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

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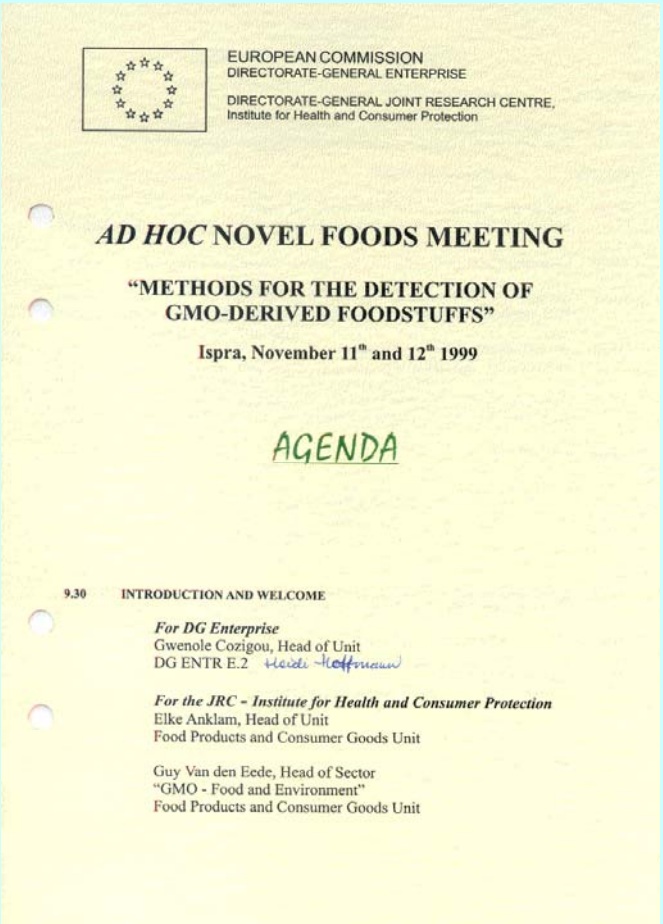
Outline

- ENGL - the beginning
- The role of ENGL
- Organisation of ENGL
- ENGL in a regulatory context
- Work carried out
- Achievements
- Information exchange between members
- ENGL – the continuation

The beginning



EUROPEAN COMMISSION
DIRECTORATE-GENERAL ENTERPRISE

DIRECTORATE-GENERAL JOINT RESEARCH CENTRE,
Institute for Health and Consumer Protection

***AD HOC* NOVEL FOODS MEETING**

"METHODS FOR THE DETECTION OF GMO-DERIVED FOODSTUFFS"

Ispra, November 11th and 12th 1999

AGENDA

9.30 INTRODUCTION AND WELCOME

For DG Enterprise
Gwenole Cozigou, Head of Unit
DG ENTR E.2 Heidi Hoffmann

For the JRC - Institute for Health and Consumer Protection
Elke Anklam, Head of Unit
Food Products and Consumer Goods Unit

Guy Van den Eede, Head of Sector
"GMO - Food and Environment"
Food Products and Consumer Goods Unit

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Ad hoc novel foods meeting, JRC, Ispra, November 1999

Recommendations from Member States Competent Authorities:

- Establish a network for the laboratories of the Member States' Competent Authorities
- Network should be structurally and functionally co-ordinated by the Commission
- JRC should have a central role for the establishment and running of this network

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Ad hoc novel foods meeting, JRC, Ispra, November 1999 (cont)

Needs identified:

- Information collection and exchange
- Co-ordination of tasks to reduce costs
- Identification of and solutions to technical gaps or needs such as reference materials and sampling plans
- On-line access to shared expertise

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The informal ENGL

JRC Ispra informally established the ENGL in year 2000:

- Kick off meeting in June 2000
- After the 2nd meeting in February 2001 a concrete proposal was made to:
  - Formalise the network
  - JRC would draft a proposal for a Consortium Agreement

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The official ENGL

ENGL was officially inaugurated in December 2002:

- JRC and 44 Member State laboratories signed a Consortium Agreement
- All 15 EU member States + Norway were represented
- JRC-through
  - Institute for Health and Consumer Protection (IHCP)
  - Institute for Reference Materials and Measurements (IRMM)

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ENGL expands

EU enlargement:

- Laboratories from the 10 new Member States join ENGL in 2004
  - Inauguration ceremony in Prague
- Laboratories from the new Member States Bulgaria and Romania join in 2007

The role of ENGL

- Act as a platform to solve problems enforcement laboratories face within the field of GMOs in food, feed, seeds and environment
- Give scientific support to the environmental and food community policies
- Act as a network of scientific excellence on the detection and traceability of GMOs and related scientific issues
- Provide support to the Community Reference Laboratory

The role of ENGL (cont)

- Develop scientific knowledge and consolidate and improve the European harmonisation and standardisation of scientific methods for detection, identification and quantification of GMOs or products produced from GMOs

  - Method development and validation
  - Sampling
  - Establishing databases
  - Technology transfer

Organisation of ENGL

Consortium Agreement:

- New members are designated by the national competent authorities operating under one of the Community acts related to GMOs
- JRC shall allocate a specific budget for the costs of the organisation of ENGL
- Each contracting party shall designate the necessary professional technical staff
- The day-to-day management of the ENGL shall be handled by a secretariat operated by the JRC

Organisation of ENGL (cont)

Consortium Agreement:

- Steering Committee
  - Supervise and coordinate the shared work
  - Chaired by the JRC, as committee president
  - One ENGL member per each Member State of EU or States to which EEA or EFTA applies
  - Power to add a party to ENGL and decide upon termination of the agreement with a party

ENGL in a regulatory context

Annex of Regulation (EC) No 1829/2003 on GM food and Feed [amended by Annex III of Regulation (EC) No 1981/2006]:

- The Community Reference Laboratory for GM food and Feed “shall be assisted by the national reference laboratories…..referred to as the European Network of GMO Laboratories”

ENGL in a regulatory context (cont)

Regulation (EC) No 641/2004 on detailed rules for the implementation of regulation (EC) No 1829/2003

- ENGL – acceptance criteria and performance requirements of methods submitted by applicants according to Regulation (EC) No 1829/2003

ENGL in a regulatory context (cont)

Regulation (EC) No 1981/2006 on detailed rules for the implementation of regulation (EC) No 1829/2003 as regards the CRL-GMFF

- Sets the applicants fees to the CRL for covering the validations costs
- Lists all the NRLs/ENGL members that can assist the CRL-GMFF in the validation process and that fulfil the specific quality requirements lied down in Annex I

ENGL in a regulatory context (cont)

Regulation (EC) No 882/2004 on official control

- CRLs, NRLs, and official laboratories
- CRL-GMO is the laboratory referred to in the Annex to Regulation (EC) No 1829/2003

Work carried out

- **JRC-IRMM**
  - Production of certified reference materials to be used in GMO analyses
- **JRC-IHCP/CRL**
  - Reception, preparation, storage, maintenance and distribution to ENGL of control samples
  - Training and capacity building
  - Information and data exchange

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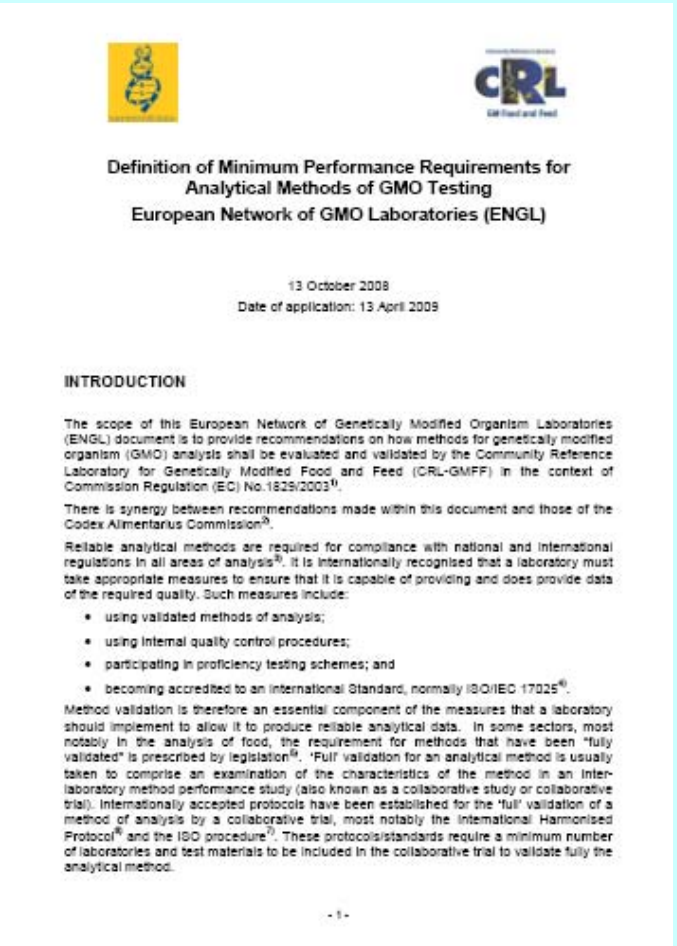
Work carried out (cont)

- **ENGL working groups (examples)**
  - Sampling
  - Performance criteria for testing methods
  - Measurement uncertainty
  - Unit of measurement
  - ENGL analytes
  - Unauthorised GMOs

Achievements

- **Reference and guideline documents (examples):**
  - 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

http://gmo-crl.jrc.ec.europa.eu/



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.1829/2003[1].

There is synergy between recommendations made within this document and those of the Codex Alimentarius Commission[2].

Reliable analytical methods are required for compliance with national and international regulations in all areas of analysis[3]. 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 17025[4].

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 legislation[5]. '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 Protocol[6] and the ISO procedure[7]. 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.

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Achievements

- **Reference and guideline documents (examples):**
  - 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

http://engl.jrc.ec.europa.eu/

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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 GENOMES" 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-den-eede@ec.europa.eu

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Achievements

- **Reference and guideline documents (examples):**
  - 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

http://irmm.jrc.ec.europa.eu/

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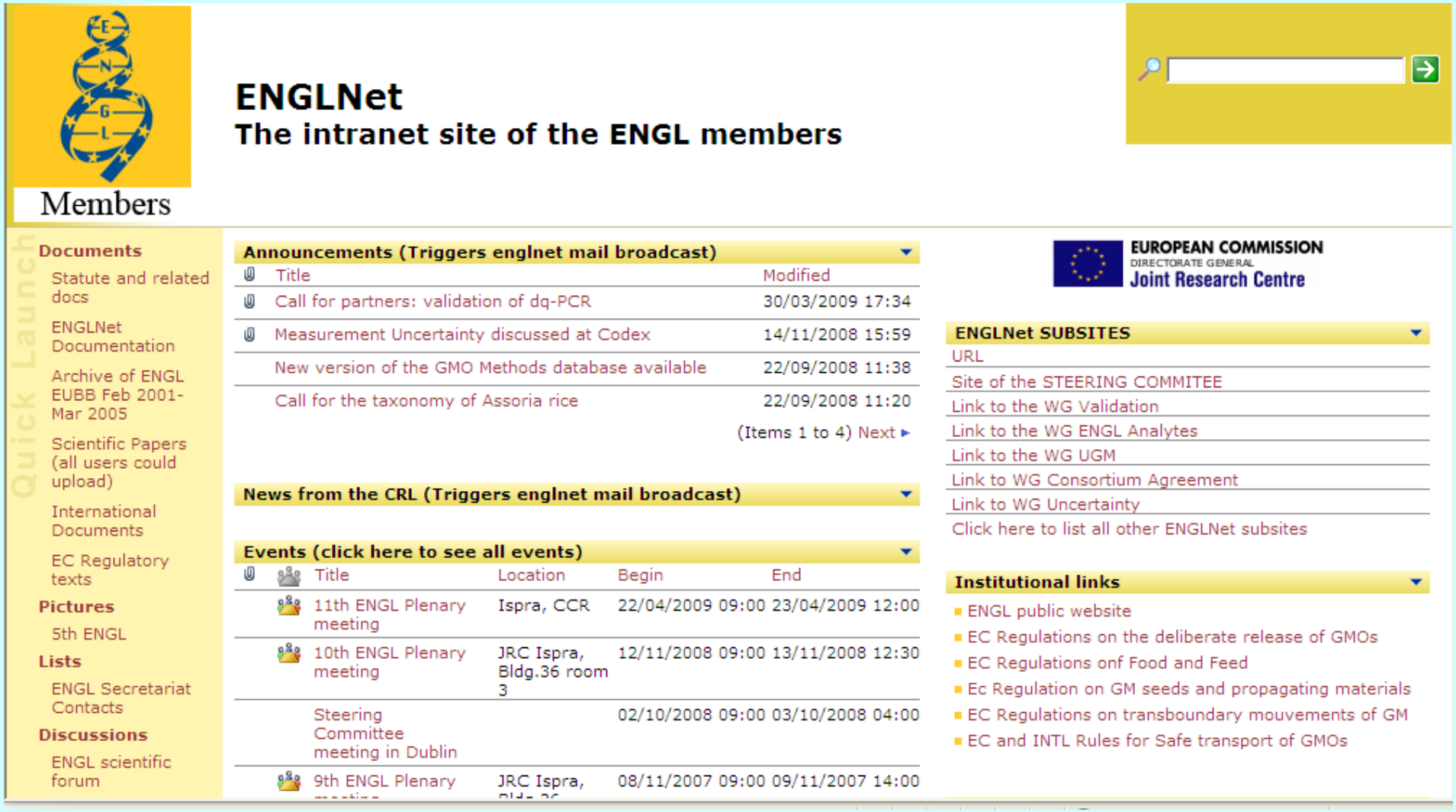
Information exchange between members

- ENGL Plenary Meetings
  - Technical discussions on routine analysis, technologies, international norms and guidelines, research activities etc.
  - Observers from EU candidate countries and others (China, Tunisia etc)

- ENGL on line forum, bulletin board (2002-2004)

- ENGLNet

ENGLNet


Members
ENGLNet
The intranet site of the ENGL 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
Pictures
5th ENGL
Lists
ENGL Secretariat Contacts
Discussions
ENGL scientific forum
Quick Launch
Announcements (Triggers englnet mail broadcast)
Title
Modified
Call for partners: validation of dq-PCR
30/03/2009 17:34
Measurement Uncertainty discussed at Codex
14/11/2008 15:59
New version of the GMO Methods database available
22/09/2008 11:38
Call for the taxonomy of Assoria rice
22/09/2008 11:20
(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
Ispra, CCR
22/04/2009 09:00
23/04/2009 12:00
10th ENGL Plenary meeting
JRC Ispra, Bldg.36 room 3
12/11/2008 09:00
13/11/2008 12:30
Steering Committee meeting in Dublin
02/10/2008 09:00
03/10/2008 04:00
9th ENGL Plenary
JRC Ispra,
08/11/2007 09:00
09/11/2007 14:00
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ENGLNet SUBSITES
URL
Site of the STEERING COMMITEE
Link to the WG Validation
Link to the WG ENGL Analytes
Link to the WG UGM
Link to WG Consortium Agreement
Link to WG Uncertainty
Click here to list all other ENGLNet subsites
Institutional links
ENGL public website
EC Regulations on the deliberate release of GMOs
EC Regulations onf Food and Feed
Ec Regulation on GM seeds and propagating materials
EC Regulations on transboundary mouvements of GM
EC and INTL Rules for Safe transport of GMOs

ENGL – the continuation

- ENGL is still needed! Many scientific issues still unsolved and more issues are coming
- ENGL serves as an excellent example of a platform for information exchange between Member States, the Commission and stakeholders worldwide
- Coordinate/integrate CRL/NRL activities under Regulations (EC) No 1829/2003 and (EC) No 882/2004 within ENGL
- New Consortium Agreement – a more efficient ENGL

Thank you!

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