

The Joint Research Centre in support to the implementation of EU legislation on GMOs:

*role,
responsibility
and activities towards harmonisation in GMO analysis*

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JRC Institute for Health and Consumer Protection (IHCP)



The Joint Research Centre (JRC)

The JRC is a Directorate-General of the European Commission under the responsibility of the European Commissioner for Science and Research

Web: www.jrc.ec.europa.eu

Contact: jrc-info@ec.europa.eu



The Mission of the JRC

Research-Based Policy Support

... to provide customer-driven scientific and technical support for the conception, development, implementation and monitoring of EU policies....

... the JRC functions as a reference centre of science and technology for the EU, independent of private or national interests...



JRC Structure: 7 Institutes in 5 Member States

IRMM - *Geel, Belgium*

Institute for Reference Materials and Measurements

ITU - *Karlsruhe, Germany*

Institute for Transuranium Elements

IE - *Petten, The Netherlands*

Institute for Energy

IPSC - *Ispra, Italy*

Institute for the Protection and Security of the Citizen

IES - *Ispra, Italy*

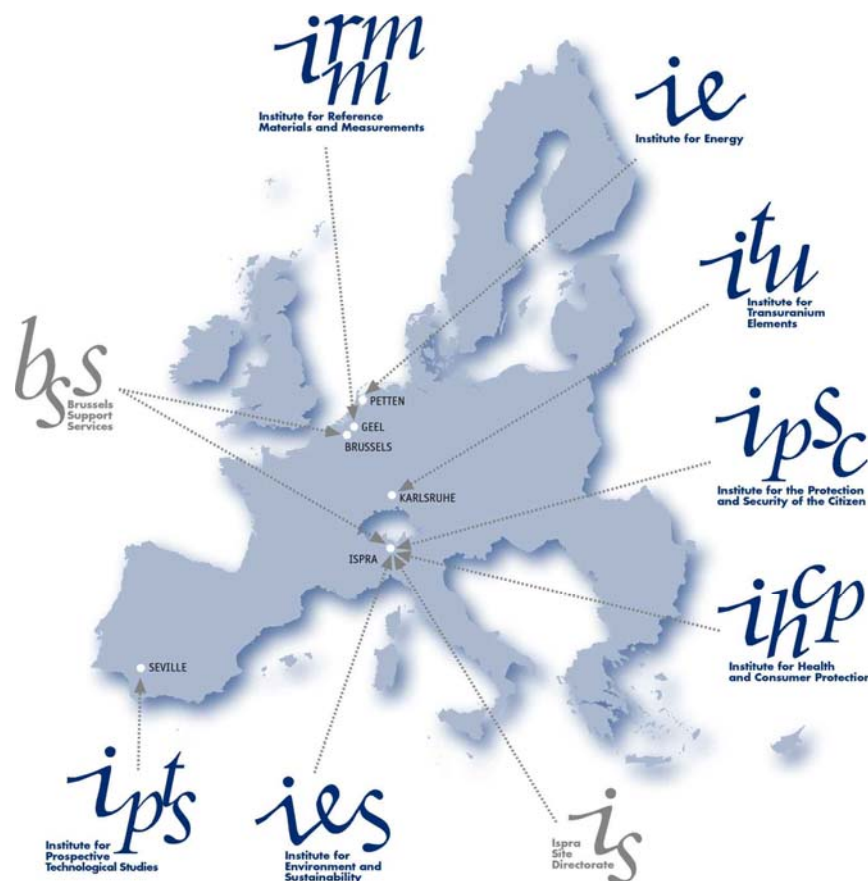
Institute for Environment and Sustainability

IHCP - *Ispra, Italy*

Institute for Health and Consumer Protection

IPTS - *Seville, Spain*

Institute for Prospective Technological Studies



The Molecular Biology & Genomics Unit:



Molecular Biology & Genomics

- **Biotechnology Research & Development:**
 - Sampling
 - Method development & validation
 - Mol. characterisation & stability studies
 - Bioinformatics & information systems in support to regulatory processes
- **Training and capacity building**



- Management & Coordination of the **European Network of GMO Laboratories (ENGL)**



- Mandate of **European Union Reference Laboratory for GM Food & Feed (EURL-GMFF)**

GMO testing requirements along the production chain

- GMO producers
 - To assure purity and segregation of products
 - To trace genetic modification in breeding
- Food & feed industry, seed companies
 - To assure purity and segregation of products
 - To assure compliance with legislation
- Competent (enforcement) authorities
 - Product control, compliance with legislation
 - When needed, to withdraw specific products
- Laboratories
 - To provide analytical services to customers

Salient points of the EU legislation:



- Labelling of GMOs and derived food and feed products at all stages (when present above 0.9%);
- Traceability from the point of production or import down to the table and vice versa;
- Co-existence between organic, traditional and GM plant from the seed throughout the production chain;
- Post-market monitoring;
- Exchange of information on GMOs cultivated among MS and the EC and GMOs transported among MS and third Countries



DIRECTIVE 2001/18/EC on the deliberate release into the environment and marketing of genetically modified organisms

The aim to develop an appropriate regulatory framework for ensuring the protection of human health and of the environment

Principle:

- **cultivation / placing on the market only after authorisation**
- **based on risk assessment**
- **case-by-case basis**

Two procedures:

Part B = experimental release
small scale field trials for R&D
(National decisional process)

Part C = placing on the market
importation, cultivation, commercialisation
(Community decisional process)

Deliberate field trials (Part B)

According to European Legislation, before undertaking a deliberate release of a GMO, a notification shall be submitted to the Competent Authority of the Member State within whose territory the release is to take place.

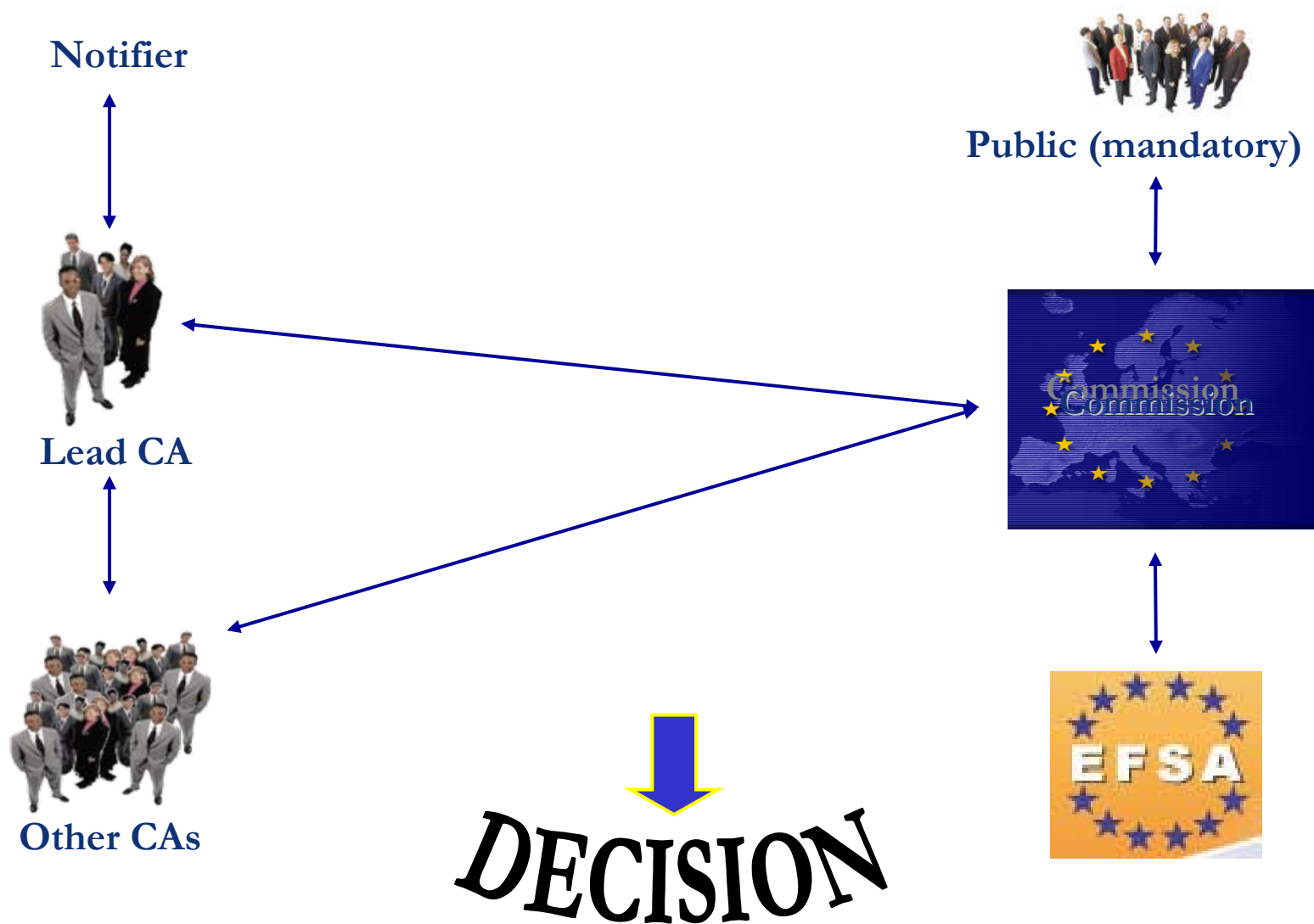
Member States shall consult the public on deliberate releases and amongst other information, without prejudice to Article 25 of Directive 2001/18/EC, the Commission shall make available to the public the information contained in the so-called “**S**ummary **N**otification **I**nformation **F**ormat” (SNIF).

The WebSNIF system



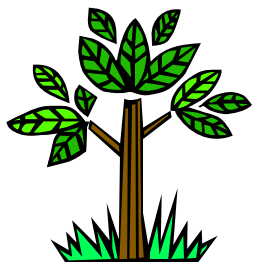
Public information is published online at <http://gmoinfo.jrc.ec.europa.eu/>, where the general public can consult the SNIFs and posted comments, where foreseen by Directive 2001/18/EC

Placing on the market (Part C)

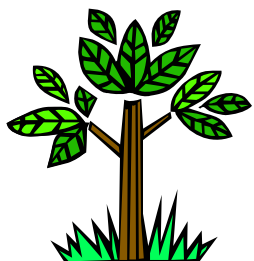


GM-F&F authorisation process: Requirements according to Regulation (EC) 1829/2003

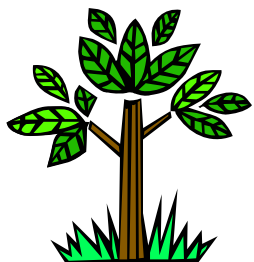
- Full dossier submission
- Safety assessment under responsibility of the European Food Safety Authority
- Applicant should provide methods for **sampling** and **identification** of GM food and feed including **controls** and **CRMs**
- Methods should be **validated** by the European Union Reference Laboratory for GM Food & Feed (EURL-GMFF)
- Thresholds for labelling
 - **0.9 %** for adventitious presence of approved GMOs
- Time-limited authorisation of **10 years** (renewable)



Grains, flour =
label required



Refined oil, with no
detectable DNA or proteins =
label required



Meat of animals =
no label required

But WATCH OUT !

Exemption of labelling obligations ONLY if the presence of GMOs is “**adventitious or technically unavoidable**”.

unexpected presence + adoption of “adequate” preventive measures.

Moreover :

Quantification per ingredient

Regulation (EC) 1946/2003 on transboundary movements of GMOs

- Last piece of legislation needed to implement the Biosafety Protocol
- Imposes notification prior to the first transboundary movement of a GMO to a given Country
- Requests written prior informed consent, on the basis of a scientific risk assessment
- Foresees information exchanges with the Biosafety Clearing House



The EU Legislation on GMOs

An overview

Damien Plan, Guy Van den Eede

<http://mbg.jrc.ec.europa.eu/home/docs.htm>



EUR 24279 EN - 2010

The European Union Reference Laboratory for GM Food & Feed



DAC-PL-0459-06-00



The European Union Reference Laboratory for GM Food & Feed: two legal mandates

- 1) European Union Reference Laboratory for GM Food and Feed (EURL-GMFF) under Regulation (EC) No 1829/2003.
- 2) European Union Reference Laboratory 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”.

Mandate of the EURL-GMFF according to Regulation (EC) 1829/2003 as part of the GM-F&F authorisation process



- Evaluation of data, testing and **validation** of GMO detection methods for detection provided by the applicants
- Operations carried out in alignment with the European Food Safety Authority (EFSA)
- It is unique in the worlds' GMO regulatory system
- >80 dossiers have been submitted to the EURL-GMFF since April 2004
- Applicants contribute to the costs of validation [Reg. (EC) 1981/2006].
- ISO 9001 certified and ISO 17025 accredited



All validated methods and validation reports are published at <http://gmo-crl.jrc.ec.europa.eu/>



Mandate of the EURL-GMFF according to Regulation (EC) 1829/2003 as part of the GM-F&F authorisation process



- Provision of **control samples**
 - To 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**
 - To provide guidance in case MS contest the outcome of test results
- Role in **emergency situations**
 - when unauthorised GMOs occur on the market



GM-F&F authorisation process: Requirements according to Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for GM food and feed legislation

Applicant

- Information about the method: event-specificity, applicability, detailed description of the methods etc.
- Information about method testing carried out by the applicant: method optimisation, inter-lab transferability, stability, specificity, LOD, LOQ etc, testing report
- Full sequence of the insert(s) + flanking sequences
- Control samples and samples of food and feed







Method acceptance criteria and method performance requirements:
ENGL/EURL guidance document "Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing"

Minimum Performance Requirements for Analytical Methods of GMO Testing: EURL-GMFF acceptance criteria and performance requirements

Applicability	Scope of the method, interferences with analytes etc.
Practicability	Equipment, timing, practical difficulties
Specificity	Event-specificity
Dynamic Range	Include the 1/10 and at least 5 times the target concentration
Accuracy	Within $\pm 25\%$ of the reference value
Linearity (R^2)	≥ 0.98
PCR efficiency	$-3.1 \geq \text{slope} \geq 3.6$
RSDr	Below 25% over the whole dynamic range
LOQ	Less than 1/10 th of the value of the target concentration with an RSDr $\leq 25\%$
LOD	Less than 1/20 th of the target concentration
Robustness	Deviate not more than $\pm 30\%$
RSDR	Below 35% at the target concentration; < 50% below 0.2%
Trueness	Within ± 25 of the accepted reference value over the whole range

Enforcement and Control

-  Member States are responsible for enforcement and control
-  All MS have designated Competent Authorities and facilities for the control of GMOs and GM-products
-  Commission has responsibility for ensuring the proper functioning and development of the single European market
-  The aim is to ensure that EC food law is enforced with equal rigor in all Member States.

EURL-GMFF: tasks according to Regulation (EC) No 882/2004

- Assisting the National Reference Laboratories (NRLs) in their duties to monitoring the European market in a context of health and consumer protection
 - Harmonisation and communication of scientific data among laboratories;
 - Monitoring the quality levels of the analytical laboratories for GMO detection;
-
- (a) providing NRLs with reference analytical methods
 - (b) coordinating application of the methods by organising comparative testing and by ensuring an appropriate follow-up in accordance with internationally accepted protocols
 - (c) coordinating practical arrangements needed to apply new analytical methods
 - (d) conducting training courses for the benefit of staff from NRLs and of experts from developing countries;
 - (e) providing S&T assistance to the Commission, especially in controversial analyses;
 - (f) collaborating with laboratories responsible for analysing feed and food in third countries.

Provision of validated reference methods for the detection of Genetically Modified Organisms (GMO)

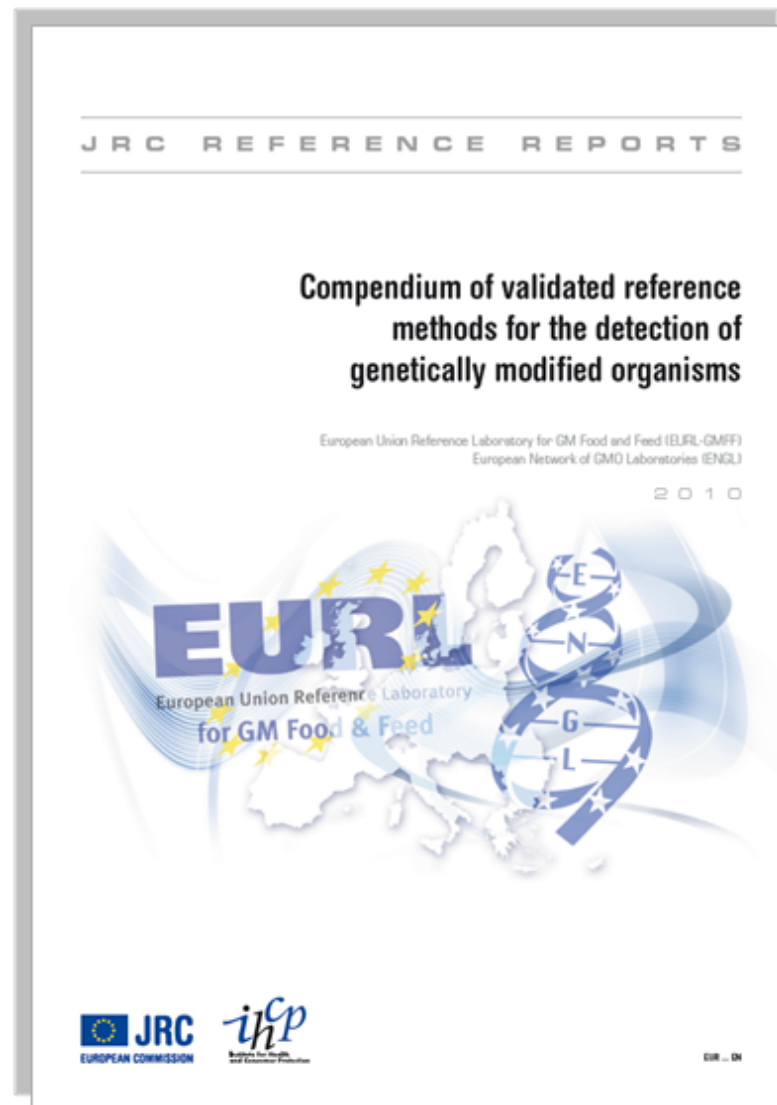
Legal framework:

Regulation (EC) No 882/2004
Recommendation 2004/787/EC

Scope:

GMO detection methods (plants, bacteria ...)
ISO collaborative trial criteria (ISO 5725)
DNA-based methods (cf. Recommendation 2004/787/EC)

Official Release: 10th November 2010



EU system in response to emergencies and crises related to the spread of GMOs into the EU market



Rapid Alert System for Food and Feed



EURL-GMFF

validation/verification of detection methods,
gathering and provision of specific
information to NRL (e.g. sequence,
molecular structure),
preparation and distribution of suitable
control samples to NRL.



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European Union Reference Laboratory for GM Food & Feed

Home Legal Basis Guidance Documents Status of Dossiers Contacts

This is the official website of the European Union Reference Laboratory for GM Food and Feed (EURL-GMFF), formerly named Community reference laboratory, which was established by Regulation (EC) No 1829/2003 on GM Food and Feed.

The core task of the EURL-GMFF is the scientific assessment and validation of detection methods for GM Food and Feed as part of the EU authorisation procedure. The Joint Research Centre (JRC) of the European Commission and, more precisely, the Molecular Biology and Genomics Unit of the Institute for Health and Consumer Protection (IHCP), has been given the mandate for the operation of the EURL-GMFF. Activities are carried out in close collaboration with European Network of GMO Laboratories (ENGL).

The EURL-GMFF operates according to a quality management system certified and accredited according to ISO 9001 and ISO 17025.



[Page dedicated to CDC Triflir flax \(FP967\)](#)

[Page dedicated to rice BT 63](#)

[Page dedicated to maize Event 32](#)

[Page dedicated to L1RICE601](#)

[Page dedicated to BT10](#)

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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 EURL-GMFF	11/06/2007	
Explanatory notes to applicants (Reg. EC No. 1981/2006)	13/04/2010	

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European Union Reference Laboratory for GM Food & Feed

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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](#)

Watch this page for changes

Last updated 25/03/2010

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: 03/08/2004	Validated method Published on: 03/08/2004
NK603 maize	MON-00603-6	Monsanto Company	Validation completed	Validation report Published on: 10/01/2005 Validation report Published on: 10/01/2005	Validated method Published on: 10/01/2005

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

Underpinning Research activities

Development of methods and approaches for routine GMO analysis

- **GMO detection methods:** development, optimisation, validation
 - PCR based approaches
 - Immunoassays
 - Microarray and novel high-throughput / multi-target approaches
- Development and validation of **decision-support systems**
 - for the optimisation of GMO screening strategies
 - for the analysis and interpretation of wet laboratory results (raw data from PCR analysis)
- Comparative testing and quality

JRC Enlargement, International Collaboration and Capacity Building Programme

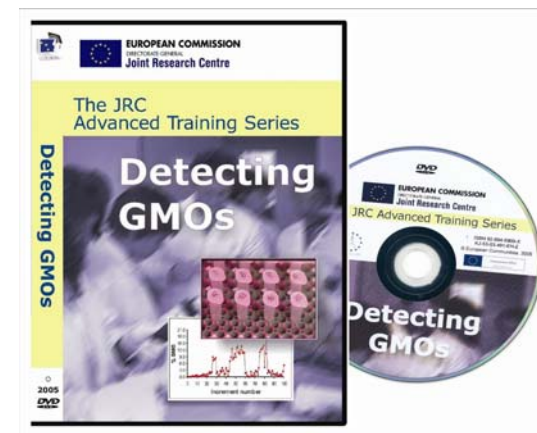
Objective:

- To help control laboratories to implement proper facilities and expertise in GMO testing
 - To contribute to the enforcement of an harmonised approach in GMO analysis
-
- ✓ Scientists from more than 120 laboratories trained worldwide
 - ✓ Specific training for trainees
 - ✓ External facilities as 'Training Sites'
 - ✓ Production and release of *ad-hoc* didactic material



TRAINING:

- In-house;
- Cyprus, Hungary, Tunisia, ...
- Together with ILSI, ICGEB, ...
- *Ad hoc*, e.g. Rumania, FVO



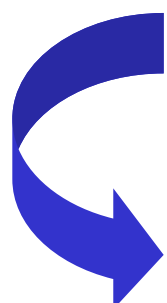
USER MANUAL:

- English
- French
- Spanish
- Russian
- Chinese
- Turkish
- Portuguese (*in preparation*)

The way towards the ‘Enlargement, International Collaboration and Capacity Building’ Project

- 1998 – *ongoing* Expertise in molecular approaches for GMO analysis
- 2000 – *ongoing* Training and capacity building programme
- 2002 Establishment of the European Network of GMO Laboratories (ENGL)
- 2003 EU Reference Laboratory for GM Food and Feed (EURL-GMFF)
- 2004 EU-RL Mandate according to Regulation (EC) No 882/2004
- 2008 1st Global Conference on GMO Analysis



- 
- 2009 International Collaboration and Capacity Building Project kick-off
 - 2011 2nd Global Conference on GMO Analysis





1st Global Conference
on
GMO Analysis

Villa Erba, Como, Italy
24-27 June 2008

<http://gmoglobalconference.jrc.it/>



‘Enlargement, International Collaboration and Capacity Building’ Project

...to face the overall growing need for enhanced harmonisation
of means and methods in GMO analysis
and to respond to the constantly increasing requests

Project Aim

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

‘Enlargement, International Collaboration and Capacity Building’ Project

Project structure

Developed at three different layers:

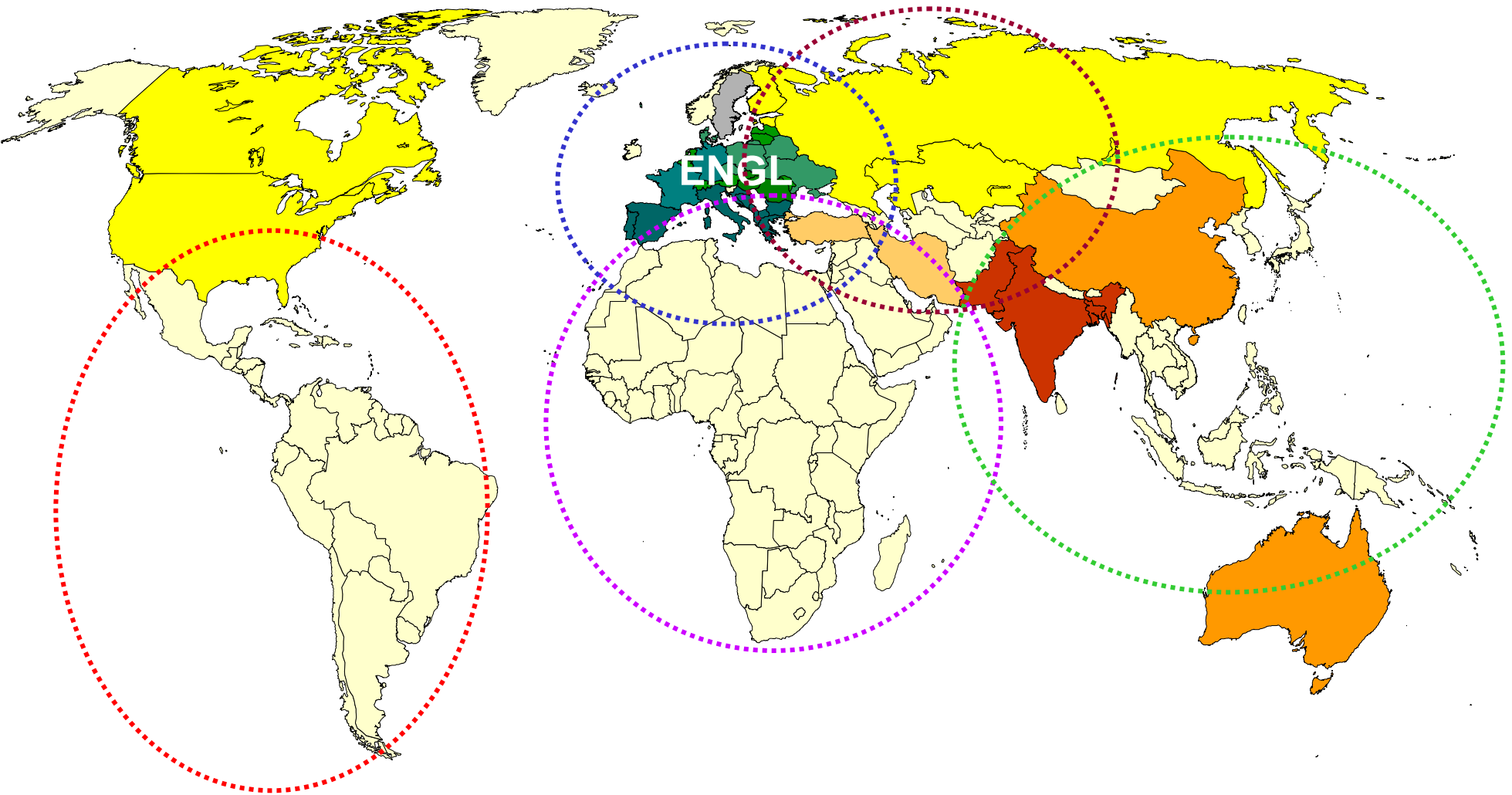
- Managerial and decisional level
- Scientific society involved in the topic
- Actors directly engaged in technical & scientific aspects of GMO analysis, control/testing laboratory staff

Developed *via*: Networking workshops

Support toward the establishment of regional networks

Regional training courses

Dedicated web page



Roadmap 2009 - 2011

2009

- Turkey, 27 - 28 April 2009 - Enlargement/Networking Workshop for new MS, Candidate Countries, Potential Candidate Countries and Territories, Countries incl. in the European Neighbourhood Policy
- Malaysia, 16 -17 June 2009 - Regional Networking Workshop for Asian Countries
- Malaysia, 15 -19 June 2009 - Training Course for Asian Countries (EC BTSF Initiative)
- Cuba, October 2009 - Training Course for Central & South American Countries
- Brazil, 3 - 4 December 2009 - Regional Networking Workshops for Central & South American Countries

Roadmap 2009 - 2011

2010

- Turkey, 12-16 April 2010 - Training Course for new MS, Candidate Countries, Potential Candidate Countries and Territories, Countries incl. in the European Neighbourhood Policy
- Singapore, 7-8 June 2010 - 2nd Regional Networking Workshop for Asian Countries
- Croatia, 27-28 September 2010 - 2nd Enlargement/Networking Workshop for new MS, Candidate Countries, Potential Candidate Countries and Territories, Countries incl. in the European Neighbourhood Policy
- South Africa, 28-29 October 2010 - Regional Networking Workshop for African Countries
- Ispra, 8-12 November 2010 - Study Tour on GMO Analysis for Central & South American Countries

Roadmap 2009 - 2011

2011

- Mexico, January 2011 - 2nd Regional Networking Workshop for Central & South American Countries
- 3rd Regional Networking Workshop for Asian Countries
- 1st Regional Networking Workshop for the Middle East
- ...



2nd Global Conference on **GMO Analysis** 20-24 June 2011

<http://gmoglobalconference.jrc.ec.europa.eu/>



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Legal notice

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



[*http://mbq.jrc.ec.europa.eu/home*](http://mbq.jrc.ec.europa.eu/home)



Thank you!