

# Introduction to the Workshop: General approach for GMO detection in the EU



**IHCP - Institute for Health and Consumer Protection**

*Ispra - Italy*

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

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

# 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*

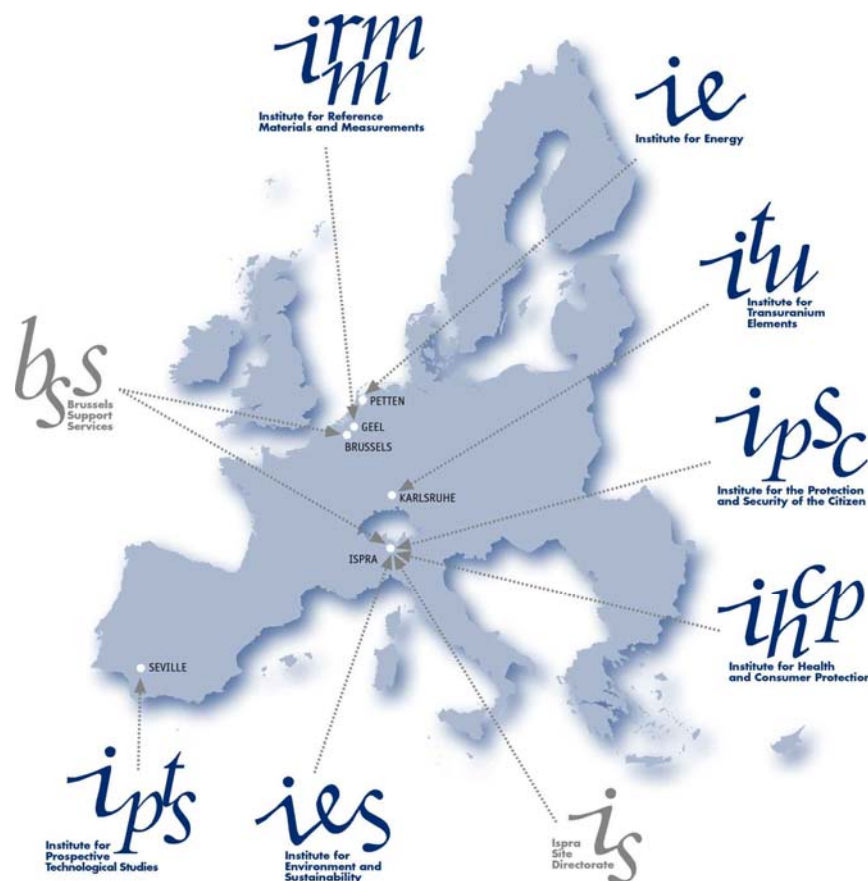
Institute for Environment and Sustainability

**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: three Institutes involved



## **IRMM – Geel, Belgium**

- World leader in production of Certified Reference Materials (including for GMOs) and bio-metrology



## **IHCP– Ispra, Italy**

- S/T support for the implementation of GMO legislation  
European Union Reference Laboratory for GM Food & Feed



## **IPTS – Seville, Spain**

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

# 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)**

# 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)

## Requirements according to Regulation (EC) 1830/2003

- Mandatory labelling extended to all food and feed, irrespective of GM-specific DNA or protein detectability
- Introduction of the Unique Identifier (Commission Regulation (EC) No 65/2004)
- Requirement to traceability
- Central Register



Community Register of Genetically Modified Food and Feed

[http://ec.europa.eu/food/dyna/gm\\_register/index\\_en.cfm](http://ec.europa.eu/food/dyna/gm_register/index_en.cfm)

*all details of GM authorised products, including provision of Reference Material*

Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling of GMOs..... in the context of Regulation (EC) No 1830/2003



# The European Union Reference Laboratory for GM Food & Feed



**EUROL**

European Union Reference Laboratory  
for GM Food & Feed



DAC-PL-0459-06-00



## 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

## 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 approx. 100 control laboratories, representing all 27 EU Member States, Norway and Switzerland, plus other Countries as observers.



## European Network of GMO Laboratories (ENGL)



**Objective:** to act as a scientific and technical platform to advance European harmonisation and standardisation of means and methods for sampling, detecting, identifying and quantifying GMOs from a wide variety of matrices including seed, grains, food, feed and environmental samples

- Methods development for qualitative and quantitative analyses
- Methods Validation
- Training, technology transfer and capacity building
- Reference Materials
- Sampling strategies for different GM-commodities
- Databases

## **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

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

# 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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Institute for Health and Consumer Protection  
European Commission > JRC > IHCP > EURL-GMFF

**European Union Reference Laboratory** for GM Food & Feed

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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 Triffid flax \(FP967\)](#)

[Page dedicated to rice BT 63](#)

[Page dedicated to maize Event 32](#)

[Page dedicated to 11RICE601](#)

[Page dedicated to BT10](#)

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Under the responsibility of the  
Molecular Biology and Genomics Unit

Accreditation ISO 17025 provided by



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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	



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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 25/05/2010

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: 03/08/2004	Validated method Published on: 05/08/2004
NK603 maize	MON-00603-6	Monsanto Company	Validation completed	Validation report Published on: 10/01/2005	Validated method Published on: 10/01/2005

## 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

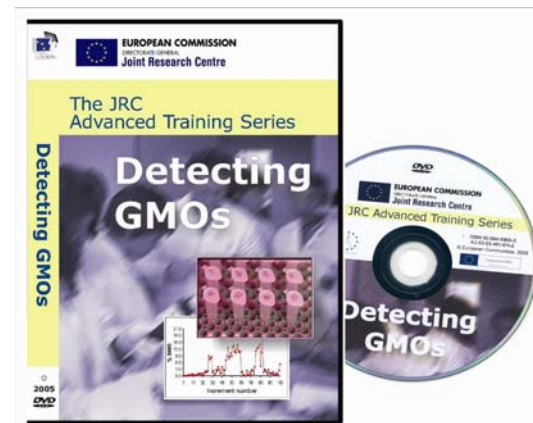
## Objective:

- 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*)



**1<sup>st</sup> Global Conference  
on  
GMO Analysis**

Villa Erba, Como, Italy  
24-27 June 2008

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

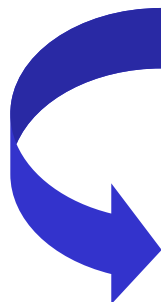


**JRC**  
EUROPEAN COMMISSION

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

## The way towards the Project Proposal on 'International Collaboration and Capacity Building'

- 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 CRL Mandate according to Regulation (EC) n. 882/2004
- 2008 1<sup>st</sup> Global Conference on GMO Analysis



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



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

...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

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

## Project structure

Developed at three different layers:

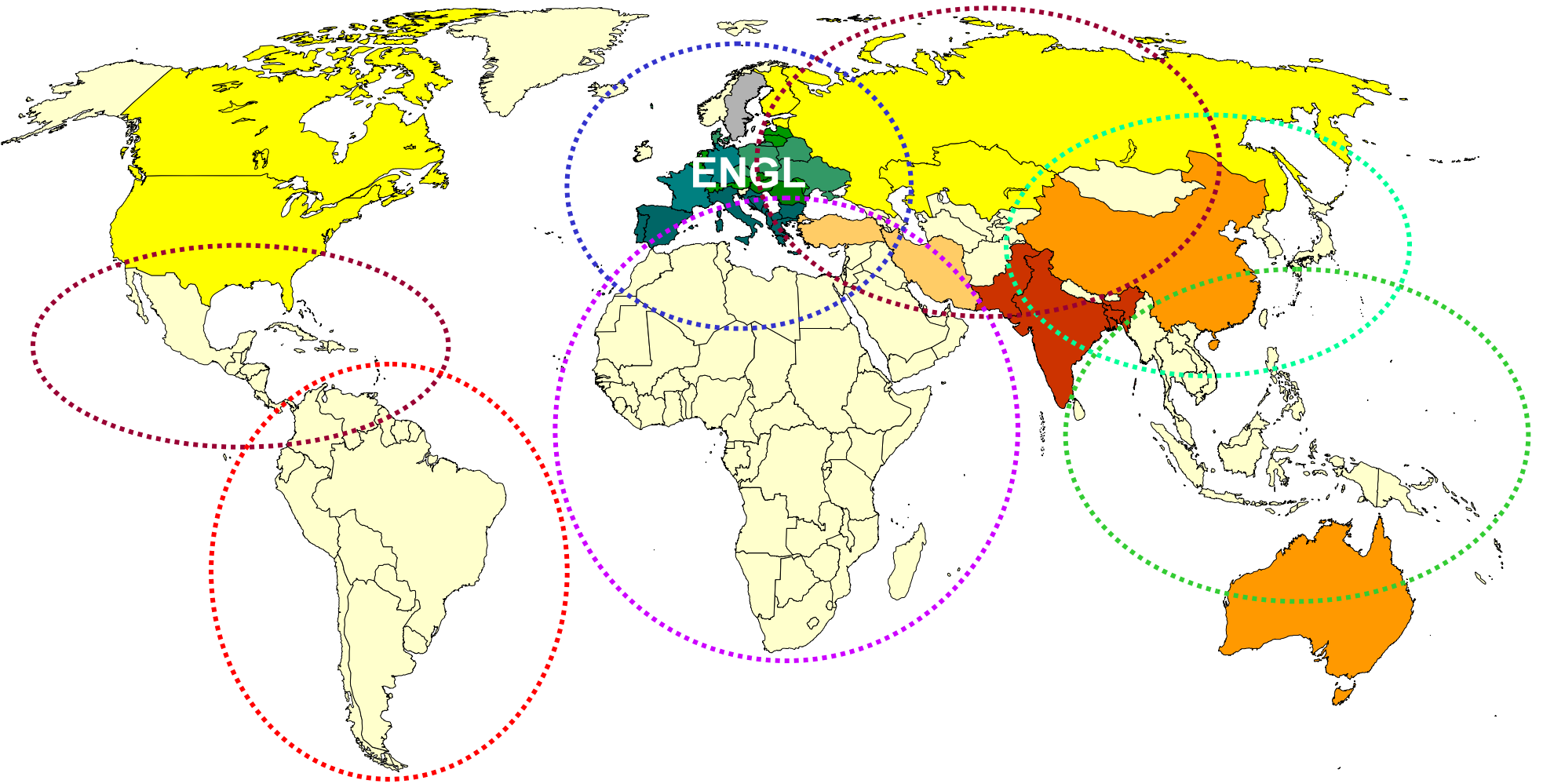
- Managerial and decisional level
- Scientific society involved in the topic
- Actors directly engaged in technical & scientific aspects of GMO analysis, control/testing laboratory staff

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. 2<sup>nd</sup> Regional Networking Workshop for Asian Countries
- Croatia 27-28 September 2010. 2<sup>nd</sup> 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 November 2010. Study Tour on GMO Analysis for Central & South American Countries

## Roadmap 2009 - 2011

### 2011

- 2<sup>nd</sup> Regional Networking Workshop for Central & South American Countries
- 3<sup>rd</sup> Regional Networking Workshop for Asian Countries
- 1<sup>st</sup> Regional Networking Workshop for the Middle East
- ...



## 2<sup>nd</sup> Global Conference on **GMO Analysis**

**20-24 June 2011**



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



# Enlargement, International Collaboration & Capacity Building



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://mbq.jrc.ec.europa.eu/home>



**Thank you!**