

The European Network of GMO Laboratories (ENGL)

The ENGL Experience in GMO detection



Damien Plan

Ljubljana, Slovenia, 12 April 2011

JRC Institute for Health and Consumer Protection (IHCP)

European Commission

The Joint Research Centre (JRC) is a Directorate-General of the European Commission under the responsibility of the European Commissioner for Science and Research .

The JRC is composed of 7 Institutes in 5 Member States (incl. the **IHCP**, Institute for Health and Consumer Protection based in Ispra, Italy)

The JRC role is to provide **scientific and technical support** for the conception, development, implementation and monitoring of **EU policies**.

Web: www.jrc.ec.europa.eu

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CONTENTS – The European Network of GMO Laboratories (ENGL)

- ENGL - history
- ENGL - regulatory background
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- ENGL - outlook

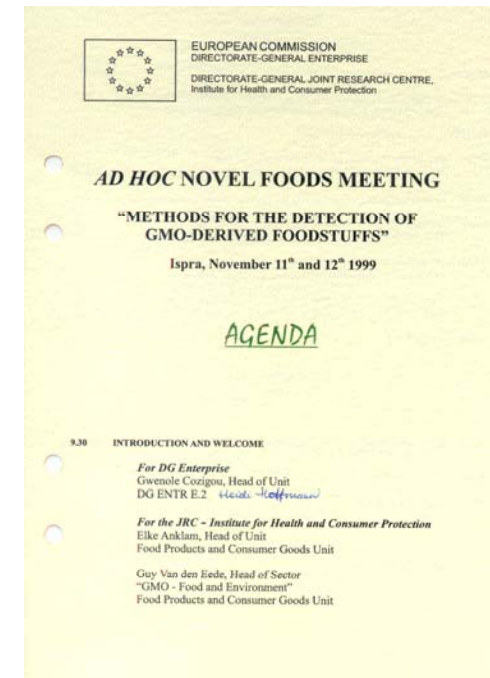
ENGL - the beginning of a long story : ad hoc Novel Foods meeting on GMO detection at JRC in Ispra on 11-12 November 1999

Recommendations:

- Establish a network for the laboratories of the Member States
- This network should be structurally and functionally co-ordinated by the European Commission

Needs identified:

- Information collection and exchange on GMO detection
- Co-ordination of tasks to reduce costs
- Identification of and solutions to technical gaps



The informal ENGL : 2000 – 2002

- **June 2000** : informal kick off meeting
- **February 2001** : 2nd informal meeting and agreement to formalise the network through a Consortium Agreement

The official ENGL : 2002 - ...

- **December 2002**: official inauguration of the ENGL in Brussels
- The European Commission JRC and 44 national laboratories sign the first ENGL Consortium Agreement
- All 15 EU member States + Norway represented
- Chairmanship by JRC



ENGL the expansion : 2003 - ...



In 2003, regulation (EC) No 1829/2003 on GM Food and Feed is adopted and gives to **ENGL** an official regulatory status (see later) : EU Member States nominate further laboratories as ENGL members

At the same time, **together with EU enlargement, the ENGL expands**

- 2004: EU-15 becomes EU-25 and laboratories from 10 new Member States join the ENGL
- 2007: EU-27 and laboratories from Bulgaria and Romania join the ENGL

Today ENGL is a unique network of expertise in GMO analysis :
96 laboratories from 27 EU Member States + Norway and Switzerland + Croatia
+ observers from non-EU countries

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ENGL and EURL – two European partners in GMO detection

- EURL - the European Union Reference Laboratory for GM Food & Feed
- 1 central lab hosted by the EU Commission JRC
- ENGL – the European Network of GMO Laboratories
- 96 labs hosted by 27 EU Member States (+ 3 non-EU)



All EURL and ENGL activities in GMO detection are based on the EU GMO legislation (see next)

Regulation (EC) No 1829/2003 on genetically modified food and feed General Provisions

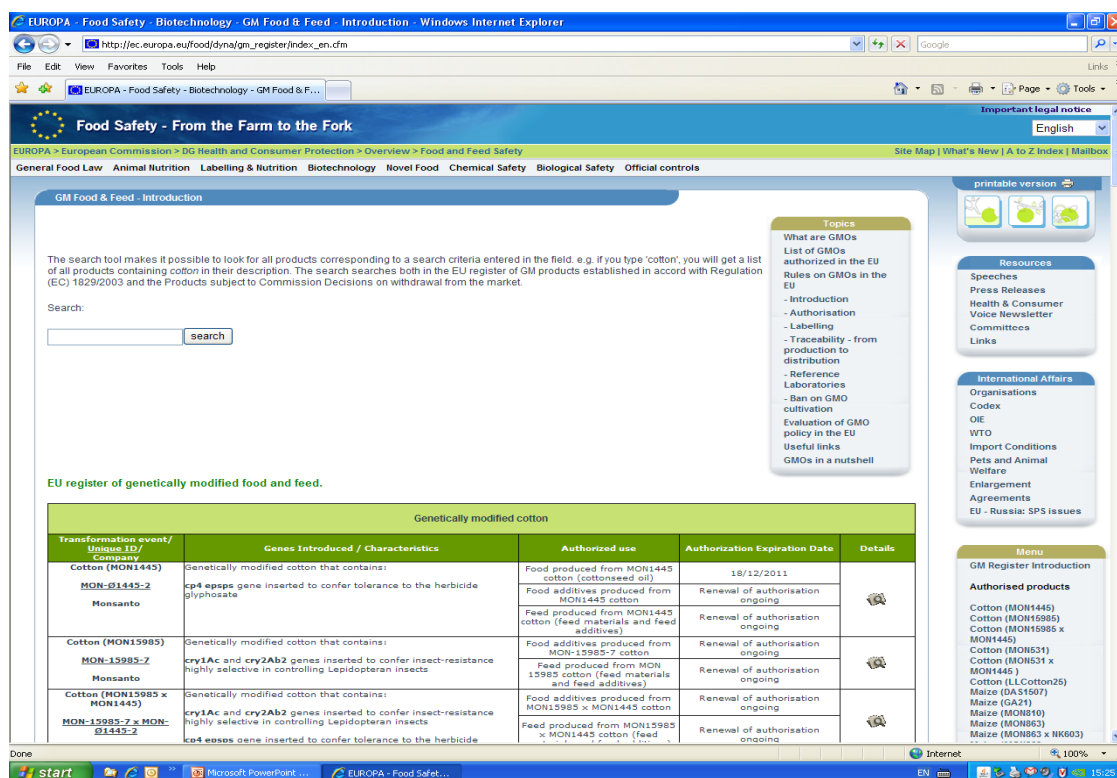
A GM food/feed can be placed on the EU market only once covered by a EU authorisation granted according to Regulation (EC) No 1829/2003 (the EU GMO approval process is based on an independent EU risk assessment carried out by the European Food Safety Authority - EFSA)

- **GMOs approved in the EU should be labelled** : EU mandatory GM labelling system to provide consumer information (incl. labelling threshold of 0,9% to exempt from GM labelling the adventitious or technically unavoidable presence of approved GM material in food or feed) – need for quantitative detection in the EU
- **GMOs unapproved in the EU should not be on the EU market** – if unapproved GMOs detected, emergency measures may be taken

Information on EU GMO approvals available on EU GM Food Feed register




http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

As of March 2011, 36 GMOs : 22 maize, 6 cotton, 3 soya, 3 oilseed rape, 1 starch potato, 1 sugarbeet are approved for food/feed use in the EU (incl. 2 for cultivation)



The screenshot shows the EU GM Food Feed register website. The main heading is "Food Safety - From the Farm to the Fork". Below it, there's a search bar and a "search" button. The page is titled "GM Food & Feed - Introduction".

EU register of genetically modified food and feed.

Transformation event/ Unique ID/ Company	Genes Introduced / Characteristics	Authorized use	Authorization Expiration Date	Details
Cotton (MON1445) MON-01445-2 Monsanto	Genetically modified cotton that contains: cp4 epsps gene inserted to confer tolerance to the herbicide glyphosate	Food produced from MON1445 cotton (cottonseed oil) Food additives produced from MON1445 cotton Feed produced from MON1445 cotton (feed materials and feed additives)	18/12/2011 Renewal of authorisation ongoing Renewal of authorisation ongoing	
Cotton (MON15985) MON-15985-2 Monsanto	Genetically modified cotton that contains: cry1Ac and cry2Ab2 genes inserted to confer insect-resistance highly selective in controlling Lepidopteran insects	Food additives produced from MON-15985-2 cotton Feed produced from MON 15985 cotton (feed materials and feed additives)	Renewal of authorisation ongoing Renewal of authorisation ongoing	
Cotton (MON15985 x MON1445) MON-15985-2 x MON-01445-2	Genetically modified cotton that contains: cry1Ac and cry2Ab2 genes inserted to confer insect-resistance highly selective in controlling Lepidopteran insects cp4 epsps gene inserted to confer tolerance to the herbicide	Food additives produced from MON15985 x MON1445 cotton (feed Feed produced from MON15985 x MON1445 cotton (feed	Renewal of authorisation ongoing Renewal of authorisation ongoing	



The EU Legislation on GMOs

An overview

Damien Plan, Guy Van den Eede



EUR 24279 EN - 2010

Regulation (EC) No 1829/2003 on genetically modified food and feed Specific provisions on GMO detection

- Submission and validation of GMO detection methods is part of the EU regulatory approval process for GMOs since GM Food/Feed applications should include (amongst others):
 - ✓ Methods for detection and identification of the transformation event
 - ✓ Samples of the food and their control samples (positive and negative sample)
- The EU Reference Laboratory for GM Food Feed (EU-RL GMFF) is responsible (amongst others) for validation of the GMO detection methods and for distribution of control samples
- The EU-RL GMFF is the Commission Joint Research Centre (JRC)
- The EU-RL GMFF is assisted by the National Reference Laboratories, consequently being considered as members of the consortium referred to as the “European Network of GMO laboratories” (ENGL)

The European Union Reference Laboratory for GM Food & Feed (EU-RL GMFF) : two legal mandates defined in two EU regulations



- 1) European Union Reference Laboratory for GM Food and Feed (EURL-GMFF) under **Regulation (EC) No 1829/2003** on GM food and feed
- 2) European Union Reference Laboratory for GM Food and Feed (EURL-GMFF) under **Regulation (EC) No 882/2004** on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

The **EU-RL GMFF** is assisted by the National Reference Laboratories, consequently being considered as members of the consortium referred to as the “**European Network of GMO laboratories**” (ENGL)



1st mandate of the EU-RL GMFF under Reg. (EC) No 1829/2003, with the support from the ENGL

- Core activity: validation of GMO detection methods as part of the EU GMO approval process under Reg. (EC) 1829/2003 : > 60 methods have been validated by the EURL-GMFF since April 2004
- Provision of **control samples** (provide laboratories with appropriate tools to carry out necessary controls)
- Provision of **guidance documents** on sampling and testing, method acceptance criteria, method performance criteria
- Role in **dispute settlements** (provide guidance in case MS contest the outcome of test results)
- Role in **emergency situations** (when unapproved GMOs occur on the market)

2nd mandate of the EU-RL GMFF under Reg. (EC) No 882/2004, with the support from the ENGL

- Providing National Reference Laboratories (NRLs) with **reference analytical methods**
 - Coordinating application of the methods by organising **comparative testing** and by ensuring an appropriate follow-up in accordance with internationally accepted protocols
 - Coordinating practical arrangements needed to apply **new analytical methods**
 - **Conducting training** courses for the benefit of staff from NRLs and of experts from developing countries;
 - Providing **technical assistance to the Commission**, especially in controversial analyses
 - Collaborating with laboratories responsible for analysing feed and food **in third countries**.
-
- Note: EU-RL and NRLs need to be accredited according to ISO 17025

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The European Network of GMO Laboratories (ENGL) today :

A network of 96 labs chaired by the European Commission JRC

All ENGL members sign a Consortium Agreement incl.

- Objectives (art. 1)
- Membership (art. 2)
- Work Programme (art. 3)
- Responsibilities of Parties (art.4)
- Plenary Meetings and Working Groups (art. 5)
- Steering Committee (art. 6)
- Secretariat (art.7)
- Reports (art.8)
- Confidentiality (art. 9)
- Liability (art. 10) ...

CONSORTIUM AGREEMENT N. CA31364

EUROPEAN NETWORK OF GMO LABORATORIES
CONSORTIUM AGREEMENT

Between
THE EUROPEAN COMMUNITY

And
THE NATIONAL LABORATORIES RESPONSIBLE FOR
THE ENFORCEMENT OF THE EU REGULATIONS
FOR GENETICALLY MODIFIED ORGANISMS

The European Community, hereinafter referred to as "the European Community", represented by the Commission of the European Communities, hereinafter referred to as "the Commission", represented for the purpose of signing this Agreement by Dr. Roland Schenkel, Director-General of the Joint Research Centre, hereinafter referred to as "the JRC", through two of its institutes: the Institute for Health and Consumer Protection (JRC-IHCP) and Institute for Reference Materials and Measurements (JRC-IRMM).

On one part, and



Hereinafter all together referred to as "The European Network of Genetically Modified Organisms Laboratories" (ENGL)

On the other part.



ENGL Objectives (art. 1):

- **Support the EU Reference Laboratory for GM FF** defined in Regulations (EC) No 1829/2003 and No 882/2004
- **Improve at European level harmonization** and standardisation of methods for the identification and quantification of GMOs
- **Act as a network of scientific excellence** for the detection of GMOs and related scientific issues
- **Provide information to worldwide stakeholders** through international relations and active communication policy

ENGL Membership (art. 2)



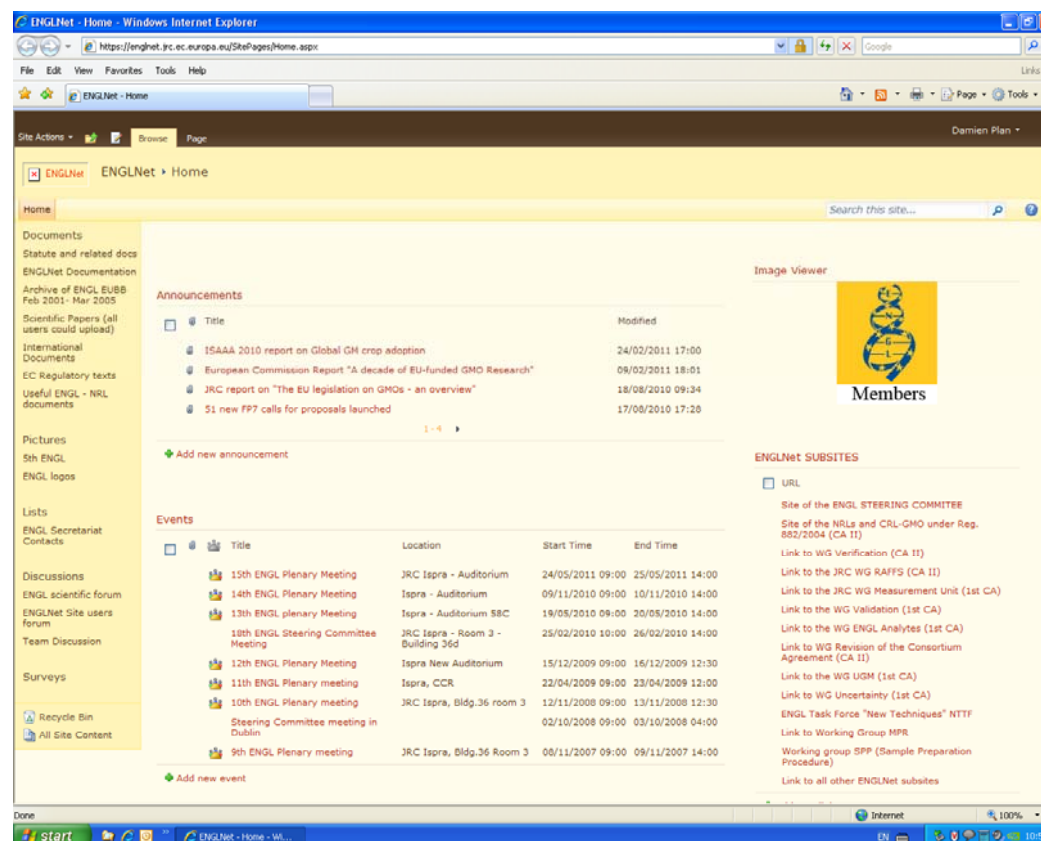
- ENGL members are designated by National Competent Authorities operating under legislation related to GMOs in the EU Member States and/or EEA + EFTA and/or EU Candidate Countries
- New membership applications must be made in writing to the ENGL President who shall refer them to the ENGL Steering Committee
- The list of ENGL members is made publicly available and is regularly updated
- ENGL observer status is also available for countries non-eligible to full membership

ENGL bodies

- **Plenary:** all ENGL members (+ observers) - 2 meetings a year to discuss scientific issues and review progress of the Work Program
 - **Steering Committee:** composed of one ENGL member per Member State - 2 meetings a year to manage the strategic operations of the ENGL, approve the annual working plan, install the appropriate working groups and monitor execution
 - **Chairmanship and Secretariat :** European Commission JRC
 - **Working Groups:** mandate approved by the ENGL Steering Committee (usually 1-2 year work programme and +/- 10 ENGL members)
- In 2011, 4 ENGL WGs : Unapproved GMOs (UGM-WG), Method Verification (MV-WG), Method Performance Requirements (MPR-WG), Sample Preparation Procedure (SPP-WG)

ENGL Internal Communication : ENGLNet

- Based on a Share Point system with access restricted to ENGL members
- Structure based on ENGL structure (eg subsites for meetings, Steering Committee, WGs)



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More than 60 GMO detection methods validated by the EURL and ENGL and publicly available at <http://gmo-crl.jrc.ec.europa.eu/>



European Commission
Joint Research Centre
Institute for Health and Consumer Protection

European Commission > JRC > IHCP > EURL-GMFF

European Union Reference Laboratory *for GM Food & Feed*

Home Legal Basis Guidance Documents Status of Dossiers Contacts

Status of dossiers

EURL-GMFF validation process

The following table lists the EURL-GMFF validation process carried out within the frame of the Regulation (EC) No 1829/2003, providing details on the current status of the validation process.

The following links provide information about additional validation studies conducted by the EURL-GMFF in support to notifications submitted according to Directive 2001/18/EC, about GMO authorised in the EU, notifications submitted according to Directive 2001/18/EC and opinions issued by the European Food Safety Authority (EFSA).

[Detection methods validated in support to notifications submitted under Directive 2001/18/EC](#)

[European Commission information on GM authorizations, legislation and alike](#)

[Information about the notifications submitted in the context of Directive 2001/18/EC](#)

[Opinions of the EFSA Scientific Panel on Genetically Modified Organisms](#)

Last updated 25/05/2010 

Event	Unique Identifier	Applicant	Status/Progress	Reports	Validated Method
Bt10 maize	-	-	Validation completed	Validation report Published on: 13/07/2005	Validated method Published on: 13/07/2005
Bt11 sweet maize	SYN-BT011-1	Syngenta Seeds	Validation completed	Validation report Published on: 05/08/2004	Validated method Published on: 05/08/2004
NK603 maize	MON-00603-6	Monsanto Company	Validation completed	Validation report Published on: 10/01/2005 Validation report Published on: 22/01/2005	Validated method Published on: 10/01/2005

Various guidance documents developed by the EURL and ENGL (e.g. definition of minimum performance requirements for analytical methods of GMO testing) and publicly available at <http://gmo-crl.jrc.ec.europa.eu/>



European Commission
Joint Research Centre
Institute for Health and Consumer Protection

European Commission > JRC > IHCP > EURL-GMFF

European Union Reference Laboratory for GM Food & Feed

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Guidance documents

Title	Date inserted / modified	Download
Definition of minimum performance requirements for analytical methods of GMO testing	13/10/2008	
Explanatory notes to applicants (Reg. EC No. 641/2004)	13/10/2008	
Note to the applicants on the type and nature of control samples according to Reg. (EC) No 1829/2003	30/01/2008	
Guideline for the submission of DNA sequences to the CRL-GMFF	11/06/2007	
Explanatory notes to applicants (Reg. EC No. 1981/2006)	13/04/2010	



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.1829/2003¹.

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.

**EURL-ENGL Report published in
November 2010:**

**Compendium of validated reference
methods for the detection of Genetically
Modified Organisms**

Scope:

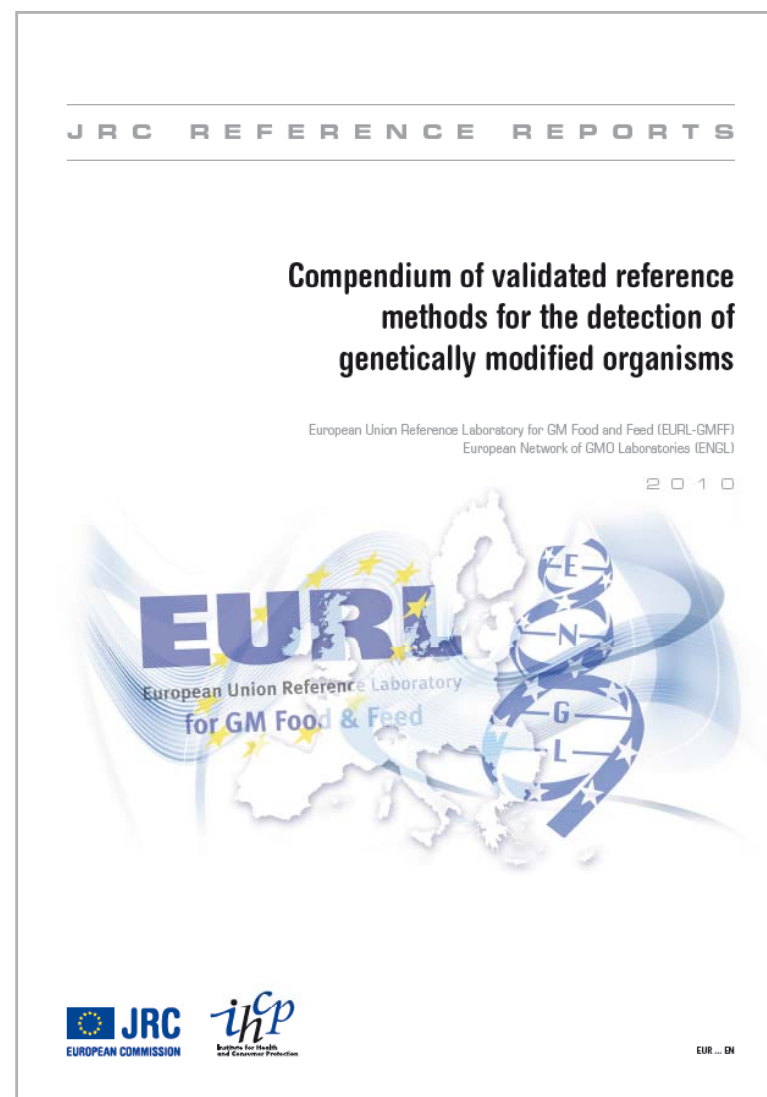
GMO detection methods

DNA-based methods

Validated according to ISO 5725 and/or IUPAC criteria

PDF version available on BCH

Searchable method database (based on compendium)
planned on-line in April 2011 (incl. link to BCH)



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ENGL Outlook

- **New methods:** development of rapid screening methods for GMO detection (incl. multi-target ready-to-use PCR plates and “matrix” approach), “not only” single event specific methods
- **New approaches:** in addition to PCR detection, DNA-sequencing (incl. bio-informatics)
- **New products:** development of detection methods for
 - GM fish and GM animals
 - New Plant Breeding Techniques
- **New global partnerships:** regional networks on GMO detection in the world (see next)



Well	Target	Assay	Control	Assay	Control	Assay	Control	Assay	Control	Assay	Control	Assay	Control	Assay	Control
1	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+
2	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-
3	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+
4	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-
5	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+
6	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-
7	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+
8	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-
9	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+
10	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-
11	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+
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23	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+
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25	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+
26	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-
27	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+
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97	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+
98	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-
99	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+	GM	PCR	+
100	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-	GM	PCR	-



Global Capacity Building Project on GMO analysis

Project funded under the EU Commission BTSF programme (Better Training for Safer Food)

Project Aim

- To share the networking experience and advantages from the ENGL experience in the EU
- To support the establishment of regional networks outside the EU
- To help building capacity by providing training to laboratories outside the EU

Developed through:

- Networking workshops (incl. support toward the establishment of regional networks)
- Training courses
- Dedicated web page



European Commission
Joint Research Centre
Institute for Health and Consumer Protection

Legal notice

European commission > JRC > IHCP > MBG Unit > Capacity Building

Enlargement, International Collaboration & Capacity Building



Workshops

Training courses

Global conference

Project team

Documentation

Pictures gallery

The Molecular Biology and Genomics Unit of the Institute for Health and Consumer Protection (European Commission, Joint Research Centre) plays a leading role in the area of analysis of food, feed and environmental samples for the presence of genetically modified organisms (GMOs).

Here we present the international activities related to capacity building and training and we provide regular updates on workshops, training sessions and conferences we organise that aim to increase expertise and to foster international collaboration and harmonisation.



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

Internet 100%



Thank you for your attention

