

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



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European Commission

## CONTENTS

- *EU GMO legislation (in short)*
- European Commission and GMO detection (EURL and ENGL)
- European Commission and Capacity-Building (BTSE programme)

## EUROPEAN COMMISSION AND GMOs (in short)

- **DG Health and Consumer Protection (SANCO)**
  - EU legislation on GMOs
  - GMO approvals (cultivation and/or Food Feed Processing)
  
- **DG Joint Research Centre (JRC)**
  - GMO detection
  - Capacity-building for GMO analysis

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

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

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



## EU Legislation on GMOs – some key texts ...

- **Directive 2001/18/EC on deliberate release into the environment of genetically modified organisms (GMOs)**
- **Regulation (EC) No 1829/2003 on genetically modified food and feed**
- **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
- And now also a **EC Regulation on Low Level Presence (LLP) adopted in February 2011** and harmonising the implementation of the EU zero tolerance policy on non-authorized GM material in feed

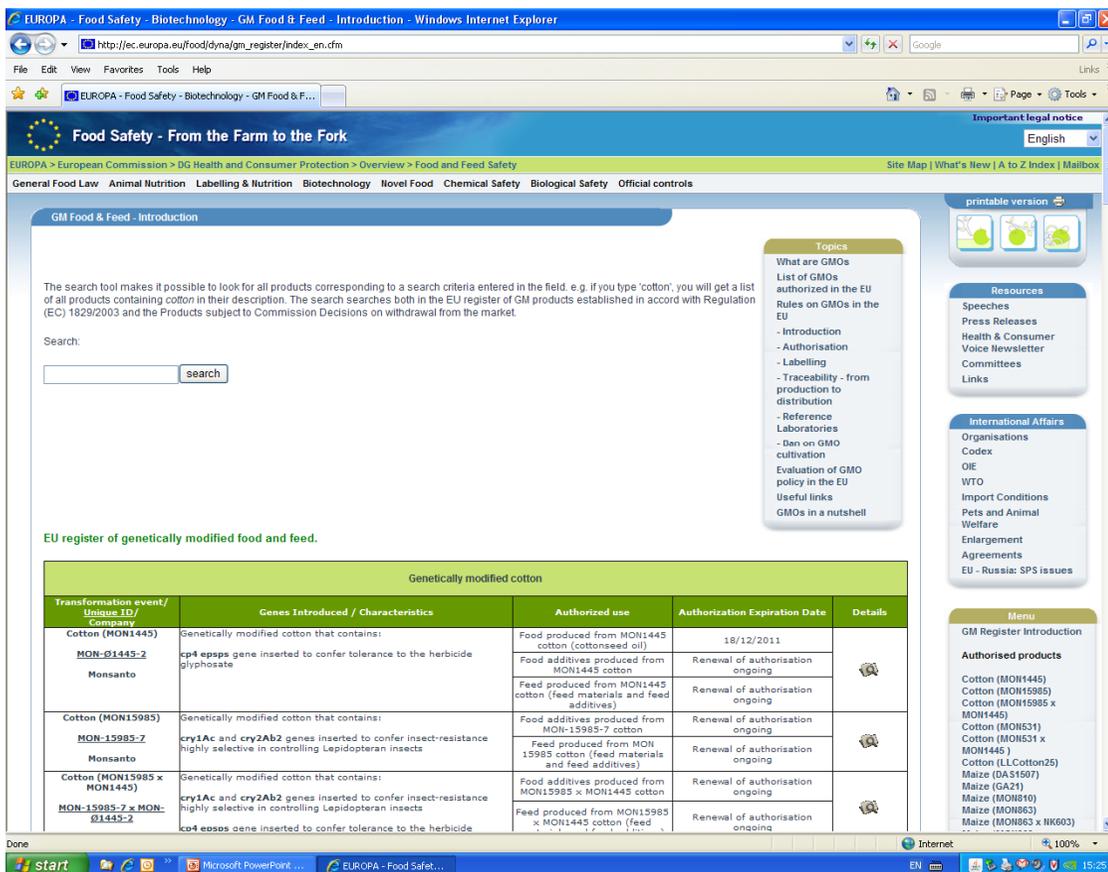
## Regulation (EC) No 1829/2003 on genetically modified food and feed Key Provisions

- A GMO food/feed can be placed on the EU market only once it is covered by an authorisation granted according to Regulation (EC) No 1829/2003 : **unapproved GMOs should not be on the EU market**
- **EU authorisation process is based on an independent EU risk assessment** carried out by the European Food Safety Authority (EFSA)
- Mandatory GM labelling for GM food/feed (incl. labelling threshold of 0,9% to exempt from GM labelling the adventitious or technically unavoidable presence of GM material in food or feed) : **approved GMOs should be labelled**

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

- 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)

Further information on EU legislation on GMOs available @ [http://ec.europa.eu/food/dyna/gm\\_register/index\\_en.cfm](http://ec.europa.eu/food/dyna/gm_register/index_en.cfm) incl. GM Food Feed register (36 GMOs approved for food/feed use as of February 2011)



EUROPA - Food Safety - Biotechnology - GM Food & Feed - Introduction - Windows Internet Explorer

http://ec.europa.eu/food/dyna/gm\_register/index\_en.cfm

Food Safety - From the Farm to the Fork

EUROPA > European Commission > DG Health and Consumer Protection > Overview > Food and Feed Safety

General Food Law Animal Nutrition Labelling & Nutrition Biotechnology Novel Food Chemical Safety Biological Safety Official controls

GM Food & Feed - Introduction

The search tool makes it possible to look for all products corresponding to a search criteria entered in the field. e.g. if you type 'cotton', you will get a list of all products containing cotton in their description. The search searches both in the EU register of GM products established in accord with Regulation (EC) 1829/2003 and the Products subject to Commission Decisions on withdrawal from the market.

Search:

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-Ø1445-2 Monsanto	Genetically modified cotton that contains: cp4 epsps gene inserted to confer tolerance to the herbicide glyphosate	Food produced from MON1445 cotton (cottonseed oil)	18/12/2011	
		Food additives produced from MON1445 cotton	Renewal of authorisation ongoing	
		Feed produced from MON1445 cotton (feed materials and feed additives)	Renewal of authorisation ongoing	
Cotton (MON15985) MON-15985-7 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-15985-7 cotton	Renewal of authorisation ongoing	
		Feed produced from MON 15985 cotton (feed materials and feed additives)	Renewal of authorisation ongoing	
Cotton (MON15985 x MON1445) MON-15985-7 x MON-Ø1445-2	Genetically modified cotton that contains: cry1Ac and cry2Ab2 genes inserted to confer insect-resistance highly selective in controlling Lepidopteran insects	Food additives produced from MON15985 x MON1445 cotton	Renewal of authorisation ongoing	
		Feed produced from MON15985 x MON1445 cotton (feed	Renewal of authorisation ongoing	



## The EU Legislation on GMOs

An overview

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EUR 24279 EN - 2010

## CONTENTS

- EU GMO legislation (in short)
- *European Commission and GMO detection (EURL and ENGL)*
- European Commission and Capacity-Building (BTSE programme)

## 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** 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

## 1829/2003 Mandate of the EU-RL GMFF

Core activity: validation of GMO detection methods as part of the EU GMO approval process



- Evaluation of data, testing and **validation of GMO detection methods** provided by the applicants under Reg. (EC) 1829/2003
- > 60 methods have been validated by the EURL-GMFF since April 2004
- ISO 9001 certified and ISO 17025 accredited
- All validated methods and validation reports are published at <http://gmo-crl.jrc.ec.europa.eu/>

## 1829/2003 Mandate of the EURL-GMFF

In addition to core activity of GMO detection method validation:

- 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)



## 882/2004 Mandate of the EURL-GMFF

### General rules for food/feed controls in the EU :



- General objective is to ensure a **harmonised framework** for controls on enforcement of food/feed law in the EU
- It is the **Member States who are responsible** for enforcement and controls on food/feed law (incl. GMO controls)
- All the Member States have designated **Competent Authorities and National Reference Laboratories (NRLs)** for food/feed controls (incl. GMO controls)
- **In addition to NRLs, European Union Reference Laboratories (EURLs)** have been established to support harmonised enforcement (incl. GMO controls)

## 882/2004 Mandate of the EURL-GMFF (see article 32) EURLs for food/feed controls (incl. GMOs) are responsible for:



- Providing 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**.

## The European Union Reference Laboratory for GM Food & Feed (EU-RL GMFF) @ <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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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.

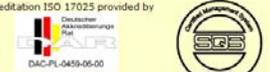
The core task of the EURL-GMFF is the scientific assessment and validation of detection methods for GM Food and Feed as part of the EU authorization procedure. The Joint Research Centre (JRC) of the European Commission and, more precisely, the Molecular Biology and Genomics Unit of the Institute for 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.



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

Accreditation ISO 17025 provided by



Click on logo to see the scope

[Page dedicated to CDC Triffid flex \(FP967\)](#)  
[Page dedicated to rice BT 63](#)  
[Page dedicated to maize Event 32](#)  
[Page dedicated to LRICE601](#)  
[Page dedicated to BT10](#)

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Under the responsibility of the Molecular Biology and Genomics Unit



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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	



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European Commission > JRC > IHCP > EURL-GMFF

**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](#)

Last updated 25/05/2010  

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: 03/08/2004	<a href="#">Validated method</a> Published on: 05/08/2004
NK603 maize	MON-00603-6	Monsanto Company	Validation completed	<a href="#">Validation report</a> Published on: 10/01/2005	<a href="#">Validated method</a> Published on: 10/01/2005

## The European Network of GMO Laboratories (ENGL)

Regulation (EC) No 1829/2003 (see before) : the EU-RL GMFF is assisted by the “European Network of GMO laboratories” (ENGL)



ENGL main objective: to act as a scientific and technical platform to advance European harmonisation of 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
- **Databases**

The European Network of GMO Laboratories (ENGL), in practice:

Operational since December 2002 under the JRC chairmanship



Unique network of expertise in GMO analysis : 96 laboratories from 27 EU Member States (+ Norway and Switzerland) + observers from non-EU countries

Working Procedures laid down in a ENGL Consortium Agreement signed by all ENGL members

Two Plenary Meetings a year (15<sup>th</sup> Plenary in May 2011)

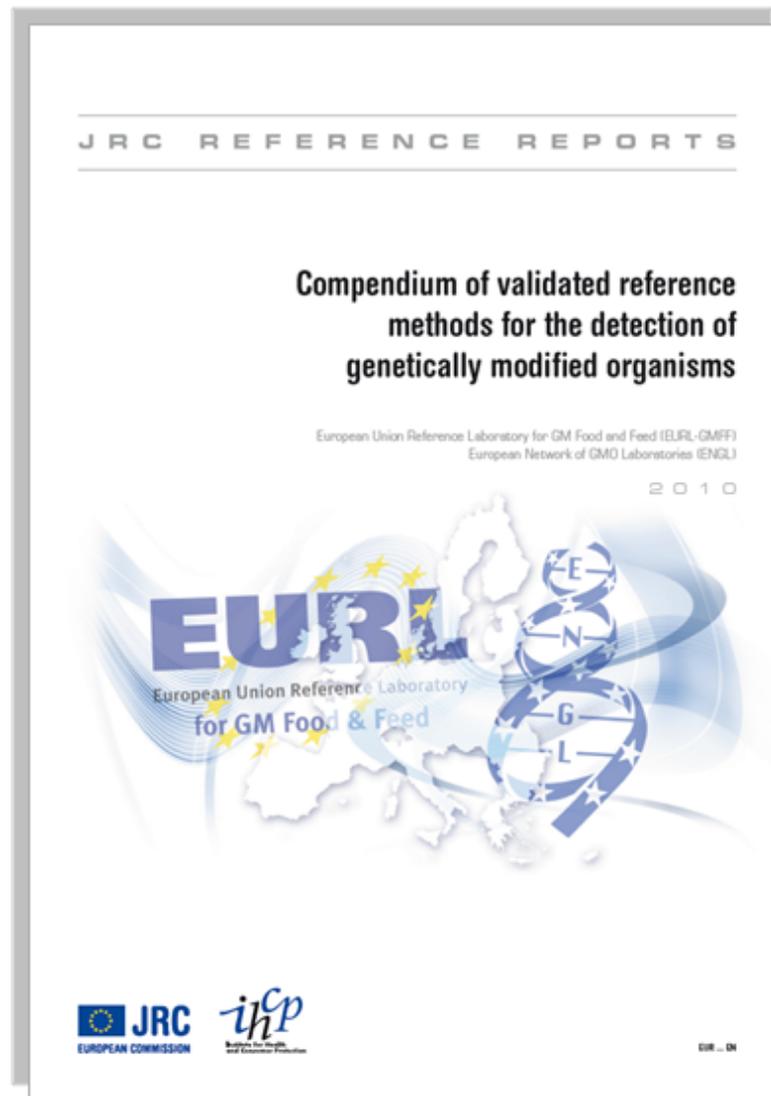
Different WGs established by the ENGL Steering Committee on topics like Unauthorised GMOs, Method Verification, Method Performance Requirements, Sample Preparation Procedure

## JRC Reference Report (November 2010)

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

Legal framework:  
Regulation (EC) 882/2004

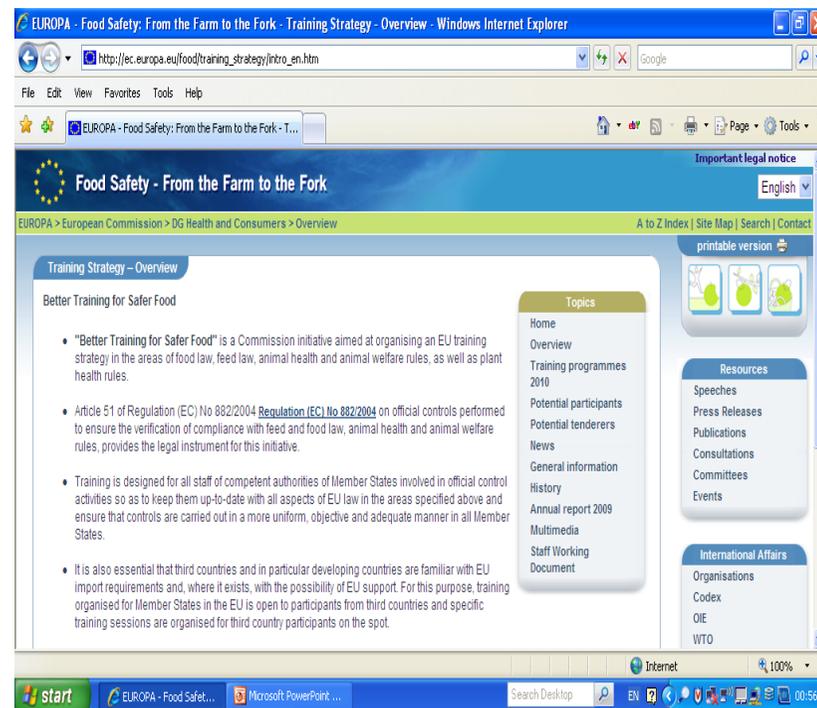
Scope:  
GMO detection methods  
ISO collaborative trial criteria (ISO 5725)  
DNA-based methods



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## The 'Better Training for Safer Food' (BTSF) Programme from the European Commission Health & Consumer Directorate-General (DG SANCO)



[http://ec.europa.eu/food/training\\_strategy/index\\_en.htm](http://ec.europa.eu/food/training_strategy/index_en.htm)

- **"Better Training for Safer Food" (BTSF) is a Commission initiative in place since 2006** and aimed at organising an EU training strategy in the areas of food law, feed law, animal health and animal welfare rules, and plant health rules (legal basis: article 51 of Regulation (EC) No 882/2004).
- **Training is designed for all staff of competent authorities of Member States involved in official control activities** so as to keep them up-to-date with all aspects of EU law in the areas specified above and ensure that controls are carried out in a more uniform, objective and adequate manner in all Member States.
- **It is also essential that third countries and in particular developing countries are familiar with EU import requirements** and, where it exists, with the possibility of EU support. For this purpose, training organised for Member States in the EU is open to participants from third countries and specific training sessions are organised for third country participants.



- **Main objectives of the BTSF initiative** are the organisation and development of an EU training strategy with a view to:
  - Ensuring and maintaining a **high level of consumer protection** and of animal health, animal welfare and plant health;
  - Promoting a **harmonised approach** to the operation of Community and national control systems;
  - **Enhancing trade of safe food**;
  - **Ensuring fair trade with third countries** and in particular developing countries.



## Examples of 2010 BTSF training courses in third countries:

- Control of Avian Influenza and other animal diseases
  - EU food standards
  - Food testing and sanitary and phytosanitary issues
  - The EU Rapid Alert System for Food and Feed
  - Better Training for Safer Food in Africa
- and...
- **Analysis of Genetically Modified Organisms**



**Thank you for your attention**

