interpretation of International norms and guidelines
 - Implementation of Regulation
 - Preparation of reference and guideline documents
 - Observers from EU candidates and third countries (Tunisia, China, etc.)
- **ENGL on line forum, Bulletin Board (2002-2004)**
- **ENGLnet (since 2005)**

ENGL – Information exchange

- ENGLnet as private intranet and collaborative content management



The screenshot shows the ENGLNet intranet interface. At the top is a navigation bar with links: Home, Documents and Lists, Create, Site Settings, Help. On the right of the bar is a search box and a link 'Up to ENGL Net'. Below the navigation bar is a large yellow banner with the ENGL logo and the text 'ENGLNet The intranet site of the ENGL members'. To the left of the banner is a 'Members' section. Below the banner is a 'Documents' section with a 'Quick Launch' sidebar. The sidebar lists: Statute and related docs, ENGLNet Documentation, Archive of ENGL EUBB Feb 2001-Mar 2005, Scientific Papers (all users could upload), International Documents, EC Regulatory texts, Useful ENGL - NRL documents, and Pictures. The main content area has three sections: 'Announcements (Triggers englnet mail broadcast)' with a table of recent updates, 'News from the CRL (Triggers englnet mail broadcast)', and 'Events (click here to see all events)' with a table of upcoming events. On the right side, there is a logo for the 'EUROPEAN COMMISSION DIRECTORATE GENERAL Joint Research Centre' and a section titled 'ENGLNet SUBSITES' with a list of links to various resources. At the bottom right is a section for 'Institutional links'.

Home Documents and Lists Create Site Settings Help Up to ENGL Net

ENGLNet
The intranet site of the ENGL members

Members

Documents

Statute and related docs

ENGLNet Documentation

Archive of ENGL EUBB Feb 2001-Mar 2005

Scientific Papers (all users could upload)

International Documents

EC Regulatory texts

Useful ENGL - NRL documents

Pictures

Announcements (Triggers englnet mail broadcast)

Title	Modified
Server Maintenance: interruption of ENGLNet	06/10/2009 16:01
Farewell message Victoria Colombo	06/10/2009 10:20
MU guidance V2 is on ENGLNet	11/05/2009 13:47
Call for partners: validation of dq-PCR	30/03/2009 17:34

(Items 1 to 4) Next ▶

News from the CRL (Triggers englnet mail broadcast)

Events (click here to see all events)

Title	Location	Begin	End
11th ENGL Plenary meeting	Ispira, CCR	22/04/2009 09:00	23/04/2009 12:00

EUROPEAN COMMISSION
DIRECTORATE GENERAL
Joint Research Centre

ENGLNet SUBSITES

URL

Site of the ENGL STEERING COMMITTEE

Site of the NRLs and CRL-GMO under Reg. 882/2004

Link to the JRC WG RAFFS

Link to the JRC WG Measurement Unit

Link to the WG Validation (1st CA)

Link to the WG ENGL Analytes (1st CA)

Link to WG Consortium Agreement (under revision)

Link to the WG UGM (1st CA)

Link to WG Uncertainty (1st CA)

Link to all other ENGLNet subsites

Institutional links

ENGL – Information exchange

- **Information and data exchange between members:**
 - Publication of a database of published methods on internet (2003)
 - Development of reference databases of reference DNA sequences, analytes and tools
 - Collaboration with the international bioinformatics network “EMBnet”

(Activities carried out at JRC-IHCP)

ENGL – Information exchange

- **Information exchanges between JRC Institutes, ENGL members, the Commission, Member-States and stakeholders**
 - Systematic participation to international meetings all over the world
 - Development of ENGL as a network of excellence for research in analytical Traceability (CoExtra Project)
 - Scientific Support to the Commission services in charge of GMO policies – translation into ENGL scientific and communication work (Chairman – Guy Van Den Eede)

ENGL – The future!

- **ENGL is still needed!**

- Many scientific issues still unsolved and more issues are coming
- ENGL serves as an excellent example of platform for information exchange between Member States, the Commission and stakeholders worldwide
- Coordinate/Integrate CRL/NRL activities under Regulations (EC)N° 1829/2003 and (EC)N° 882/2004 within ENGL
- New Consortium Agreement – going on a more efficient ENGL

ENGL – The future!

- **ENGL is still needed!**
 - Openness to the world! Priority of ENGL members and JRC. Global oversight is a concrete perspective



- “Listen the stakeholders” – understand their needs and difficulties to trace the way to modern solutions.
- Scientific support to the CRL - GMFF and to NRLs is an ENGL institutional priority



European Network of GMO Laboratories

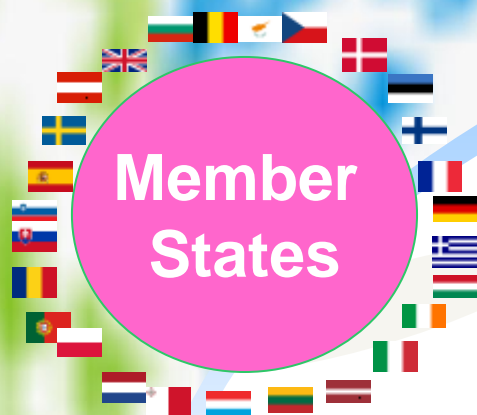
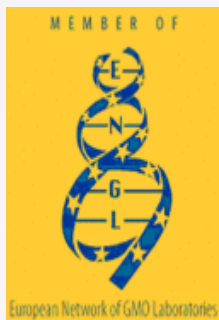
- ENGL - network of scientists carrying research and routine activities for the Member States
- ENGL works in coordination with the international norms, guidelines and Quality methodologies
- ENGL is a place for real time reciprocal information exchange between Member States and the Commission

European Network of GMO Laboratories

◆ The key elements of the ENGL success are

- A common web based platform for exchange of information and reciprocal support
- Biannual plenary meetings with all ENGL members
- Defined working plan carried out by working groups dedicated to specific technical topics related to GMO control
 - unauthorized GMOs
 - validation criteria
 - certified reference material
 - Sampling
 - Uncertainty measurements

◆ As a result, a very high level of harmonization has been already achieved in Europe



ENGL



European Network of GMO Laboratories

Useful links:

<http://engl.jrc.ec.europa.eu/> (ENGL web site)

<http://gmo-crl.jrc.ec.europa.eu/> (CRL web site)

<http://mbg.jrc.ec.europa.eu/> (IHCP – Biotechnology and GMO unit)

<http://mbg.jrc.ec.europa.eu/capacitybuilding/training.htm>

(information about training activities)

<http://gmoinfo.jrc.ec.europa.eu> (overview of field releases and of products notified on the EU market under Directive 2001/18)

<http://mbg.jrc.ec.europa.eu/home/ict/methodsdatabase.htm>.
(database of GMO methods)

<http://gmoinfo.jrc.ec.europa.eu> (database of DNA sequences)

<http://irmm.jrc.ec.europa.eu> (IRMM – Institute of Reference Materials and Measurements)

Thanks South Africa