

# 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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# 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](http://www.jrc.ec.europa.eu)

Contact: [jrc-info@ec.europa.eu](mailto: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*

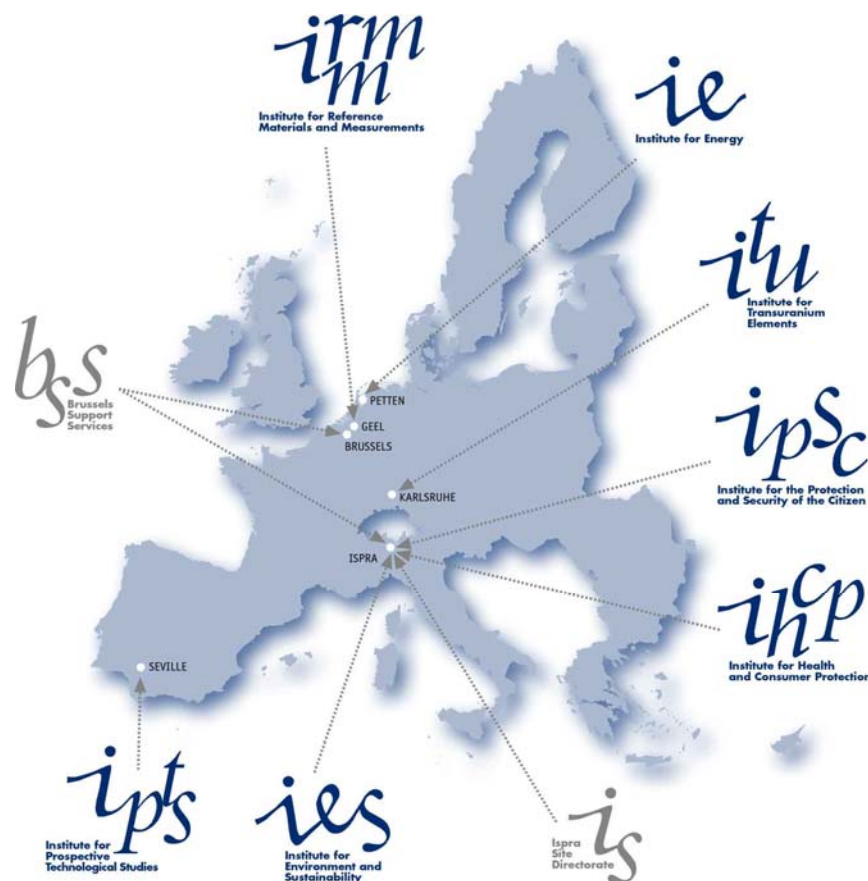
Institute for Environment and Sustainability

**IHCP** - *Ispra, Italy*

Institute for Health and Consumer Protection

**IPTS** - *Seville, Spain*

Institute for Prospective Technological Studies



# Research-based policy support in the GMO area is a pan-JRC activity: three Institutes involved



## **IRMM – Geel, Belgium**

- World leader in GMO Certified Reference Materials and bio-metrology



## **IHCP– Ispra, Italy**

- S/T support for the implementation of GMO legislation  
Community Reference Laboratory for GM Food and Feed



## **IPTS – Seville, Spain**

- Biotechnology foresight; Model simulations and expert opinions on the co-existence of GM and non-GM crops in European agriculture



## 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



# 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)**

Community Reference Laboratory



GM Food and Feed

- Mandate of **Community Reference Laboratory for GM Food & Feed (CRL-GMFF)**

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

# WebSNIF



European Commission  
**Joint Research Centre**  
Institute for Health and Consumer Protection

## Deliberate releases and placing on the EU market of Genetically Modified Organisms - GMO Register

The purpose of this web site, managed by the [Joint Research Centre](#) of the [European Commission](#) on behalf of the [Directorate General for the Environment](#) is to publish information and to receive comments from the public regarding notifications about deliberate field trials and placing on the market of genetically modified organisms, as defined in [Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001](#).

Click [here](#) for details

According to Article 31(2) of Directive 2001/18/EC, the Commission is also to establish one or several register(s), for the purpose of recording the information on genetic modifications in GMOs specified in Section A, point 7 of Annex IV to that Directive. The contents of this register is described in [Commission Decision 2004/204/EC of 23rd February](#). Therefore, this website contains also the required information about GMOs authorized, under Directive 2001/18/EC for marketing purposes which include authorization for cultivation, food, feed and processing.

GMOs can also be approved for placing on the market under [Regulation 1829/2003/EC \(GM food and feed\)](#) for which a register is available at the [Community register of genetically modified food and feed](#).

**Deliberate release into the environment of GMOs for any other purposes than placing on the market (experimental releases)**

[Plants](#)



[Other than plants](#)



[All products](#)



*In order to view and print PDF files, you need the latest version of the free Adobe Acrobat Reader. Click on the link below to download and install the version for your computer.*



**Links**

[Member States national websites](#)

[EFSA - GMO Panel](#)

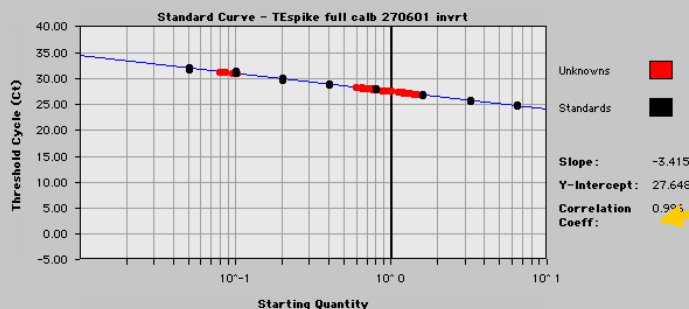
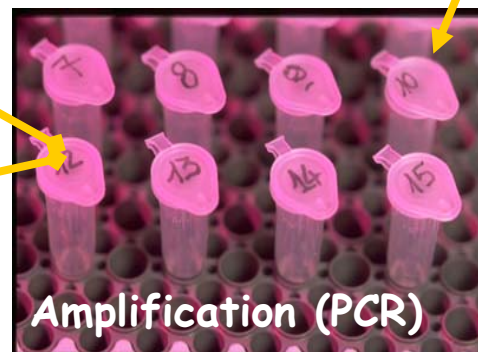
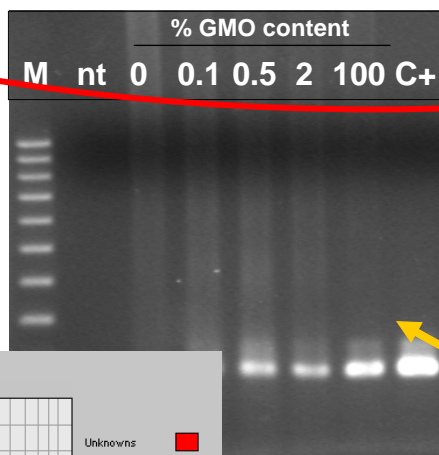
[European Commission - Community register of genetically modified food and feed](#)

[Community Reference Laboratory for GM Food and Feed](#)



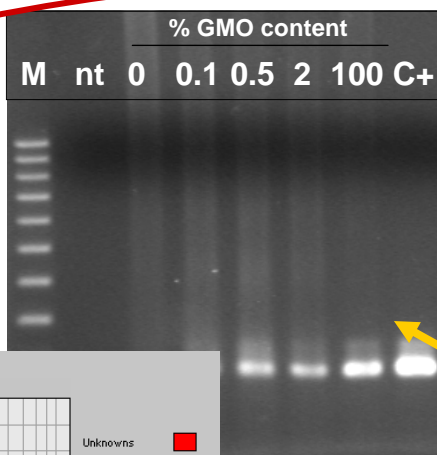
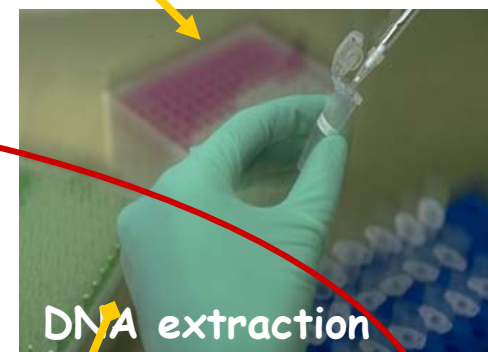


**Sampling error**



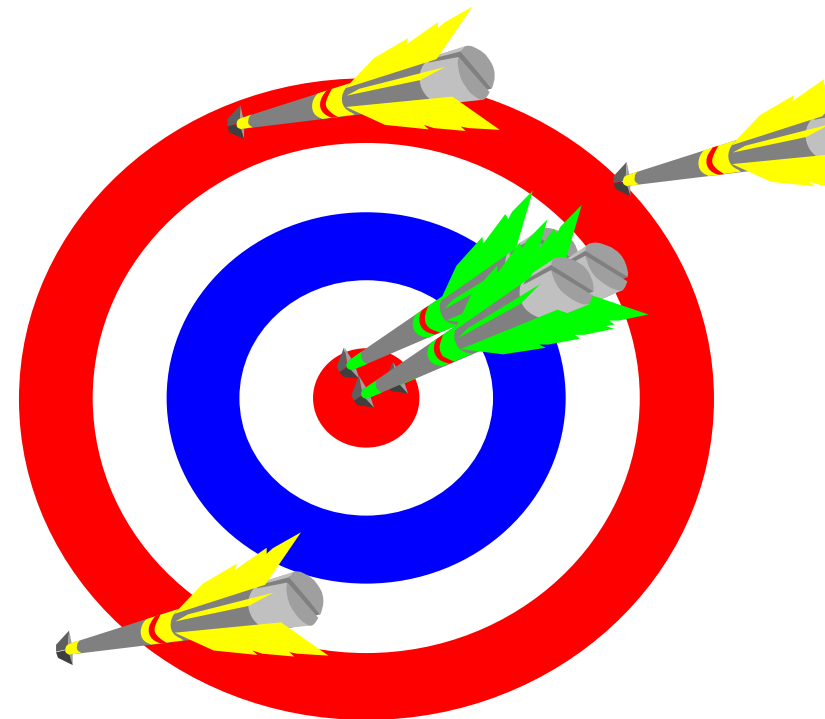
Off-loading soy from a ship....





Analytical error

- Use validated methods;
  - Use (Certified) Reference Materials;
  - Participate in proficiency tests;
- Be accredited according to ISO 17025.



## Why Validation Studies ?

- Conducting a validation study is a tool to check whether the method is fit for the purpose
- The validation study delivers performance *characteristics*

## How to validate the analytical method?

- By performing an in-house validation
- By conducting a collaborative study



# The Community Reference Laboratory for GM Food and Feed

Community Reference Laboratory



GM Food and Feed



DAC-PL-0459-06-00



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



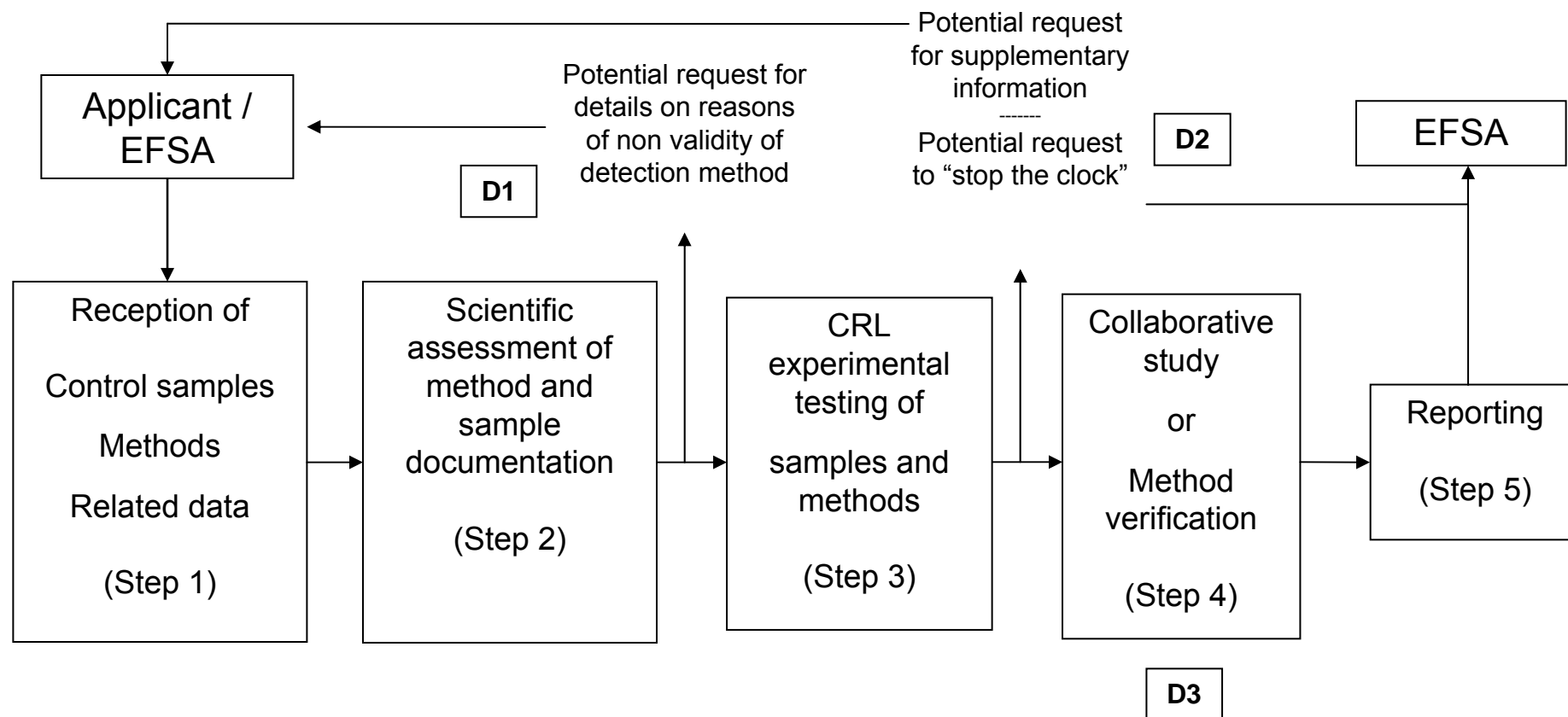
- Official mandate in the EU regulatory process
- It's key role is in the description of the performance of a method for the event-specific detection of a GMO that must be “fit for the purpose of regulatory compliance” .
- Operations are carried out, aligned with the European Food Safety Authority.
- It has a role in disputes and in response to crises.
- It is unique in the worlds' GMO regulatory system.
- It chairs the “European Network of GMO Laboratories” (ENGL).
- >80 dossiers have been submitted to the CRL-GMFF since April 2004
- Applicants contribute to the costs of validation (Reg. (EC) No 1981/2006).
- It is ISO 9001 certified and ISO 17025 accredited.
- All methods validated and validation reports are published at <http://gmo-crl.jrc.ec.europa.eu/>

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

For all info see: <http://gmo-crl.jrc.ec.europa.eu/>

- ENGL: Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing – Version 13/10/2008
- ISO 5725 – Accuracy (trueness and precision) of measurements methods and results
- IUPAC, 1995 – Protocol for the Design, Conduct and Interpretation of Method-Performance Studies
- Codex Alimentarius Commission - Consideration of the methods for the detection and identification of foods derived from biotechnology general approach and criteria for the methods. Accepted 2008.
- Codex Alimentarius Commission – Single Laboratory Validation – Consideration of Harmonized IUPAC guidelines for Single-Laboratory Validation of Methods of Analysis





**The process is a step-by-step procedure and can be stopped or re-initiated as required**



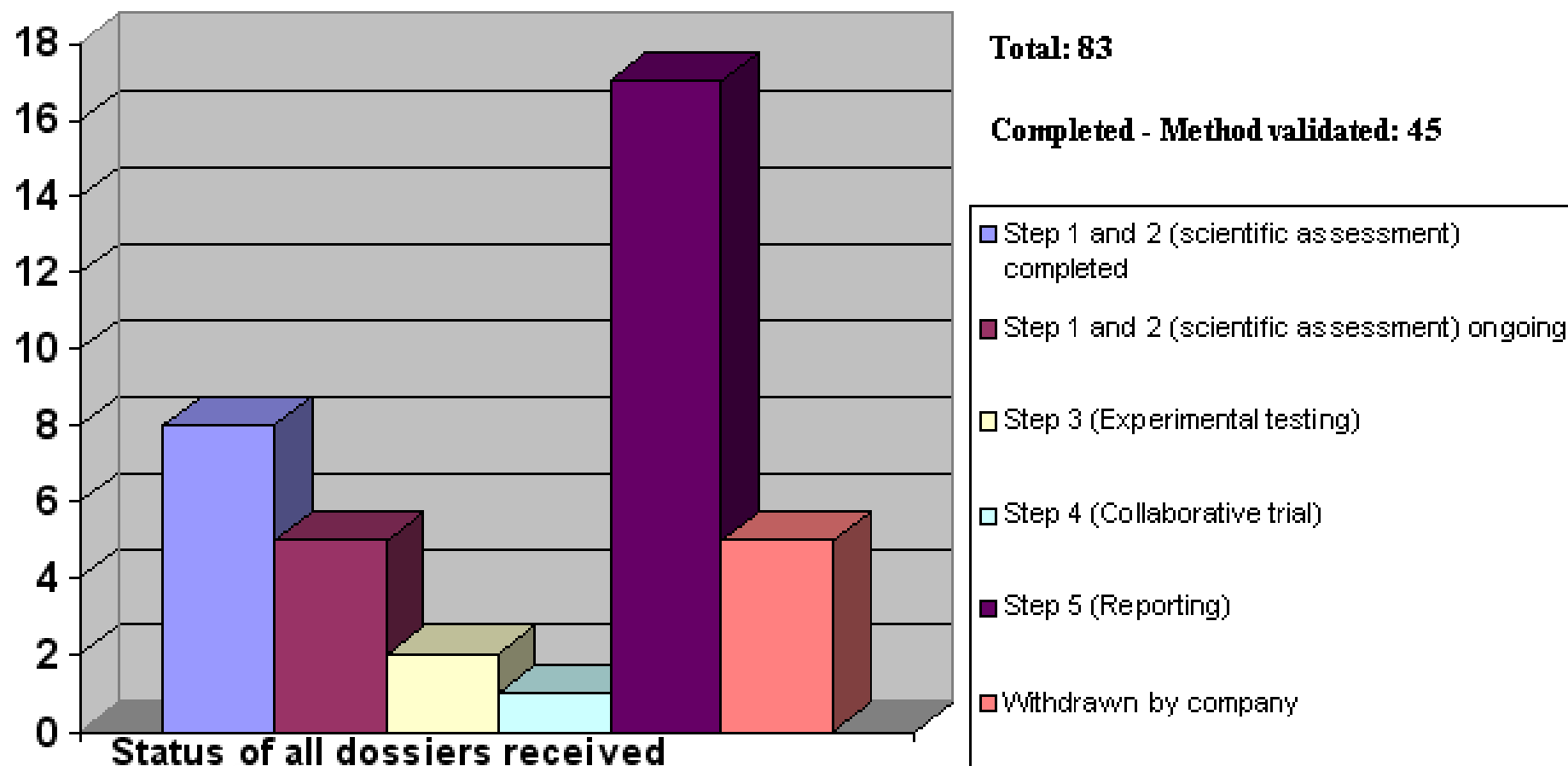
Applicability	Scope of the method, interferences with analytes etc.
Practicability	Equipment, timing, practical difficulties
Specificity	Event-specificity
Dynamic Range	Include the 1/10 and at least 5 times the target concentration
Accuracy	Within $\pm 25\%$ of the reference value
R <sup>2</sup> Coefficient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

# TESTING METHOD INTER-LABORATORY PERFORMANCE: Example of the CRL-GMFF validation of a method for regulatory compliance: TC1507 *Herculex* maize “fit for the purpose”


## Validation 1507 (*Herculex*<sup>TM</sup> I – Pioneer) maize


Sample	0,00	0,1	0,5	0,9	2	5
Number of laboratories	14	14	14	14	14	14
Number of outliers	0	0	1	2	1	0
Number of laboratories retained after eliminating outliers	14	14	13	12	13	14
Mean value	0,000	0,106	0,480	0,933	1,966	5,420
Bias (%)	0	6	-4	4	-2	8
Repeatability standard deviation $s_r$	0,00	0,02	0,06	0,07	0,17	0,78
Repeatability relative standard deviation $RSD_r$ (%)	0,00	18,11	11,70	7,68	8,48	14,41
Repeatability limit $r$ ( $r = 2.8 \times s_r$ )	0,00	0,05	0,16	0,20	0,47	2,19
Reproducibility standard deviation $s_R$	0,00	0,02	0,07	0,10	0,42	1,17
Reproducibility relative standard deviation $RSD_R$ (%)	0,00	19,91	14,78	10,24	21,19	21,65
Reproducibility limit $R$ ( $R=2,8 \times s_R$ )	0,00	0,06	0,20	0,27	1,17	3,29

## Dossiers in CRL:



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






EUROPEAN COMMISSION  
 INTERNATIONAL  
 Joint Research Centre

# COMMUNITY REFERENCE LABORATORY

[Home](#)
[Legal Basis](#)
[Guidance Documents](#)
[Status of Dossiers](#)
[Contacts](#)

## For GM Food & Feed



### Status of dossiers

GM Food and Feed

### CRL-GMFF validation process

The following table lists the CRL-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 CRL-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 17/09/2009 

Event	Unique identifier	Applicant	Status/Progress	Reports	Validated Method
Bt10 Maize	-	-	Validation completed	<a href="#">Validation report</a> Published on: 13/07/2005	<a href="#">Validated method</a> Published on: 13/07/2005
Bt11 Sweet Maize	SYN-BT011-1	Syngenta Seeds	Validation completed	<a href="#">Validation report</a> Published on: 05/08/2004	<a href="#">Validated method</a> Published on: 05/08/2004
NK603 Maize	MON-00603-6	Monsanto	Validation completed	<a href="#">Validation report</a> Published on: 10/01/2005 <a href="#">Validation report</a> Published on: 30/01/2008	<a href="#">Validated method</a> Published on: 10/01/2005
GA21 Maize	MON-00021-9	Monsanto	Validation completed	<a href="#">Validation report</a> Published on: 17/01/2005	<a href="#">Validated method</a> Published on: 17/01/2005



## **The CRL-GMO: tasks as outlined by Article 32 of Reg. (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 with three main objectives:
  - Solving scientific issues related to harmonisation and communication of scientific data among laboratories;
  - Monitoring the quality levels of the analytical laboratories for GMO detection;
  - Building capacities through training, workshops and any common scientific normative tool available.

## **The role of the CRL-GMFF in response to emergencies and crises related to the spread of GMOs into the EU market**



The CRL-GMFF has become a key actor in emergency/crises cases for fast 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.

- Decision 2005/317/EC on emergency measures regarding the non-  
authorised genetically modified organism Bt10 in maize products
- Decision 2006/754/EC on emergency measures regarding the non-  
authorised genetically modified organism LLRICE601 in rice products
- Commission Decision 2008/289/EC of 3 April 2008 on emergency  
measures regarding the unauthorised genetically modified organism  
'Bt 63' in rice products
- 2008: GM-maize line DAS-59132-8 (Event 32 or E-32)
- 2009: CDC Triffid Flax (Event FP967)

- Percentage of what?
- What methods to use?
- How to express the results?
- What are adequate control samples (and where do I find them?)
- What are adequate methods (and where do I find them?)
- How to sample and how many samples to analyse?
- How can I distinguish between a GMO that is legally allowed to be and not allowed to be present?
- ???

## European Network of GMO Laboratories (ENGL)



*...an enforcement network of GMO Laboratories  
established in June 2000 and officially inaugurated in Brussels  
on December 4<sup>th</sup> 2002, chaired and coordinated by the IHCP  
"Molecular Biology & Genomics Unit"*

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

The ENGL is comprised of more than 120 control laboratories, representing all EU, Norway and Switzerland, plus other Countries as observers.





# JRC Capacity Building and Training 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 150 laboratories trained worldwide
  - ✓ Specific training for trainees
  - ✓ External facilities as 'Training Sites'
  - ✓ Production and release of *ad-hoc* didactic material



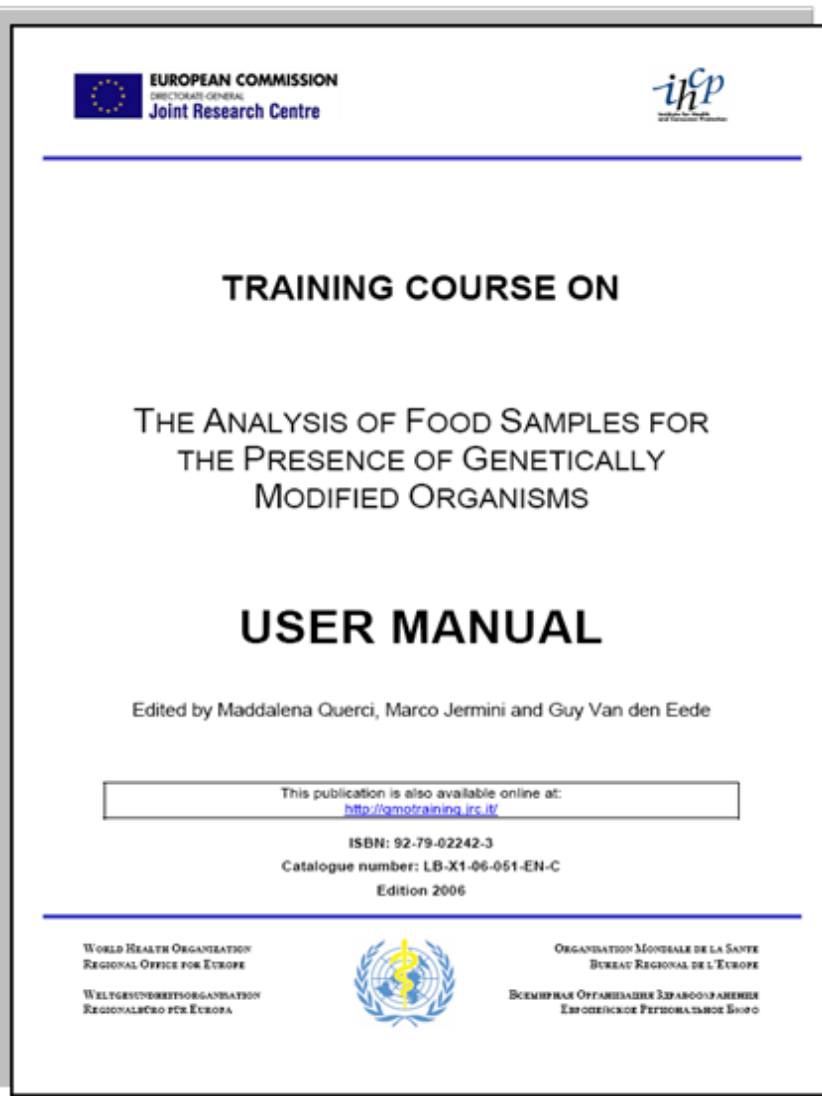
## Training Courses

### Theoretical lectures:

- EU legislation on GMOs and specific requirements
- Experimental planning and sample preparation
- DNA extraction
- PCR principles
- Qualitative and quantitative PCR
- Protein based GMO detection
- Sampling
- Lab. implementation
- Method validation criteria and laboratory accreditation

### Experimental work:

- Experimental planning and sample preparation
- DNA extraction from raw and processed materials
- Simple and nested PCR for qualitative GMO analysis
- GMO quantitative analysis by real-time PCR
- Protein based GMO detection approaches



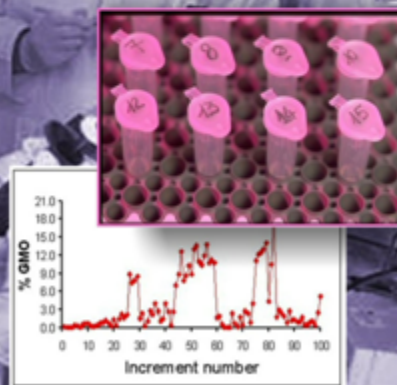
- **English**  
(edition 2006 – available *on line*)
- **French**  
(edition 2006 – available *on line*)
- **Spanish**  
(edition 2007 – available *on line*)
- **Russian**  
(edition 2007 – available *on line*)
- **Chinese**  
(edition 2007 – available *on line*)
- **Polish**  
(*in preparation* – 3 chapters *on line*)
- **Rumanian and Turkish**  
(*in preparation*)

Downloadable from:

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

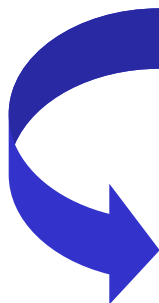
## The JRC Advanced Training Series

# Detecting GMOs



## The way towards the Project Proposal

- 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 Community Reference Laboratory for GM Food and Feed (CRL-GMFF)
- 2004 Community Reference Laboratory under Re. (EC) No 882/2004
- 2008 1<sup>st</sup> Global Conference on GMO Analysis



- 2009 Enlargement, International Collaboration and Capacity Building
- 2011 2<sup>nd</sup> Global Conference on GMO Analysis

# ‘Towards Global Harmonisation of GMO Analysis by Creating and Supporting Regional Networks of Excellence’



The slide features a green header bar with the text "Health & Consumers Directorate-General" and the European Union flag. Below this, the "BT SF" logo is displayed with the tagline "Better Training for Safer Food". To the right, the "Directorate-General for Health & Consumers" logo is shown. The central text reads: "Project conducted by European Commission Joint Research Centre (JRC) in collaboration with Health & Consumer Directorate-General (DG SANCO) under the 'Better Training for Safer Food' (BT SF) Programme". At the bottom, there are three small icons depicting food safety and health, and the "BT SF" logo is repeated in the bottom left corner.

Health & Consumers Directorate-General

**BT SF**  
Better Training for Safer Food

Directorate-General for Health & Consumers

Project conducted by  
European Commission Joint Research Centre (JRC)  
in collaboration with  
Health & Consumer Directorate-General (DG SANCO)  
under the 'Better Training for Safer Food' (BT SF) Programme

**BT SF**  
Better Training for Safer Food



## Project Aim

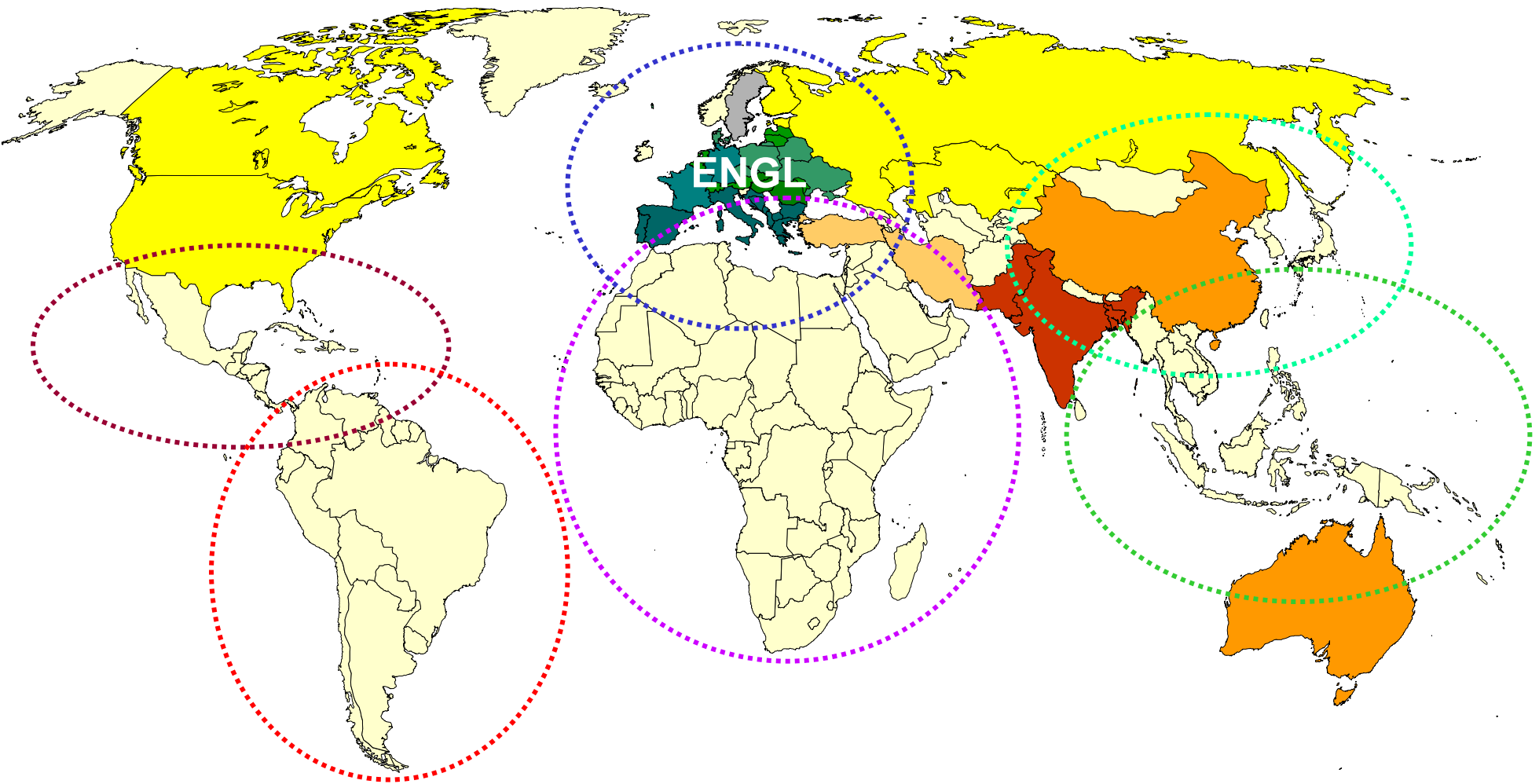
- To foster the concept of networking, to diffuse awareness on the benefits derived from such a networking in Europe and on the potential benefits that could derive from the establishment of similar initiatives in other parts of the world
- To facilitate the establishment of regional networks outside the EU following the concept of the ENGL
- To build capacity by providing training to enforcement laboratories

# **‘Towards Global Harmonisation of GMO Analysis by Creating and Supporting Regional Networks of Excellence’**

## **Project structure**

- Developed at 3 different layers:
- Managerial and decisional level
  - Scientific society
  - 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





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.



JRC  
EUROPEAN COMMISSION



Directorate-General for  
Health & Consumers



European Network of GMO Laboratories

Internet 100%



# **2<sup>nd</sup> Global Conference** **on** **GMO Analysis** **20-24 June 2011**



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

What are your needs regarding the set-up of enforcement laboratories  
Taking into account the information of this workshop?

How could those needs be met?

In which way could the JRC/European Commission collaborate with you?

Contact: [jrc-bgmo@ec.europa.eu](mailto:jrc-bgmo@ec.europa.eu)



# Muito Obrigado!

