

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 (BTSF programme)

EUROPEAN COMMISSION AND GMOs (in short)

- **DG Health and Consumer Protection (SANCO)**
 - EU legislation on GMOs
 - GMO approvals (for Cultivation and/or for Food Feed Processing)
- **DG Joint Research Centre (JRC)**
 - Scientific support to implementation of EU legislation on GMOs
 - GMO detection methods
 - 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

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EU Legislation on GMOs – some key texts ...

- 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
- Regulation (EU) No 619/2011 on official controls of feed about presence of GM material for which an authorisation is pending (**so-called Low Level Presence (LLP) regulation**)

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

- **Mandatory approval of GM Food Feed** before placing on the EU market: 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 (the EU authorisation process is based on an independent EU risk assessment carried out by the European Food Safety Authority - EFSA)
- **Mandatory labelling of GM food/feed** once approved for placing on the market (incl. labelling threshold of 0,9% to exempt from GM labelling the adventitious or technically unavoidable presence of GM material in food or feed)

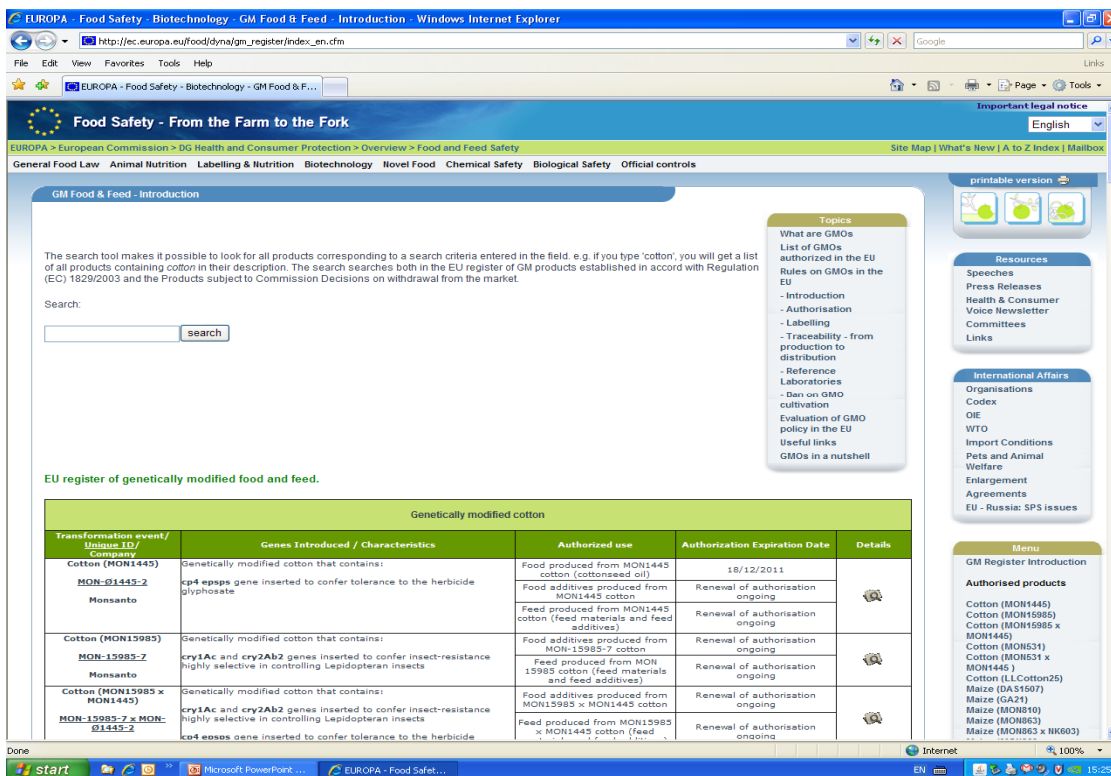
Regulation (EC) No 1829/2003 on genetically modified food and feed

- **Mandatory EU validation of GMO detection method** : is part of the EU regulatory approval process for GMOs. GM Food/Feed applications should include:
 - ✓ Methods for detection and identification of the transformation event
 - ✓ Samples of the food and their control samples (positive and negative sample)

A GMO cannot be approved in the EU without a validated detection method
- **The EU Reference Laboratory for GM Food Feed (EU-RL GMFF) is responsible for validation** of the GMO detection methods and **is assisted by** the National Reference Laboratories, as members of the consortium referred to as **the “European Network of GMO laboratories” (ENGL)**
- **The EU-RL GMFF is the Commission Joint Research Centre (JRC)**


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 January 2012, 42 GMOs approved for food/feed use in the EU (incl. 2 for cultivation): 26 maize, 8 cotton, 3 soya, 3 oilseed rape, 1 starch potato, 1 sugarbeet



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 materials and feed additives)	18/12/2011 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	Feed additives produced from MON15985-2 cotton Feed produced from MON15985 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 produced from MON15985 x MON1445 cotton (feed materials and feed additives)	Renewal of authorisation ongoing Renewal of authorisation ongoing	



The EU Legislation on GMOs

An overview

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EUR 24279 EN - 2010

- **Another mandate** of the EU Commission JRC under the U.N. CBD Cartagena Biosafety Protocol:
- **The JRC is also the BCH focal point for the EU**
- **Notification of all EU GMO legislation and EU GMO approvals on the Cartagena Biosafety Protocol BCH (incl. information on detection methods)**

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- European Commission and Capacity-Building (BTSF programme)

ENGL and EURL – two European partners in GMO detection

- EURL GMFF - 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
- 97 labs hosted by 27 EU Member States (+ 4 non-EU)



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

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

- 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
- Provision of guidance documents
- Role in dispute settlements
- Role in emergency situations (unapproved GMOs on EU market)



2nd mandate of the EU-RL GMFF under Reg. (EC) No 882/2004

- Providing National Reference Laboratories (NRLs) in the EU with **reference analytical methods**
- Coordinating application of the methods by organising **comparative testing** and by ensuring an appropriate follow-up
- **Conducting training** courses for the benefit of staff from NRLs in the EU and of laboratories responsible for analysing feed and food **in third countries**.
- Note: EU-RL and NRLs need to be accredited according to ISO 17025



The European Network of GMO Laboratories (ENGL)




Operational since December 2002 under the JRC chairmanship

Unique network of expertise in GMO analysis : 97 laboratories from 27 EU Member States (+ Norway, Switzerland, Turkey, Croatia) + observers from non-EU countries

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

Two Plenary Meetings (and two Steering Committees) a year
+ Different WGs established by the ENGL Steering Committee on topics like Unauthorised GMOs, Method Verification....

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



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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	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/ENGL publicly available at <http://gmo-crl.jrc.ec.europa.eu/>



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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	11/05/2007	
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.

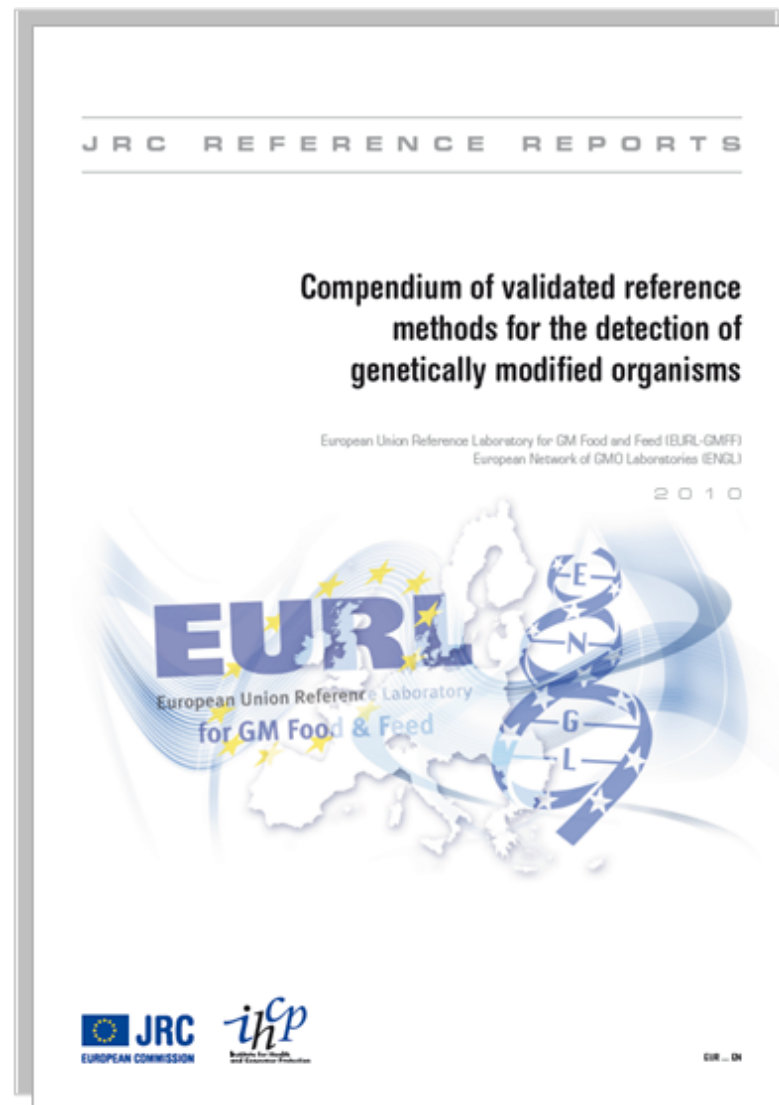
Method validation is therefore an essential component of the measures that a laboratory should implement to allow it to produce reliable analytical data. In some sectors, most notably in the analysis of food, the requirement for methods that have been "fully validated" is prescribed by legislation⁵. "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 (updated in April 2011):

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

Searchable method database GMOMethods (based on compendium) on-line since May 2011 at <http://gmo-crl.jrc.ec.europa.eu/>

Both Compendium and Database linked to BCH



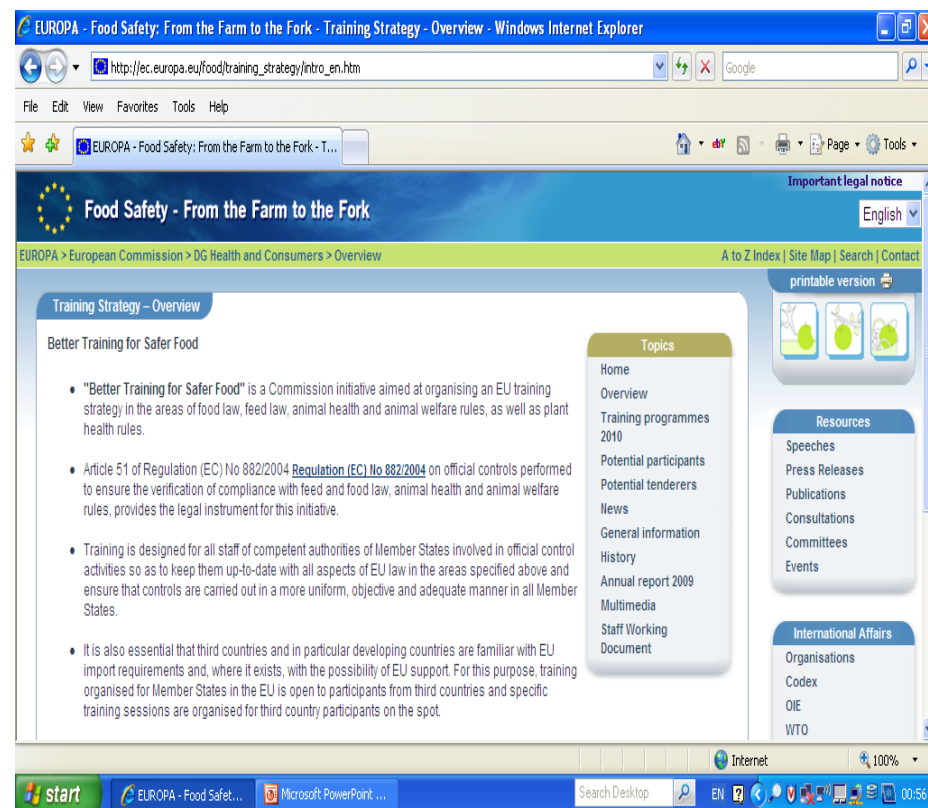
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The 'Better Training for Safer Food' (BTSF) Programme of the European Commission Health & Consumer Directorate-General (DG SANCO) http://ec.europa.eu/food/training_strategy/index_en.htm

"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 and feed law.

Training is designed for competent authorities of EU Member States involved in official control activities and also from third countries, in particular developing countries, so that they are familiar with EU import requirements





- **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 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**

See details at http://ec.europa.eu/food/training_strategy/index_en.htm

'Towards Global Harmonisation of GMO Analysis by Creating and Supporting Regional Networks of Excellence'

Project carried out under the BTSF programme

- 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



Thank you for your attention

