

Global Harmonisation Networking In GMO Analysis - Update



3rd EU-Asia Network Meeting, Singapore, 7th June 2011

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European Commission

CONTENTS

- Update on EU developments related to:
 - Regulatory Framework (LLP)
 - Detection Methods (Compendium + Database)
 - GMO Proficiency Testing
- Update on EU Global Capacity Building Project

COMMISSION REGULATION (EU)

laying down the methods of sampling and analysis for the official control of feed as regards the presence of genetically modified material for which an authorisation procedure is pending or the authorization of which has expired

Whereas (9):

Accordingly, the scope of this Regulation should cover the detection in **feed** of GM material authorised for commercialisation in a third country and **for which an authorisation procedure is pending for more than 3 months** under Regulation (EC) No 1829/2003 where the event-specific quantitative methods of analysis submitted by the applicant have been **validated by the EU-RL** and provided that the **certified reference material** is available.

Whereas 14

It is appropriate to set as a **Minimum Required Performance Limit (MRPL)** the lowest level of GM material which is considered by the EU-RL for the validation of quantitative methods.

This level corresponds to **0.1% related to mass fraction** of GM material in feed and is the lowest level where results are satisfactorily reproducible between official laboratories when appropriate sampling protocols and methods of analysis for measuring feed samples are applied.

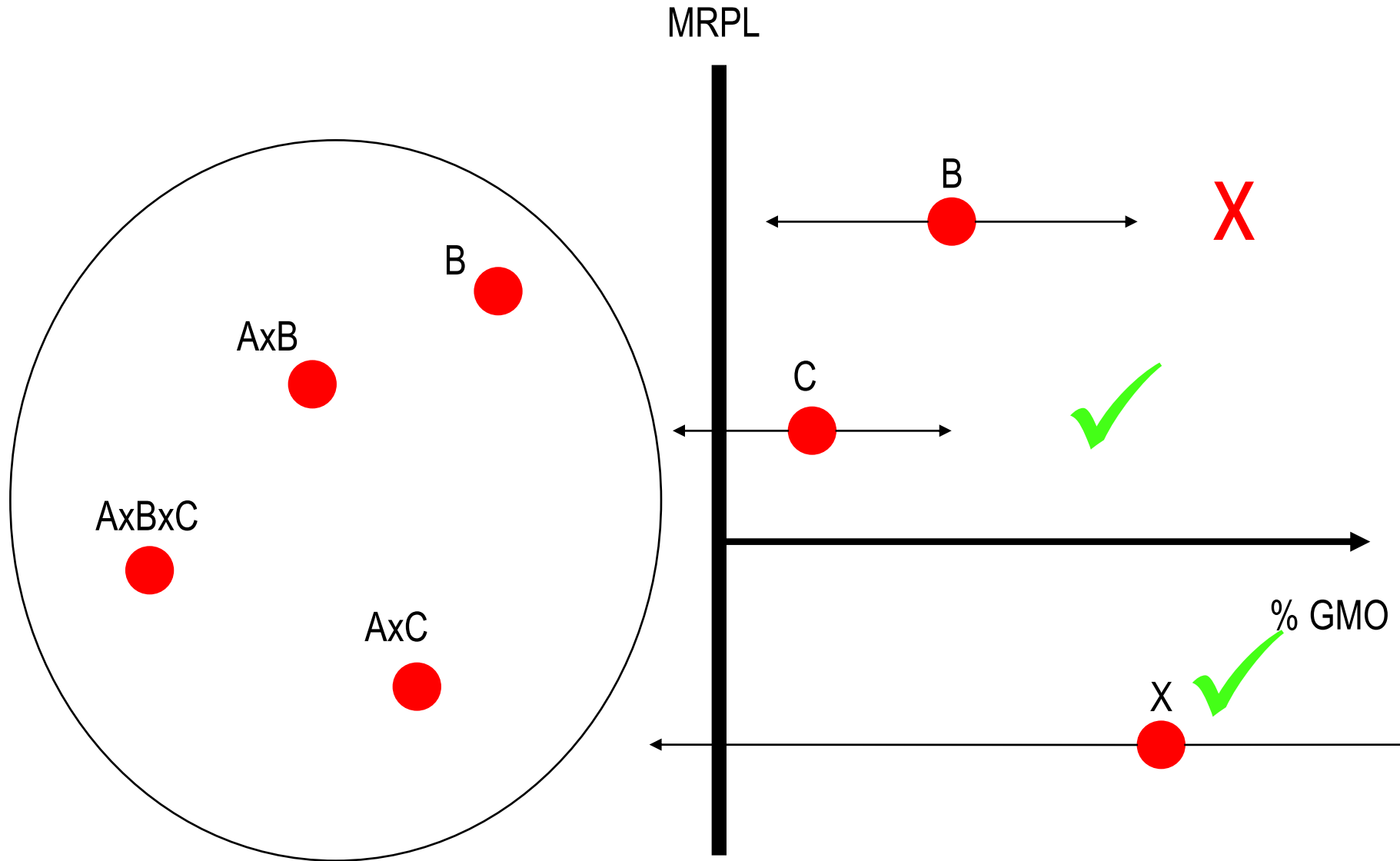
Method of sampling:

Regulation (EC) No 152/2009 predominantly applies.

- The EU-RL GMFF accepts only methods where the applicant proves that the RSDr at the level of 0.1 % related to mass fraction of GM material $\leq 25\%$; this value will be published in the validation reports
- The EU-RL GMFF will determine in-house the RSDr at the level of 0.1 % related to mass fraction of GM material and will publish that data in the validation report.
- Following a ring-trial, the EU-RL GMFF calculates again the RSDr, this time according to ISO standard 5725. This value has been and will continue to be published in the validation reports.
- In order to be fit for the purpose of meeting the requirements of the LLP regulation, all RSDr values mentioned above have to be below 25%.

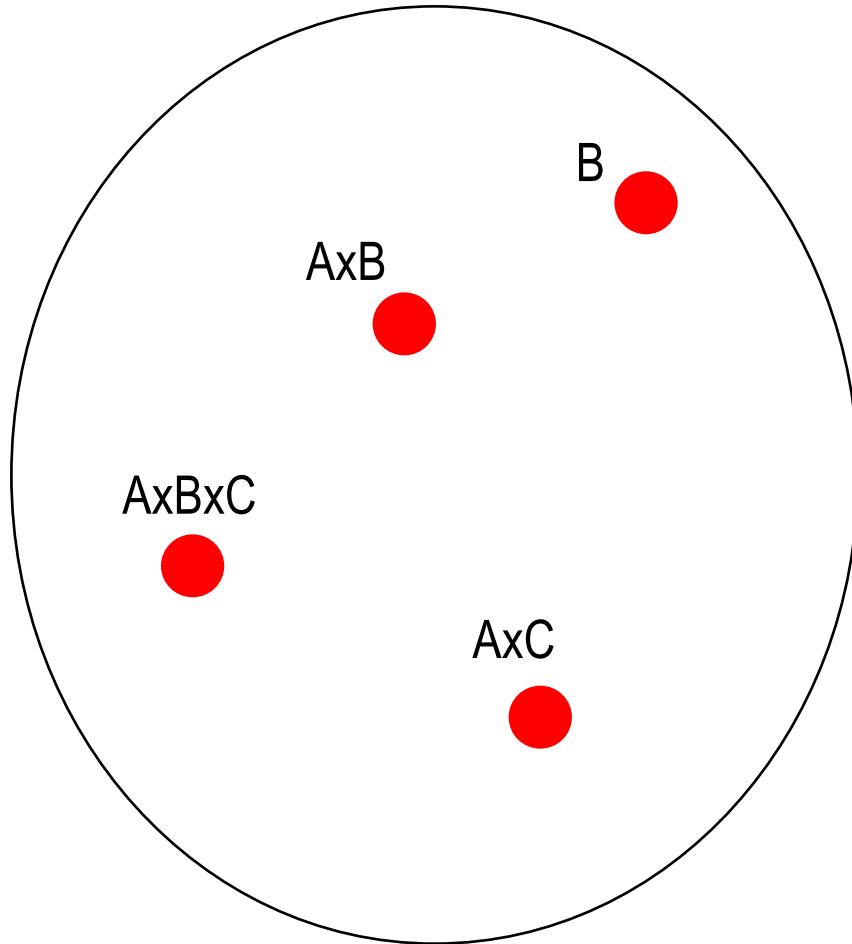
- According to the provisions of ISO 17025:2005 section 5.4.2, **the official laboratory shall provide evidence that it can properly run a reference method** by meeting the described performance parameters using actual laboratory data. In particular, the RSD_r of the method shall not exceed 25% at the GMO concentration of 0.1% expressed.

- To ensure a level of confidence of approximately 95 %, the outcome of the analysis shall be reported as $x \pm U$ whereby x is the analytical result for one measured transformation event and U is the appropriate **expanded measurement uncertainty**.



Whereas (15):

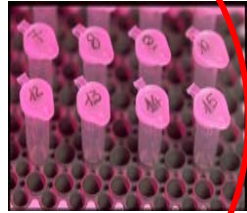
The methods validated by the EU RL are **specific to each transformation event** irrespective of the fact that the transformation event is present in one or several GMOs containing one or several transformation events.



Assume A approved,
B and C not approved:

If B or C are at or above the
MRPL (as defined in
accordance with the rules of
interpretation), the feed shall
be considered as non-
compliant

Sampling error



GMO identification

GMO test

Negative

GMO detection

Positive

Authorised?

No

Illegal

Yes

Assay individual ingredients

Analytical error

No need for labelling

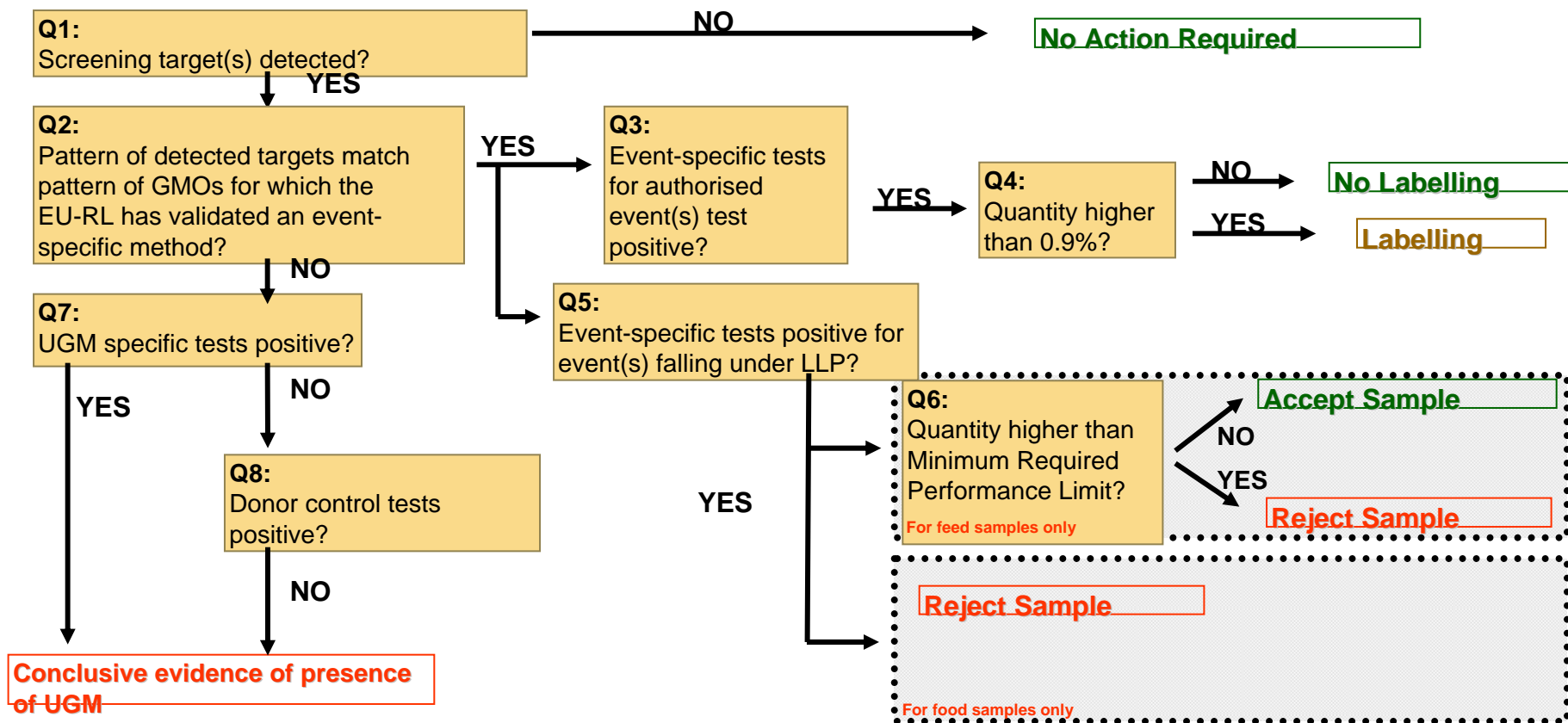
Less than 0.9%

Labelling required

More than 0.9%

GMO quantification

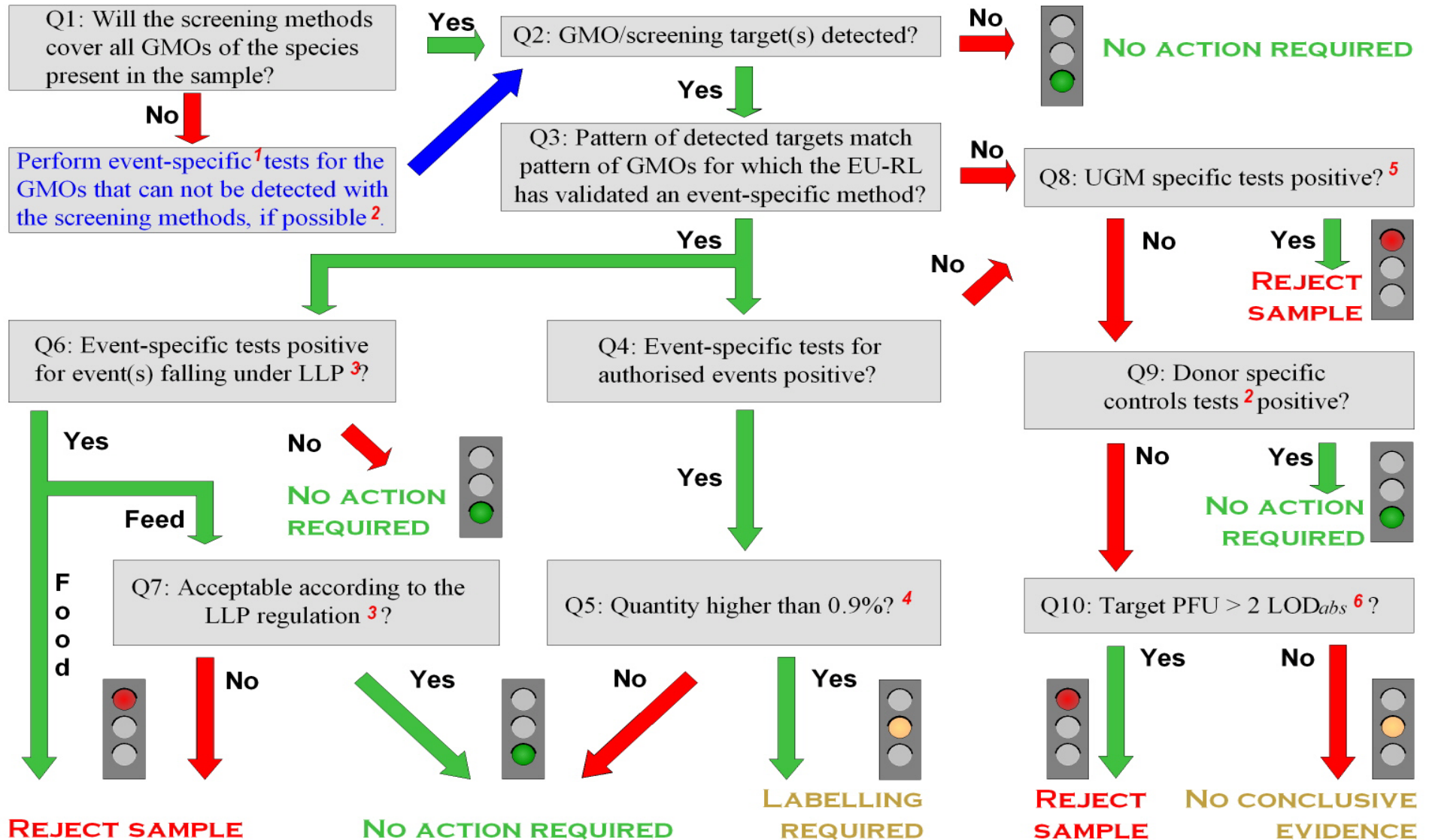
Decision Tree for the Analysis of Unknown Samples for the Presence of Genetically Modified Organisms (GMOs)



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New proposed version: Holst-Jensen et al., WG ENGL



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ENGL and EURL – two European partners in GMO detection

- EURL - 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
- 96 labs hosted by 27 EU Member States (+ 4 non-EU countries)



The EURL and ENGL activities in GMO detection are based on the EU GMO legislation



- 1st EURL mandate (Reg. (EC)1829/2003)
- Validation of GMO detection methods as part of the EU GMO approval process
- 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
- 2nd EURL mandate (Reg. (EC) 882/2004)
- Provision of reference analytical methods
- Organisation of comparative testing and appropriate follow-up in accordance with internationally accepted protocols
- Collaboration with laboratories responsible for analysing feed and food in third countries.

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



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Joint Research Centre
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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 |

EU Harmonisation : Compendium of validated reference methods for the detection of Genetically Modified Organisms (November 2010)

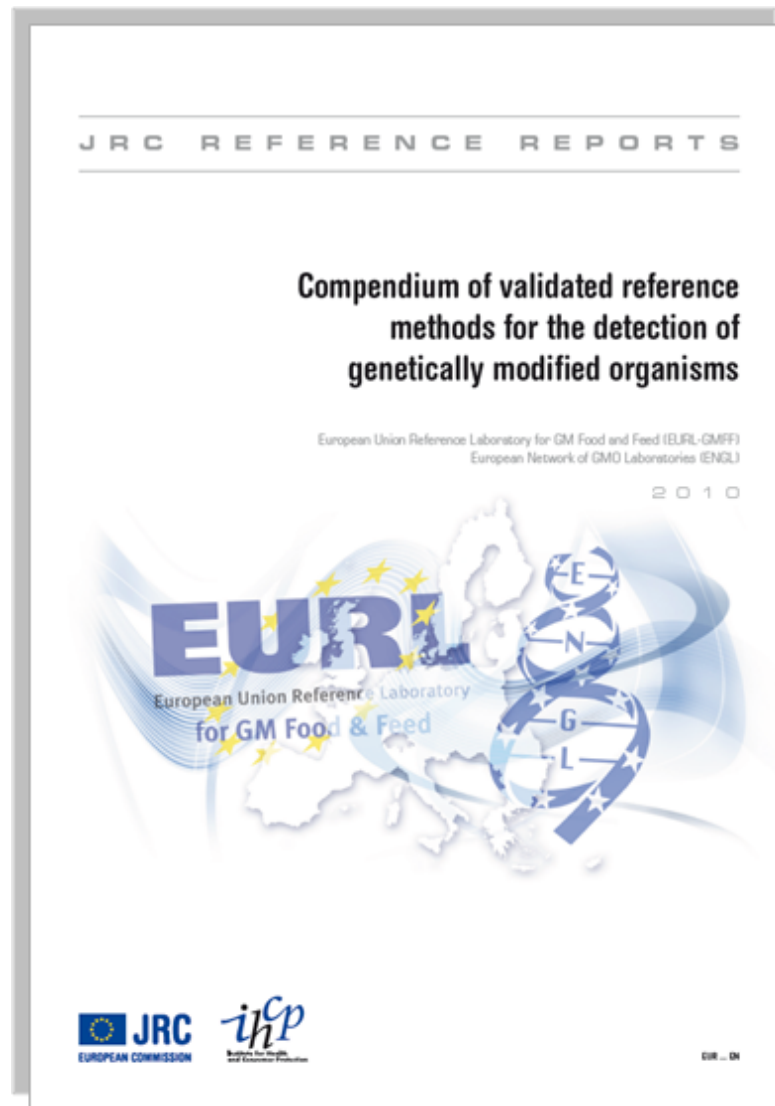
V2 (April 2011) publicly available at
<http://gmo-crl.jrc.ec.europa.eu/gmomethods/>

Scope:

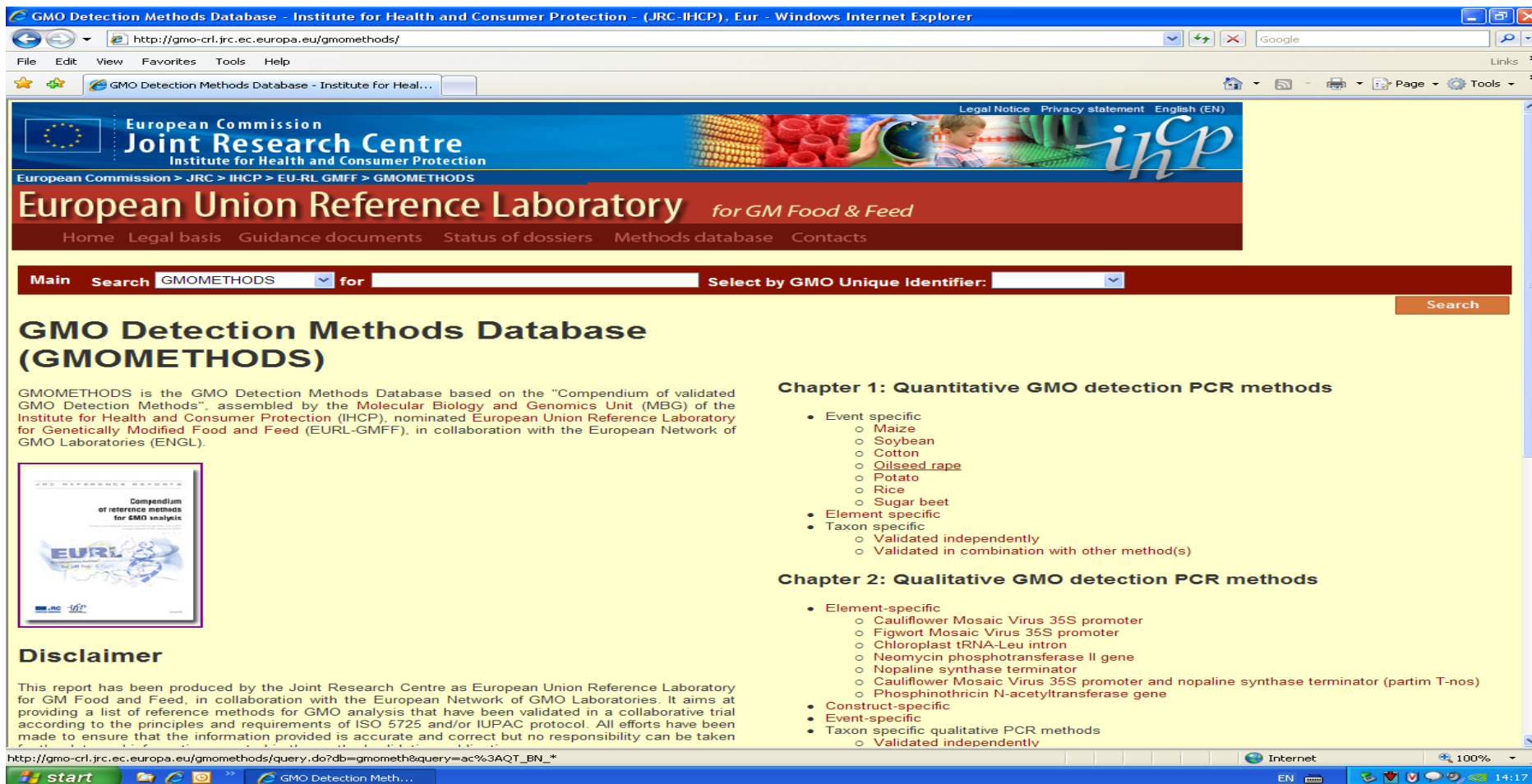
79 GMO detection methods

DNA-based methods

Validated according to ISO 5725 and/or IUPAC criteria



EU Harmonisation : GMOMETHODS database (based on Compendium) publicly available at <http://gmo-crl.jrc.ec.europa.eu/gmomethods/>



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European Commission > JRC > IHCP > EU-RL GMFF > GMOMETHODS

European Union Reference Laboratory for GM Food & Feed

Home Legal basis Guidance documents Status of dossiers Methods database Contacts

Main Search for Select by GMO Unique Identifier:

GMO Detection Methods Database (GMOMETHODS)

GMOMETHODS is the GMO Detection Methods Database based on the "Compendium of validated GMO Detection Methods", assembled by the Molecular Biology and Genomics Unit (MBG) of the Institute for Health and Consumer Protection (IHCP), nominated European Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF), in collaboration with the European Network of GMO Laboratories (ENGL).

Chapter 1: Quantitative GMO detection PCR methods

- Event specific
 - Maize
 - Soybean
 - Cotton
 - Oilseed rape
 - Potato
 - Rice
 - Sugar beet
- Element specific
- Taxon specific
 - Validated independently
 - Validated in combination with other method(s)

Chapter 2: Qualitative GMO detection PCR methods

- Element-specific
 - Cauliflower Mosaic Virus 35S promoter
 - Figwort Mosaic Virus 35S promoter
 - Chloroplast tRNA-Leu intron
 - Neomycin phosphotransferase II gene
 - Nopaline synthase terminator
 - Cauliflower Mosaic Virus 35S promoter and nopaline synthase terminator (partim T-nos)
 - Phosphinothricin N-acetyltransferase gene
- Construct-specific
- Event-specific
- Taxon specific qualitative PCR methods
 - Validated independently

Disclaimer

This report has been produced by the Joint Research Centre as European Union Reference Laboratory for GM Food and Feed, in collaboration with the European Network of GMO Laboratories. It aims at providing a list of reference methods for GMO analysis that have been validated in a collaborative trial according to the principles and requirements of ISO 5725 and/or IUPAC protocol. All efforts have been made to ensure that the information provided is accurate and correct but no responsibility can be taken

http://gmo-crl.jrc.ec.europa.eu/gmomethods/query.do?db=gmometh&query=ac%3AQT_BN_*

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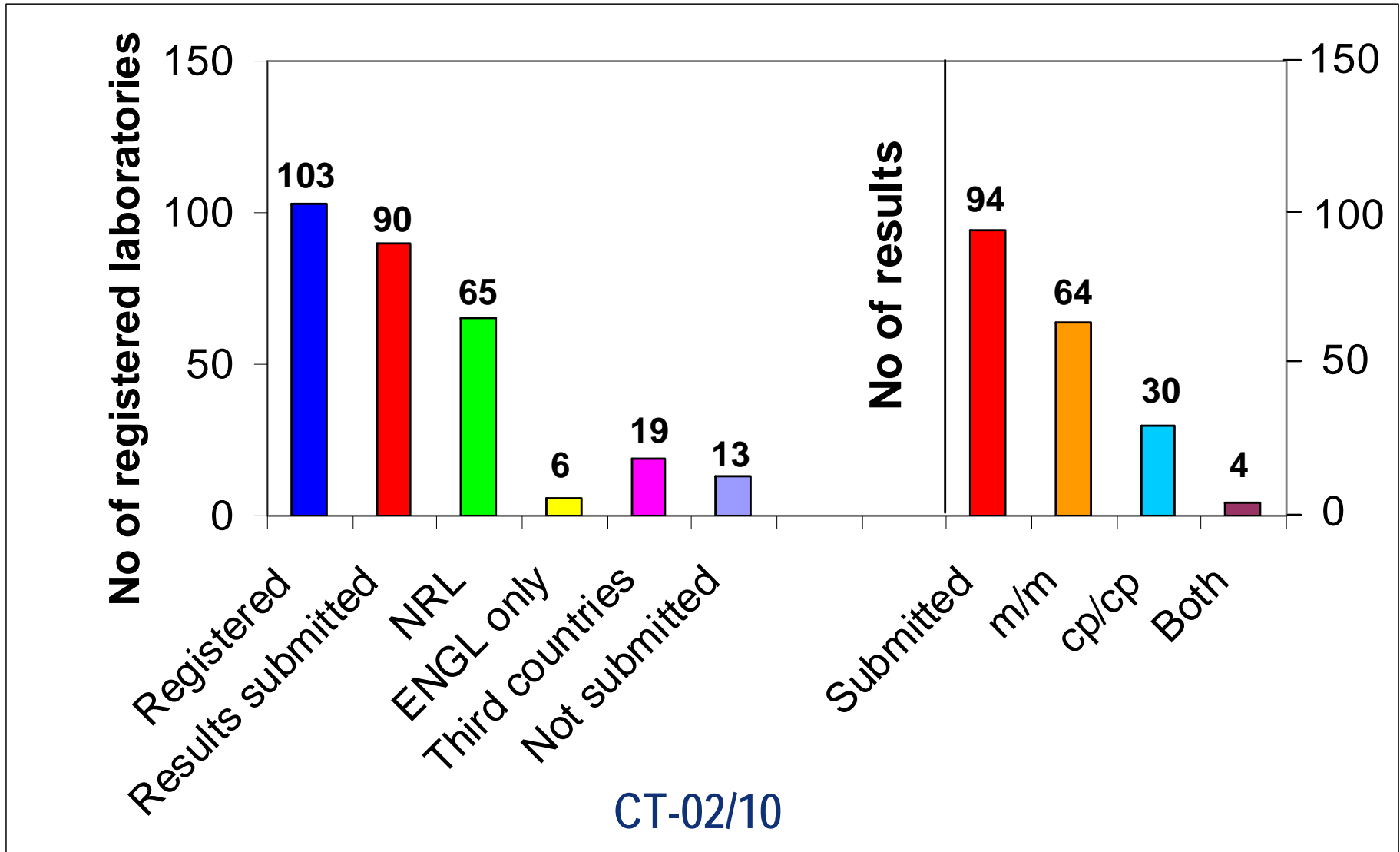
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EURL Comparative/Proficiency Testing Programme

- EURL GMFF mandate to organise proficiency testing (also called comparative testing) under Reg. EC (No) 882/2004
Note: Proficiency testing: evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons
- Two rounds per year
- Participants: European laboratories (National Reference Laboratories and ENGL members) + invited participants from third countries
- First three rounds (2010 – mid-2011) : one GM event per round + two test materials representing different GM levels
- From fourth round (end 2011) onwards: mixtures of GM events possible. Combination of qualitative and quantitative PCR

EURL Proficiency Testing Programme Interpretation of Results

- Participants' results are converted into z-scores : $z = (x_i - m)/s_t$
- x_i is a participant's measurement result, m is the assigned value (or alternatively, the robust mean of the test material) and s_t is the standard target deviation of the proficiency test.
- z-scores between -2 and +2 are satisfactory
- z-scores <-3 and >+3 are unsatisfactory
- z-scores between -2 and -3 or +2 and +3 might signal problems, but could also be caused by chance variation.
- Note: z-scores can vary between successive rounds of PTs. Z-scores that vary in the interval of -2 and +2 do not indicate a change in performance, but reflect natural variation

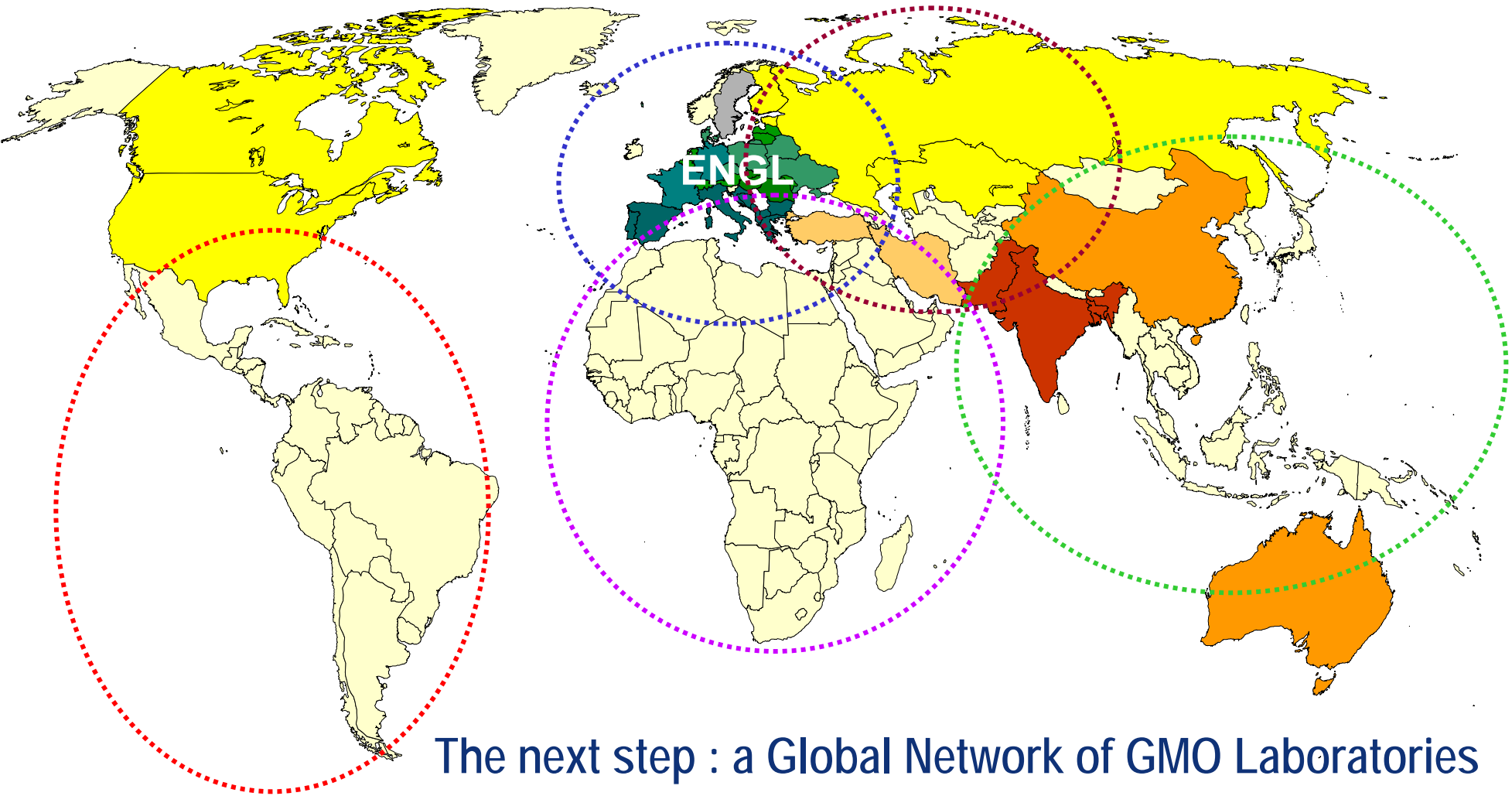


CT-02/11

- Two test items containing different GM percentages
- List of 10 GM maize events: 3272, Bt11, Bt176, DAS59122, GA21, MIR604, MON 810, MON 863, NK603, TC 1507
- Qualitative PCR
- Detection of certain GM event → Quantitative PCR to quantify content
- Shipment planned: September 2011

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The next step : a Global Network of GMO Laboratories

'Enlargement, International Collaboration and Capacity Building' Project Project funded since 2009 under the EU Commission BTSF programme (Better Training for Safer Food)

Project Objectives

- 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

Developed through:

- Networking workshops (incl. support toward the establishment of regional networks)
- Training courses
- Dedicated web page

Dedicated Webpage <http://mbg.jrc.ec.europa.eu/capacitybuilding/>



Legal notice

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Joint Research Centre
Institute for Health and Consumer Protection

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%

Global Capacity Building Project - Roadmap 2009 - 2012 Year 2010

- Turkey, 12-16 April 2010 - Training Course for new EU Member States, Candidates and Potential Candidates, 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 Networking Workshop for new EU Member States, Candidates and Potential Candidates, Countries incl. in the European Neighbourhood Policy
- South Africa, 28-29 October 2010 - Regional Networking Workshop for African Countries
- Italy, 8-12 November 2010 - Study Tour on GMO Analysis for Central & South American Countries

Global Capacity Building Project - Roadmap 2009 - 2012 Year 2011

- Mexico, 1-3 March 2011: 2nd Regional Networking Workshop for Central & South American Countries (creation of RLAC Net)
- Singapore, 7 June 2011: 3rd Regional Networking Workshop for Asian Countries
- Q3- 2011 (tentative): 1st Regional Networking Workshop for the Middle East
- Q4-2011 (tentative): 2nd Regional Networking Workshop for Africa

Global Capacity Building Project - Roadmap 2009 - 2012 2012

- Colombia, Q1- 2012 (tentative) – 3rd Regional Networking Workshop for Central & South American Countries

- Brussels, Belgium June 2012 : “Networking the Networks”,
the First Global Forum for GMO Analysis Networks

- Brussels, Belgium June 2012 : “Networking the Networks”, the First Global Forum for GMO Analysis Networks
- Concept : 3 days of networking opportunity on GMO Analysis for:
- +/- 200 non EU-participants (mainly representatives from regional networks on GMO detection being developed in different regions of the world as well as representatives from relevant international organisations FAO, CBD, ISO)
- +/- 100 EU participants (mainly representatives from the Member States National Reference Laboratories on GMOs as well as representatives from relevant Commission services e.g JRC, SANCO, AIDCO, TRADE, RTD, TAXUD, RELEX, ...)



Thank you for your attention!