General introduction on the scope of the seminar and overview on EU legislation on GMO authorisation and on labelling provision

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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

Contact: jrc-info@ec.europa.eu

The Mission of the Joint Research Centre:

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

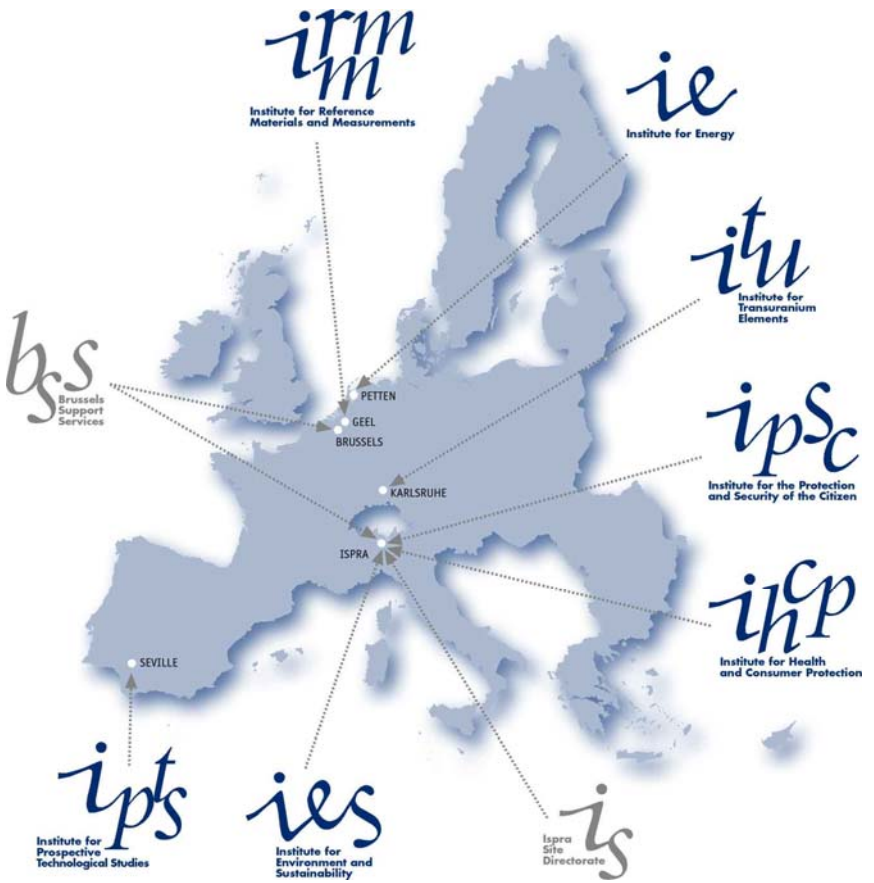
IE - *Petten, The Netherlands*
Institute for Energy

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, Community Reference Laboratory for GMOs

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 **Community Reference Laboratory for GM Food & Feed (CRL-GMFF) and Community Reference Laboratory for GMOs (CRL-GMO)**

Community Reference Laboratory
GM Food and Feed

EU Policy Basis

- Horizontal **Directive 2001/18/EC** (DG ENV) on **deliberate release** and **marketing** of genetically modified organisms (GMOs);
- **Regulation (EC) No 1829/2003** of the European Parliament and of the Council of 22 September 2003 on **genetically modified food and feed** (DG SANCO) nominates the JRC as Community Reference Laboratory;
- **Regulation (EC) No 1830/2003** of the European Parliament and of the Council of 22 September 2003 concerning the **traceability and labelling** of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (DG SANCO and DG ENV);
- The **Cartagena Protocol** in force since 11 September 2003 provides provisions for international exchange of information on trans-boundary movements (DG ENV).
- Upcoming issue: definition of thresholds for tolerance of GM contamination in seeds.
- Upcoming issue: low level presence of non-approved GMOs.

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Directive 2001/18/EC

Objectives & Obligations

- To protect human health and the environment via a system for authorisation for the release of GMOs.
- Notifiers to carry out an environmental risk assessment.
- Member States (MS), and where appropriate, Commission, to ensure that potential adverse effects on human health and environment are accurately assessed on a case-by-case basis, and to ensure traceability measures.
- MS Competent Authorities are responsible for ensuring compliance with the Directive, carrying out inspections, etc.

Directive 2001/18/EC

The objective of Directive 2001/18/EC is to develop an appropriate regulatory framework for ensuring the protection of human health and of the environment

Principle: → **cultivation / placing on the market**

only after authorisation

→ **based on risk assessment**

→ **case-by-case basis**

Two procedures:

Part B = experimental release

small scale field trials for R&D

(National decisional process)

Part C = placing on the market

importation, cultivation, commercialisation

(Community decisional process)

Placing on the market (Part C)

Notifier

Public (mandatory)

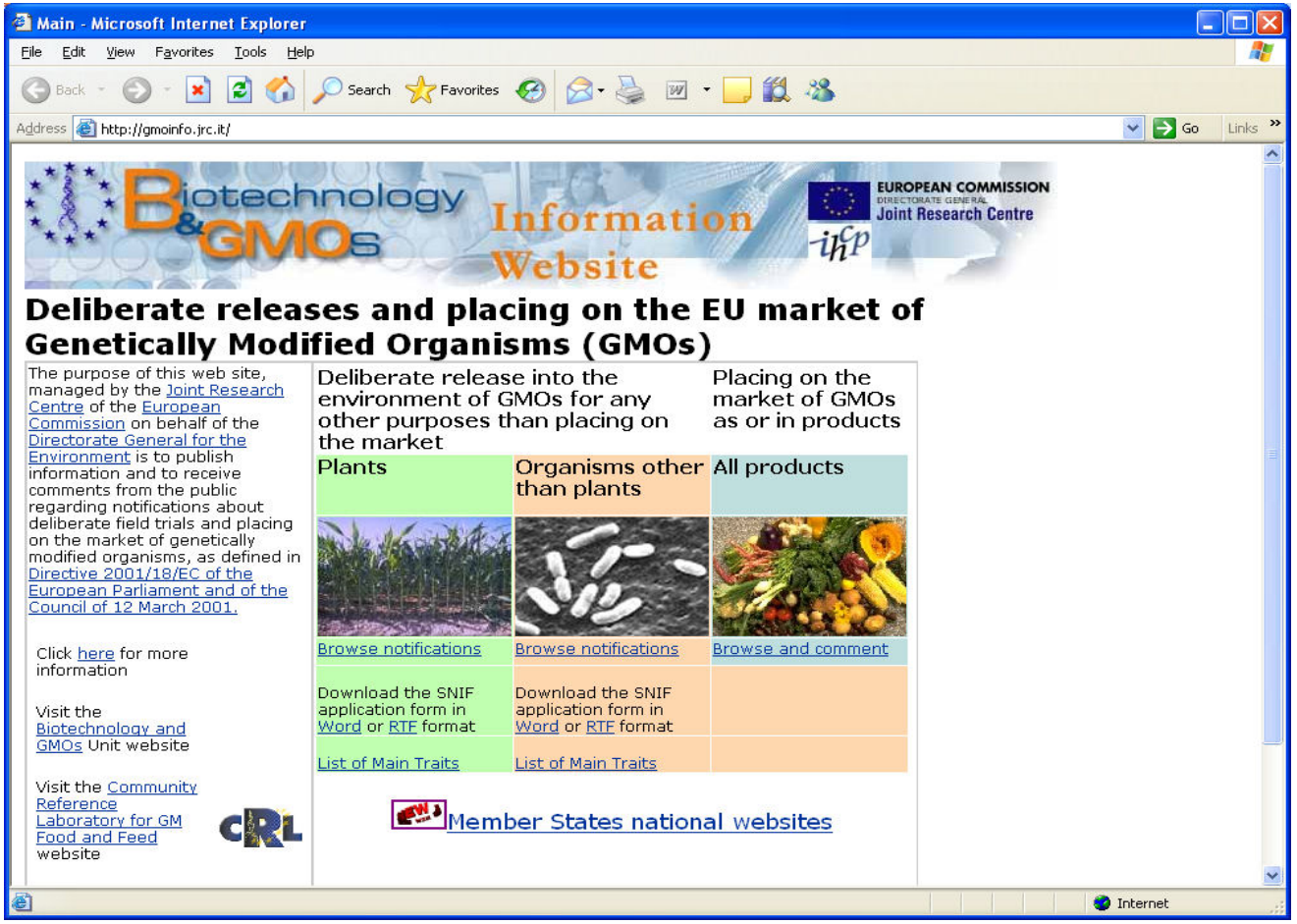
Lead CA

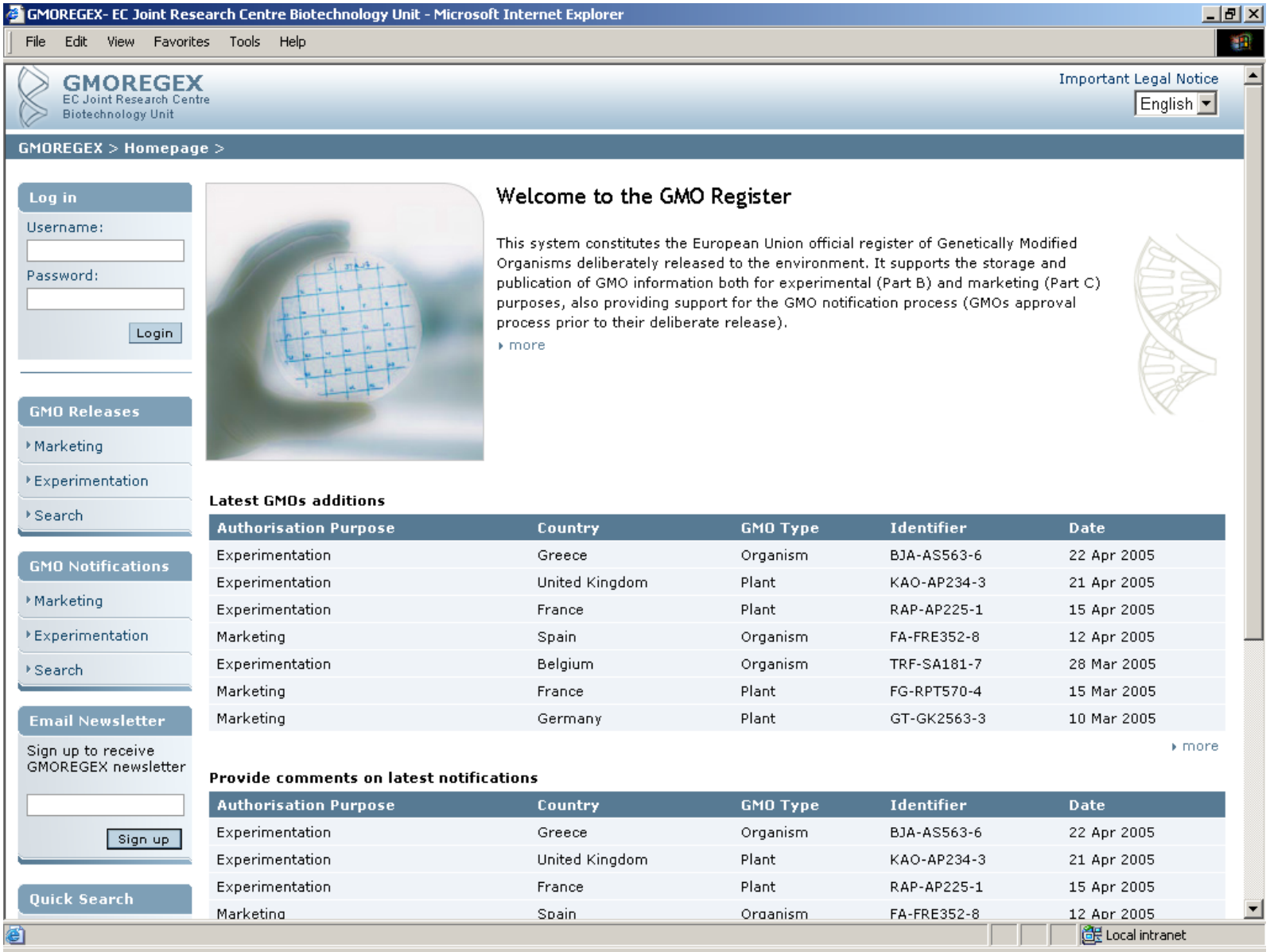
Other CAs

DECISION

The WebSNIF system

Public information is published online at http://gmoinfo.jrc.it, where the general public can consult the SNIFs and posted comments, where foreseen by Directive 2001/18/EC

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Password:
Login
GMO Releases
Marketing
Experimentation
Search
GMO Notifications
Marketing
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Sign up to receive GMOREGEX newsletter
Sign up
Quick Search
Welcome to the GMO Register
This system constitutes the European Union official register of Genetically Modified Organisms deliberately released to the environment. It supports the storage and publication of GMO information both for experimental (Part B) and marketing (Part C) purposes, also providing support for the GMO notification process (GMOs approval process prior to their deliberate release).
more
Latest GMOs additions
Authorisation Purpose | Country | GMO Type | Identifier | Date
Experimentation | Greece | Organism | BJA-AS563-6 | 22 Apr 2005
Experimentation | United Kingdom | Plant | KAO-AP234-3 | 21 Apr 2005
Experimentation | France | Plant | RAP-AP225-1 | 15 Apr 2005
Marketing | Spain | Organism | FA-FRE352-8 | 12 Apr 2005
Experimentation | Belgium | Organism | TRF-SA181-7 | 28 Mar 2005
Marketing | France | Plant | FG-RPT570-4 | 15 Mar 2005
Marketing | Germany | Plant | GT-GK2563-3 | 10 Mar 2005
more
Provide comments on latest notifications
Authorisation Purpose | Country | GMO Type | Identifier | Date
Experimentation | Greece | Organism | BJA-AS563-6 | 22 Apr 2005
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Local intranet

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Regulation (EC) 1829/03 on GM Food and Feed

- Full dossier requirement (e.g. including detection method, controls and CRM)
- Very clear role for the European Food Safety Authority
- Establishment of the Community Reference Laboratory
- New *de minimis* thresholds for labelling
  - 0.9 % threshold for adventitious presence of approved GMOs
- Time-limited authorisation of 10 years (renewable)
- Methods for **sampling**, **identification** and detection of GM food and feed should be provided by the applicant
- Methods should be **validated** by the Community Reference Laboratory for GM Food and Feed (CRL-GMFF)

Regulation (EC) 1829/03 on GM Food and Feed

(Annex):

“ The **Community Reference Laboratory** referred to in Article 32 is the Commission's Joint Research Centre”

And:

“ For the tasks outlined in this Annex, the Commission's Joint Research Centre shall be assisted by a consortium of National Reference Laboratories, which will be referred to as the **‘European Network of GMO Laboratories’**

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Regulation (EC) 1830/2003 on traceability and labelling

- Definition of traceability
- Requirement to traceability
- Mandatory labelling extended to all food and feed, irrespective of GM-specific DNA or protein detectability
- Introduction of the Unique Identifier (Commission Regulation (EC) 65/2004)
- Register

Commission **Recommendation** 2004/787/EC of 4 October 2004 on technical guidance for sampling of GMOs…… in the context of Regulation (EC) 1830/2003

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Regulation (EC) 1946/2003 on transboundary mov. of GMOs

- Last piece of legislation needed to implement the Biosafety Protocol
- Imposes notification prior to the first transboundary movement of a GMO to a given Country
- Requests written prior informed consent, on the basis of a scientific risk assessment
- Foresees information exchanges with the Biosafety Clearing House

Quick Search

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Finding Information

- Competent National Authorities
- GMO Decisions

Registering Data

- Management Centre

Resources

- Related Websites
- Help
- About

Welcome to the Central Portal

The Biosafety Clearing-House (BCH) is an information exchange mechanism established by the Cartagena Protocol on biosafety to assist Parties to implement its provisions and to facilitate sharing of information on, and experience with, living modified organisms (LMOs). Learn more »

Organisms, Decisions and Declarations

The BCH provides access to information relevant to the Biosafety Protocol. Users can search the BCH databases for information in the following categories:

- Decisions under AIA
- Decisions under Article 11

National Contacts

Competent National Authorities are responsible for performing the administrative functions required by the Protocol. Each Competent National Authority entry contains contact information and a brief description of the functions of the organization

- Competent National Authorities
- Related Websites

Register Information

The BCH website has been created to assist governments and other users to fulfill their information-sharing obligations under the Biosafety Protocol.

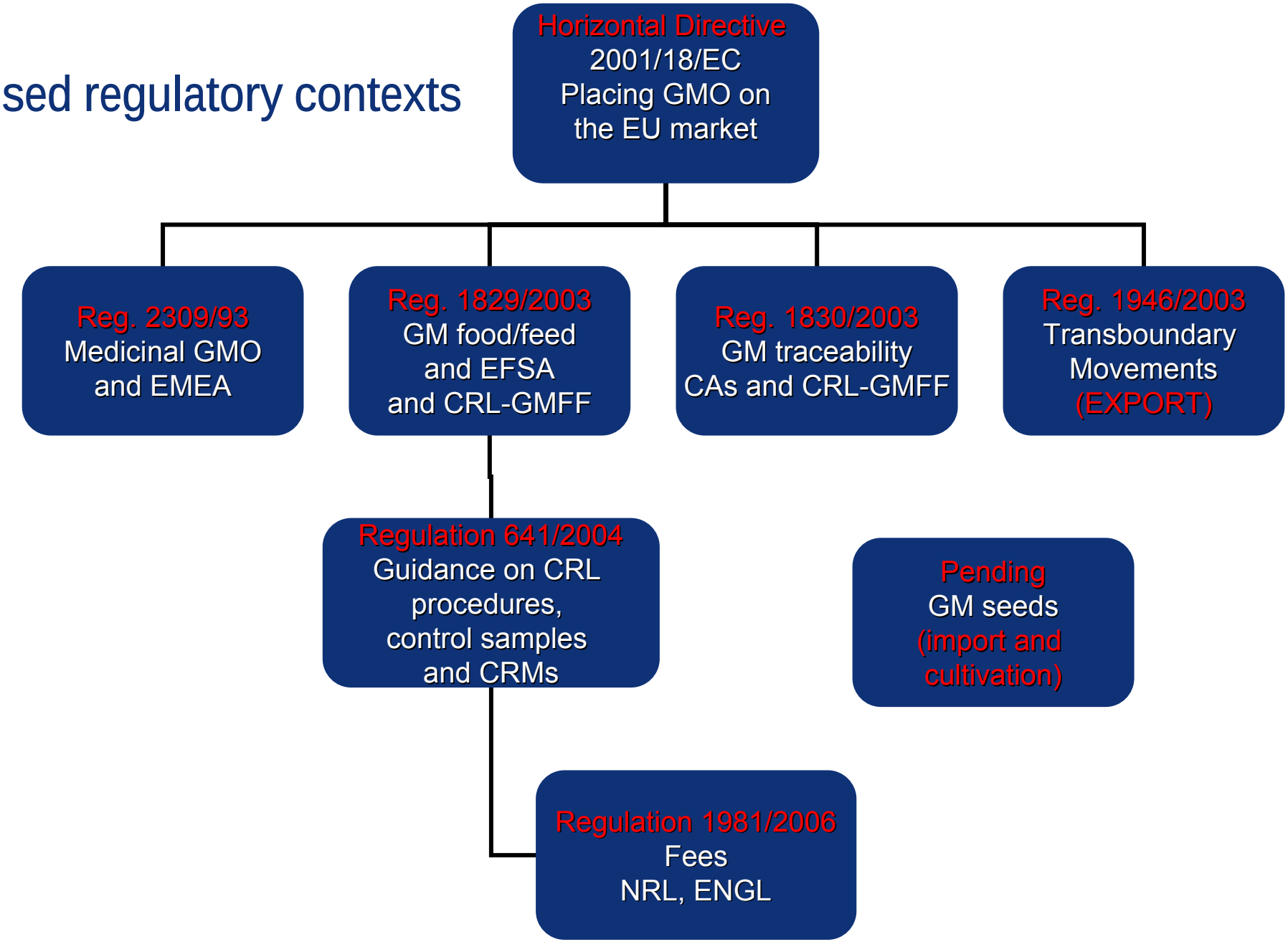
- Enter the Management Centre

Latest Additions

Date	Country	Type
2005-09-30	France	Risk Assessment
2005-09-30	France	Risk Assessment
2005-09-29	Spain	Competent National Authority
2005-09-29	UK	LMO
2005-09-30	France	Risk Assessment
2005-09-30	France	Risk Assessment
2005-09-30	France	Risk Assessment
2005-09-30	France	Risk Assessment

- More additions

Revised regulatory contexts



Salient points of the EU regulation: a strict regulation with a strong consumers' involvement

- 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

Consumer's rights

Products
that contain GMOs
or that have been derived from GMOs should be labelled

Although the need for labelling is not a safety issue….

Example: GM soybean

marketed as

Grains, flour =
label required

processed in

Refined oil, with no detectable DNA or proteins =
label required

transformed into

Meat of animals =
no label required

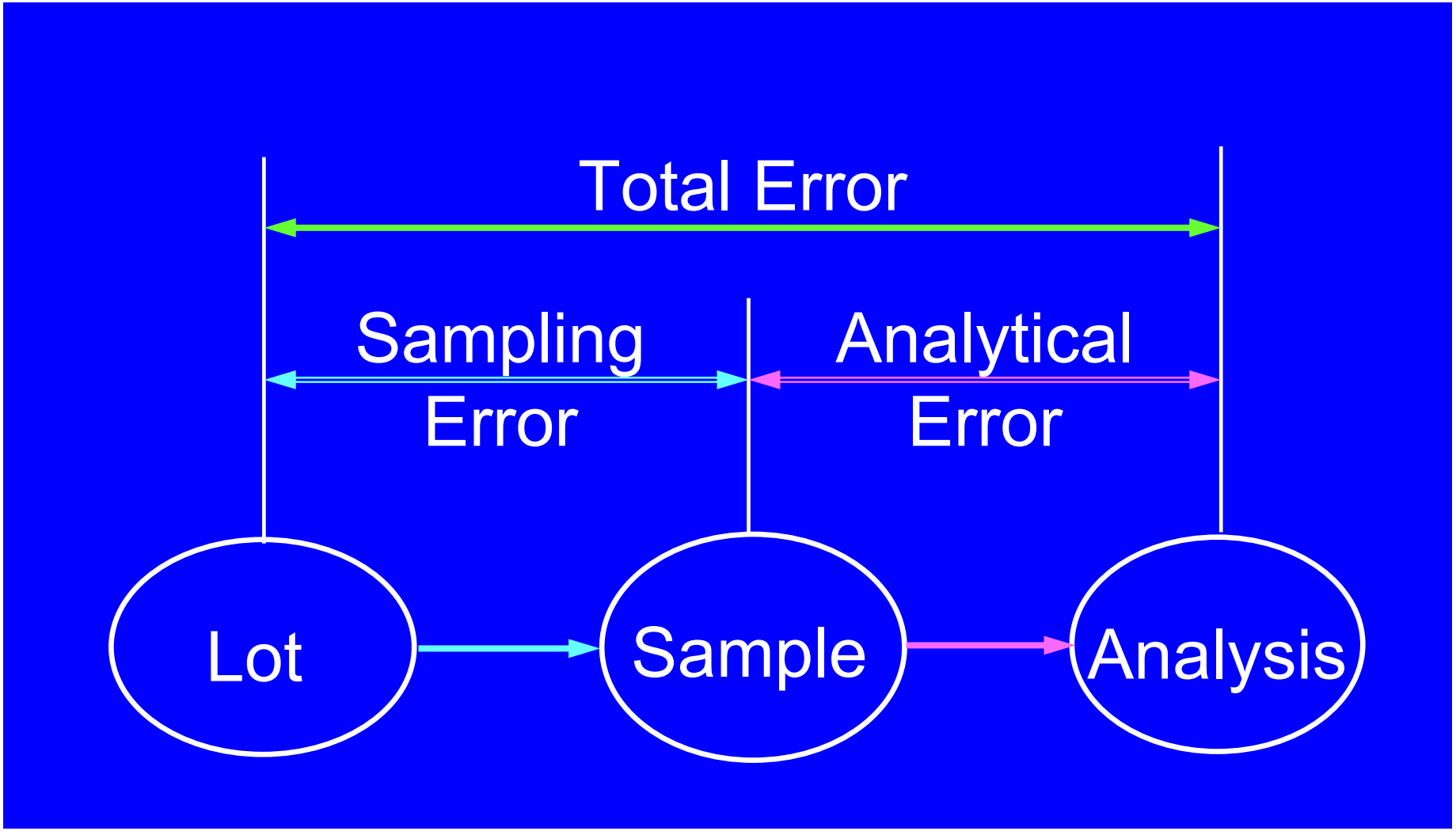
GENETIC ID

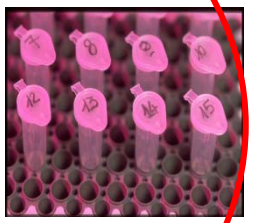
CERT ID ID CERTIFIED Non-GMO

Clients who require this test may have, for example, a contract calling for soybeans at less than 1% GMO content. If they have one lot of soybeans at 1.5% GMO and another at 0.1%, the precise results of the Real-Time test will allow them to mix the two lots in the correct proportions to bring their shipment under 1% with the least waste.

http://www.genetic-id.com/pages/services_test_quantitative.asp

GMO analysis: sources of errors





Sampling error

GMO test

Negative

Positive

GMO detection

Authorised?

No

Yes

Illegal

GMO identification

Assay individual ingredients

Analytical error

Less than 0.9%

No need for labelling

More than 0.9%

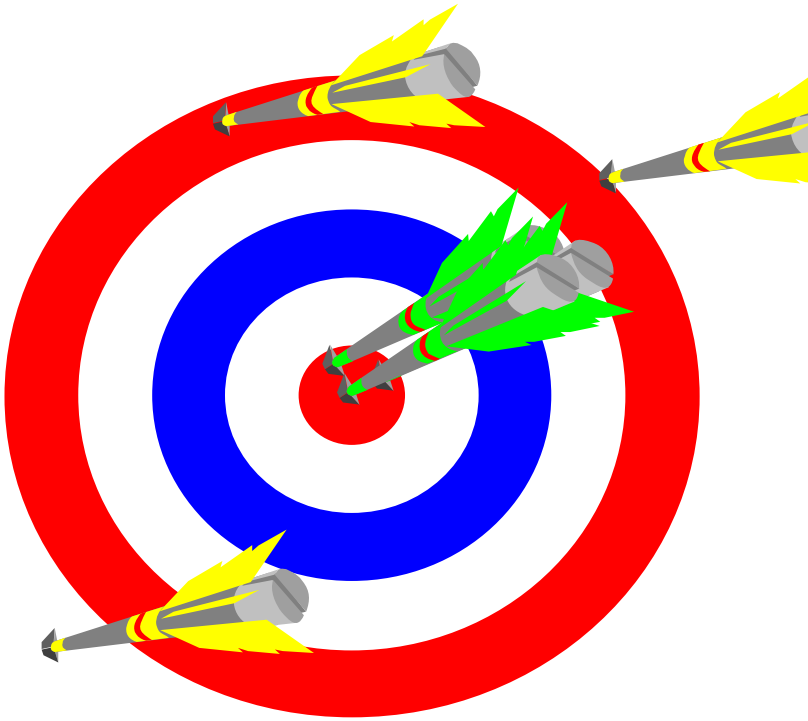
Labelling required

GMO quantification

Reduction of analytical error

- Use validated methods;
- Use (certified) reference materials;
- Participate in proficiency tests;

⟶ Be accredited according to ISO 17025.



European Network of GMO Laboratories - (ENGL)

…an enforcement network of GMO Laboratories established in June 2000 and officially inaugurated in Brussels on December 4th 2002, chaired and coordinated by the IHCP "Molecular Biology and Genomics Unit"

http://engl.jrc.it/

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

The Community Reference Laboratory for GM Food and Feed

DAC-PL-0459-06-00

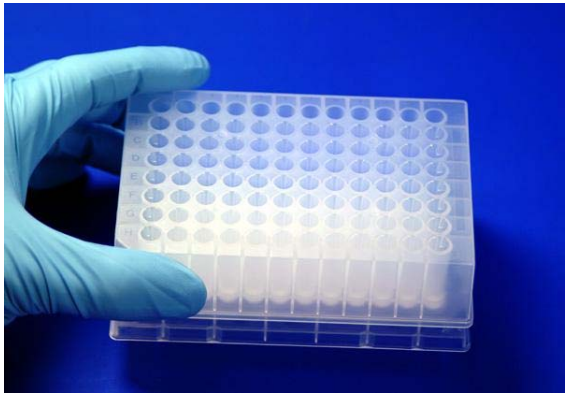
- Official mandate in the EU regulatory process
- Operations are carried out, aligned with the European Food Safety Authority.
- It has a crucial role in (dis)approval of methods that are “fit for the purpose of regulatory compliance”.
- It has a role in disputes and in response to crises.
- It is unique in the worlds’ GMO regulatory system.
- It chairs the “European Network of GMO Laboratories” (ENGL).
- It carries out extensive training programs.

The role of the JRC in response to crises

- Starlink (BayerCropscience);
- Bt-10 (Syngenta);
- LLRICE601 (BayerCropscience);
- Bt63 (Chinese Authorities);
- Event-32 (Dow-Pioneer);
- …??

Monitoring the EU Market for Unapproved GMOs

- **The JRC developed an analytical tool that allows to test for all known events (authorised and not yet authorised) in a single experiment;**
- **Ideally this tool should be used by all control laboratories → harmonisation and comparable results;**



- **This tool should allow a first screening of food/feed/environmental samples for presence of GMOs, not for their quantities.**

Plate layout:

	1	2	3	4	5	6	7	8	9	10	11	12
A	HMG Maize Ref	SAH7 Cotton Ref	PLD Rice Ref	CruA Oilseed Ref	Lectin Soybean Ref	GS Sugarbeet Ref	UGPase Potato Ref	Bt11 Maize	NK603 Maize	GA21Maize Monsanto	MON863 Maize	1507 Maize
B	T25 Maize	59122 Maize	H7-1 Sugar beet	MON810 Maize	281-24-236 Cotton	3006-210-23 Cotton	LLRICE62 Rice	T45 oilseed rape	EH92-527-1 Potato	Ms8 Oilseed rape	Rf3 Oilseed rape	GT73 (RT63) Rapeseed
C	LLCotton25 Cotton	MON 531 Cotton	A2704-12 Soybean	MIR604 Maize	Rf1 Rapeseed	Rf2 Rapeseed	Ms1 Rapeseed	Topas 19/2 Rapeseed	MON1445 Cotton	Bt176 Maize	MON15985 Cotton	40-3-2 Soybean
D	GA21 Maize Syngenta	MON88017 maize	LY038 Maize	3272 Maize	MON89788 soybean	MON89034 Maize	DP-356043 soybean	MON88913 cotton	Rice GM events P35S::bar	LLRice601 Rice	Bt63 Rice	Bt10 Maize
E	HMG Maize Ref	SAH7 Cotton Ref	PLD Rice Ref	CruA Oilseed Ref	Lectin Soybean Ref	GS Sugarbeet Ref	UGPase Potato Ref	Bt11 Maize	NK603 Maize	GA21Maize Monsanto	MON863 Maize	1507 Maize
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H	GA21 Maize Syngenta	MON88017 maize	LY038 Maize	3272 Maize	MON89788 soybean	MON89034 Maize	DP-356043 soybean	MON88913 cotton	Rice GM events P35S::bar	LLRice601 Rice	Bt63 Rice	Bt10 Maize

Sample 1

Sample 2

Examples of pending technical issues

- 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?
- ???

Thank you!