



The GMOs regulatory framework to be enforced in the EU

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Main objective of EU legislation on GMOs

Protection of human life and health, animal health and welfare, environment



Protection of consumer interests in relation to GMOs

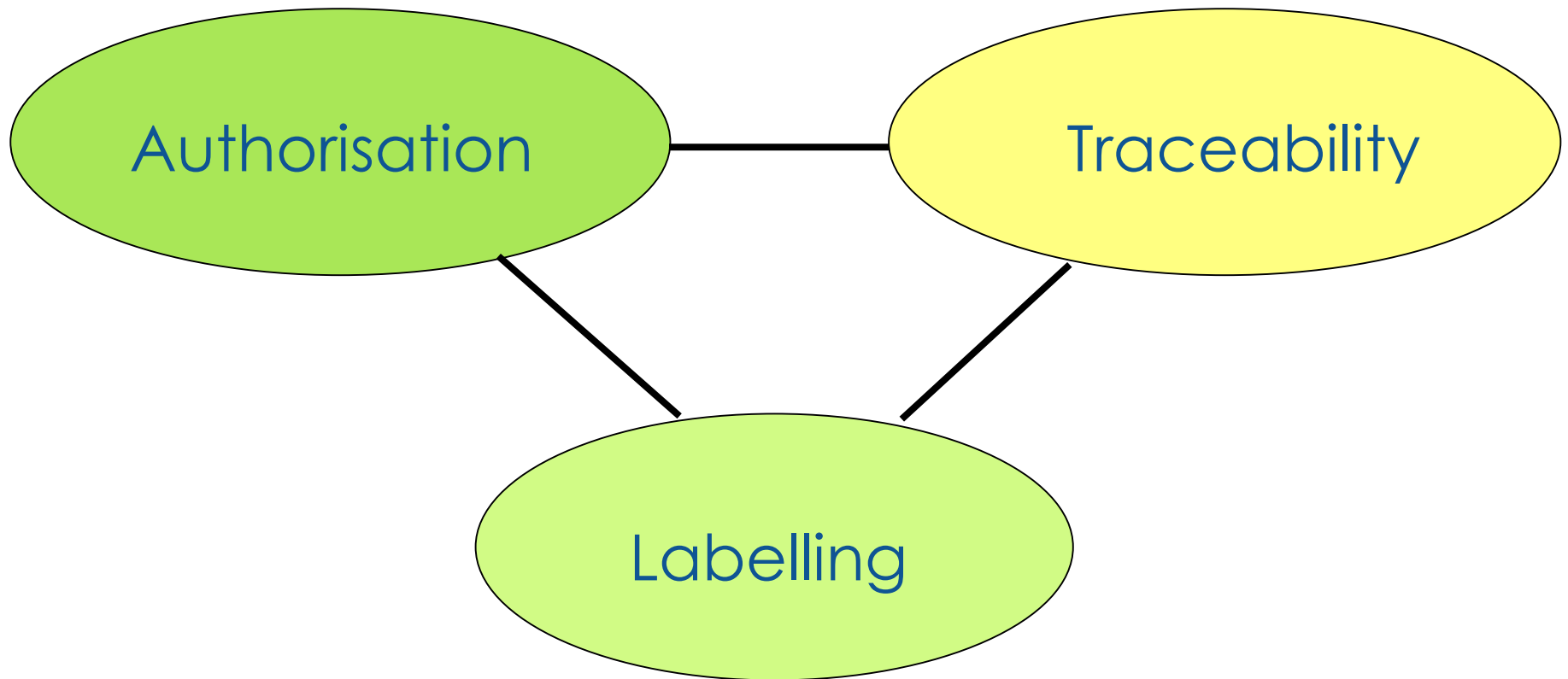
Ensuring the effective functioning of the internal market

O v e r v i e w



- ❑ **Directive 2001/18/EC** on the deliberate release into the environment of GMOs
- ❑ **Directive 2009/41/EC** on the contained use of GMMs
- ❑ **Regulation (EC) 1829/2003** on GM food and feed
- ❑ **Regulation (EC) 1830/2003** concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs and amending Directive 2001/18/EC
- ❑ **Commission Regulation (EC) 641/2004** on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new GM food and feed, the notification of existing products and adventitious or technically unavoidable presence of GM material which has benefited from a favourable risk evaluation
- ❑ **Commission Regulation (EC) 65/2004** establishing a system for the development and assignment of unique identifiers for GMOs
- ❑ **Regulation (EC) 1946/2003** on transboundary movements of GMOs
- ❑ **Commission Regulation (EC) 1981/2006** on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for GMOs
- ❑ **Recommendation 2004/787/EC** on technical guidance for sampling and detection of GMOs and material produced from GMOs as or in products in the context of Regulation (EC) No 1830/2003
- ❑ **Commission Regulation (EU) 619/2011** laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired
- ❑ **Commission Implementing Regulation (EU) 503/2013** on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006

EU legislation on GMOs



Directive 2001/18/EC on the deliberate release of GMOs into the environment



- *Experimental release of GMOs into the environment (part B)*
- *Placing on the market of GMOs: e.g. cultivation, import, transformation (part C)*

Regulation (EC) No 1829/2003

On genetically modified food and feed

Authorisation

Labelling

Regulation (EC) No 1830/2003

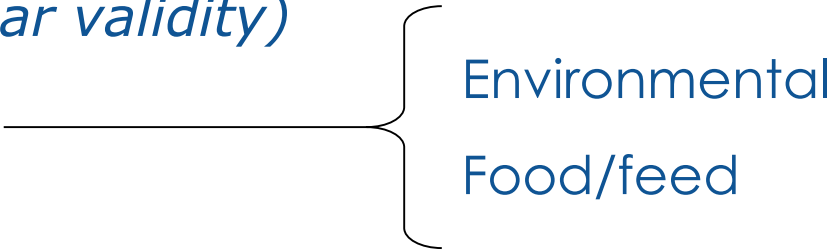
on the traceability and labelling of GMOs and
the traceability of GM food and feed

Traceability

Labelling

EU legislation on the placing on the market of GMOs

P r i n c i p l e s

- *Authorisation (10-year validity)*
 - *Risk assessment*
 - *Labelling and traceability*
 - *Monitoring plan in order to identify potential effects of the GMO(s) on human health or the environment*
 - *Consultation of and information to the public*
 - *Information and material for GMOs identification and detection*
- 
- Environmental
Food/feed



European
Commission

Information to the public

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



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JOINT RESEARCH CENTRE

Deliberate Release and Placing on the EU Market of GMOs - GMO Register

[European Commission](#) > [JRC](#) > [IHCP](#) > [Our Databases](#) > [GMOinfo - GMOregister](#)

Deliberate Release and Placing on the EU Market of GMOs - GMO Register

[Home](#)

Overview

The purpose of this web site, managed by the [Joint Research Centre](#) of the [European Commission](#) on behalf of the [Directorate General for Health and Consumers](#) is to publish information and to receive comments from the public regarding notifications submitted from the applicants to the Member States Competent Authorities about deliberate field trials and placing on the market of genetically modified organisms, as defined in [Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001](#).
Click [here](#) for details

According to Article 31(2) of Directive 2001/18/EC, the Commission is also to establish one or several register(s), for the purpose of recording the information on genetic modifications in GMOs specified in Section A, point 7 of Annex IV to that Directive. The contents of this register is described in [Commission Decision 2004/204/EC of 23rd February](#). Therefore, this website contains also the required information about GMOs authorized, under Directive 2001/18/EC for marketing purposes which include authorization for cultivation, food, feed and processing.

GMOs can also be approved for placing on the market under [Regulation 1829/2003/EC \(GM food and feed\)](#) for which a register is available at the [Community register of genetically modified food and feed](#)

Useful links

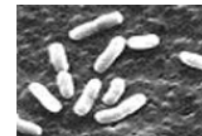
[Member States national websites](#)

Deliberate release into the environment of GMOs for any other purposes than placing on the market (experimental releases)

[Plants](#)



[Other than plants](#)



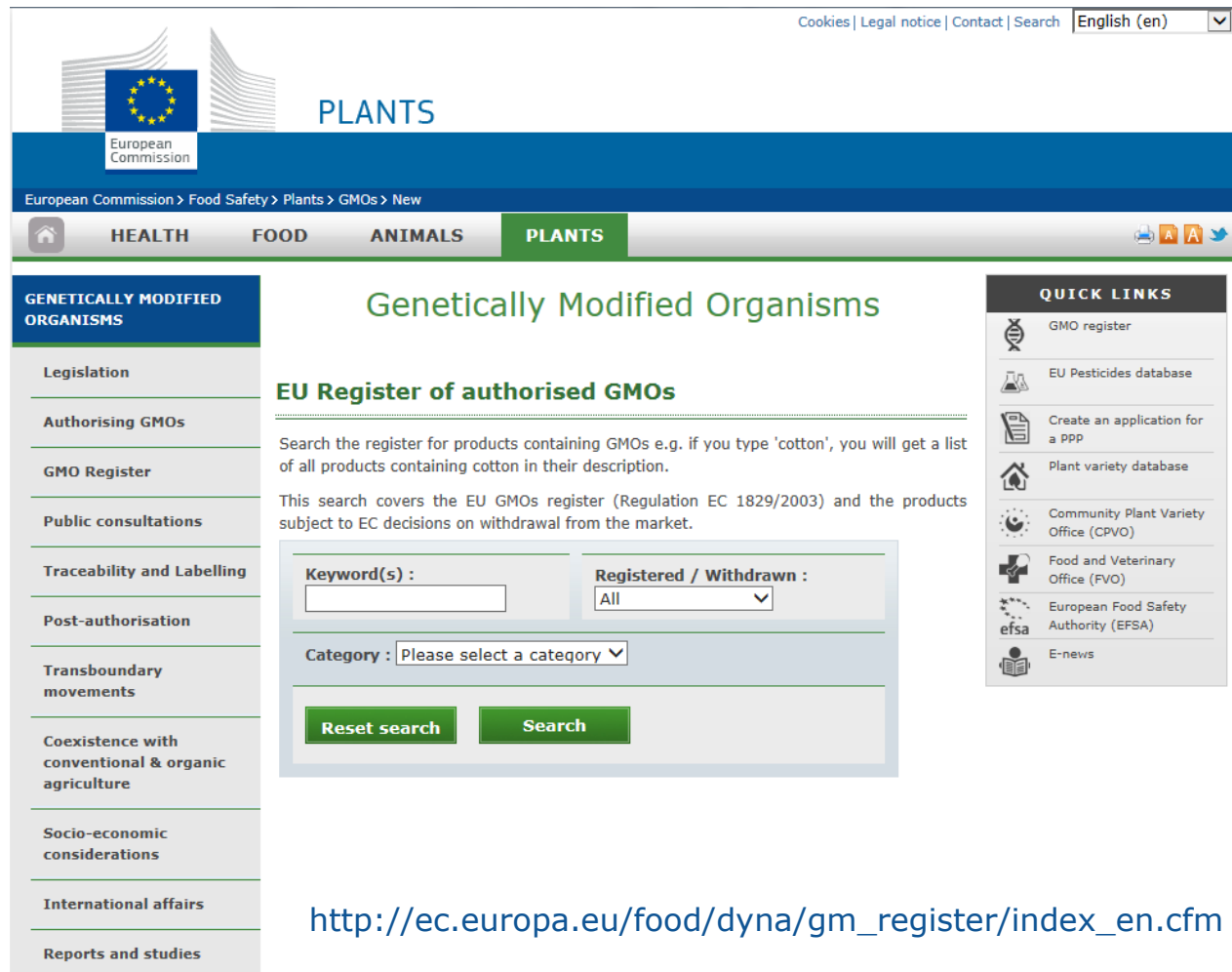
Placing on the market of GMOs as or in products (commercial releases)

[Authorised and pending](#)



18.10
10/02/2015

The EU Register of authorised GMOs



The screenshot shows the website interface for the EU Register of authorised GMOs. At the top, there is a navigation bar with the European Commission logo and the word "PLANTS". Below this is a breadcrumb trail: "European Commission > Food Safety > Plants > GMOs > New". A main navigation menu includes "HEALTH", "FOOD", "ANIMALS", and "PLANTS". The page title is "Genetically Modified Organisms". The main content area is titled "EU Register of authorised GMOs" and contains a search form with fields for "Keyword(s)", "Registered / Withdrawn", and "Category". A sidebar on the left lists various topics related to GMOs, and a sidebar on the right provides "QUICK LINKS" to various databases and services.

European Commission > Food Safety > Plants > GMOs > New

HEALTH FOOD ANIMALS **PLANTS**

Genetically Modified Organisms

EU Register of authorised GMOs

Search the register for products containing GMOs e.g. if you type 'cotton', you will get a list of all products containing cotton in their description.

This search covers the EU GMOs register (Regulation EC 1829/2003) and the products subject to EC decisions on withdrawal from the market.

Keyword(s) :

Registered / Withdrawn :

Category :

GENETICALLY MODIFIED ORGANISMS

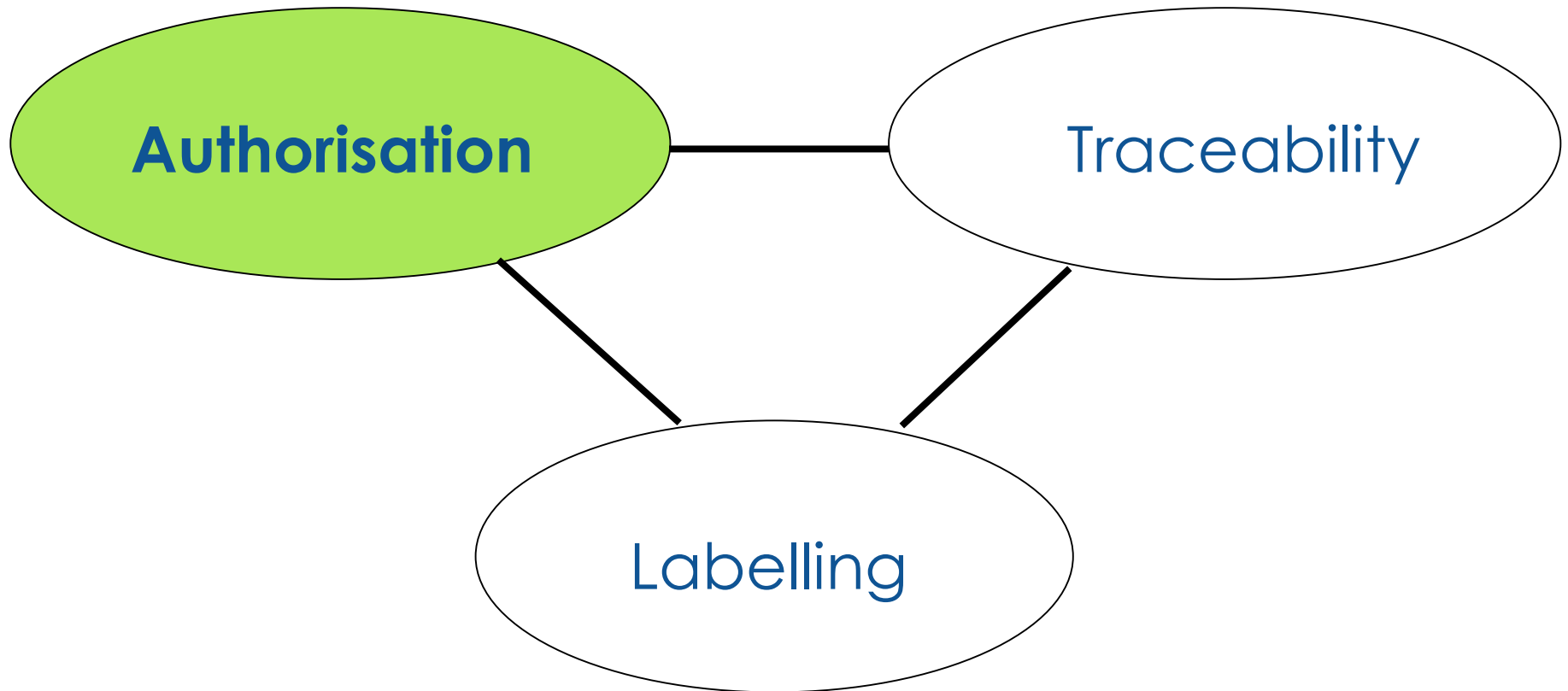
- Legislation
- Authorising GMOs
- GMO Register
- Public consultations
- Traceability and Labelling
- Post-authorisation
- Transboundary movements
- Coexistence with conventional & organic agriculture
- Socio-economic considerations
- International affairs
- Reports and studies

QUICK LINKS

- GMO register
- EU Pesticides database
- Create an application for a PPP
- Plant variety database
- Community Plant Variety Office (CPVO)
- Food and Veterinary Office (FVO)
- European Food Safety Authority (EFSA)
- E-news

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

EU legislation on GMOs





GMOs: EU decision-making process explained

GMOs for CULTIVATION

(under Regulation 1829/2003)

APPLICATION TO A MEMBER STATE

Risk Assessment by a Member State

GMOs for FOOD AND FEED

(under Regulation 1829/2003)

APPLICATION TO A MEMBER STATE

efsa
Risk Assessment
Member States may comment on the application

EFSA'S OPINION

Validation of analytical method by the EU Reference Laboratory

Validation of analytical method by the EU Reference Laboratory



EU countries

MEMBER STATES EXPERTS COMMITTEE

decides by Qualified Majority



Adopted



Not adopted

No opinion



EU Commission

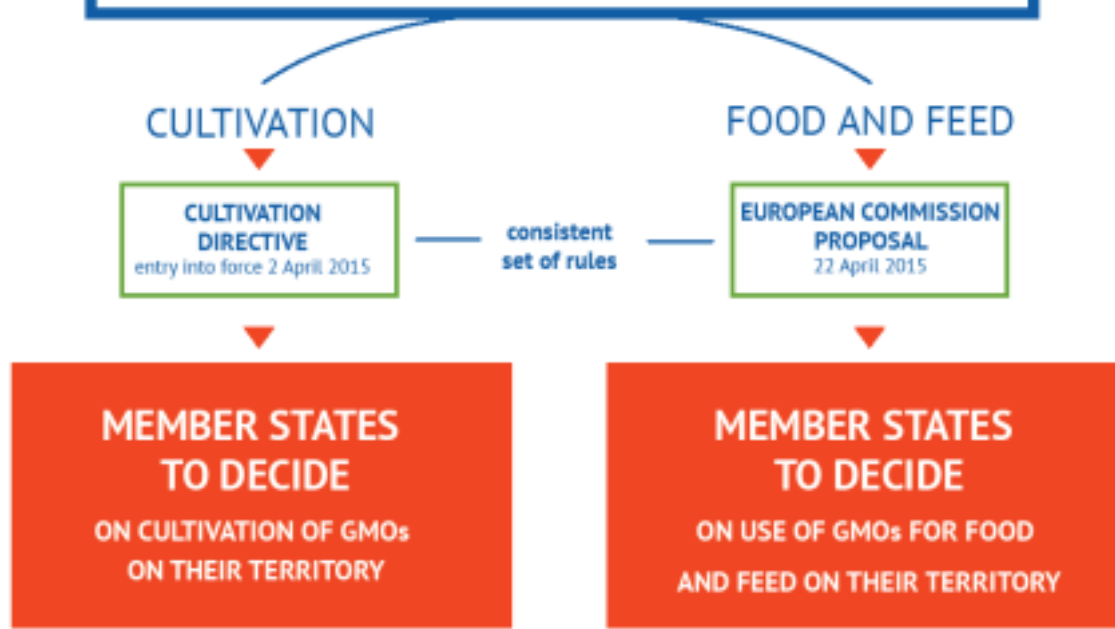
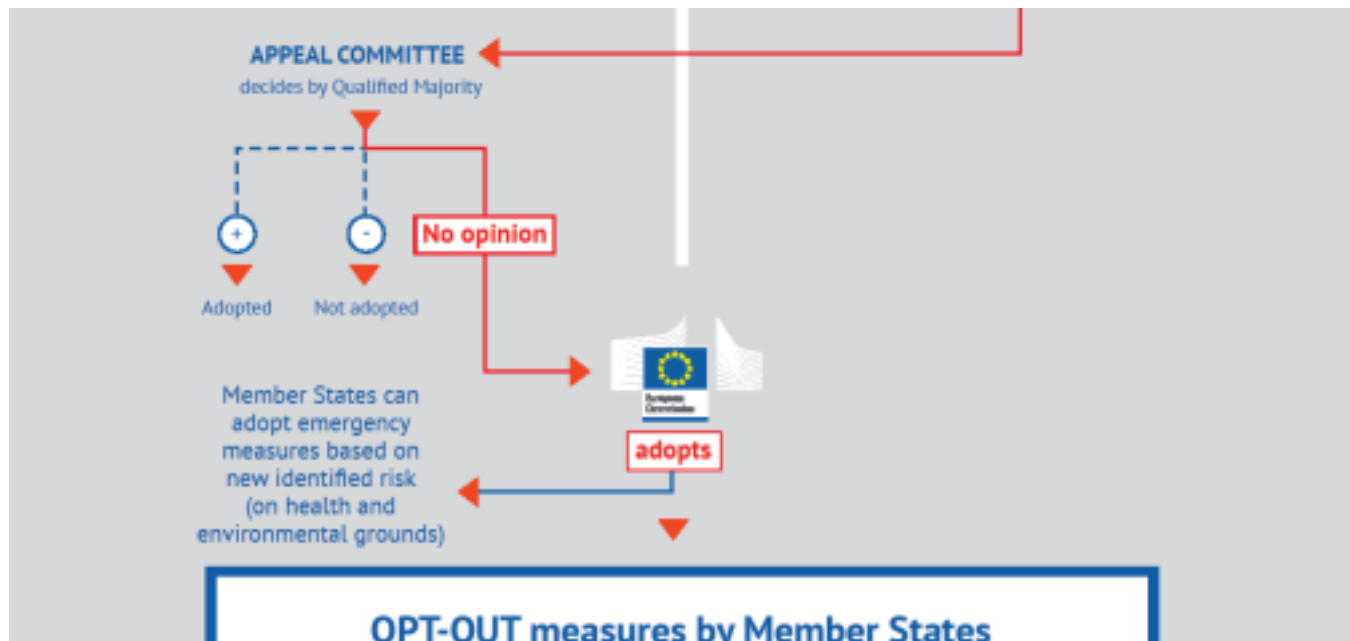
DRAFT DECISION



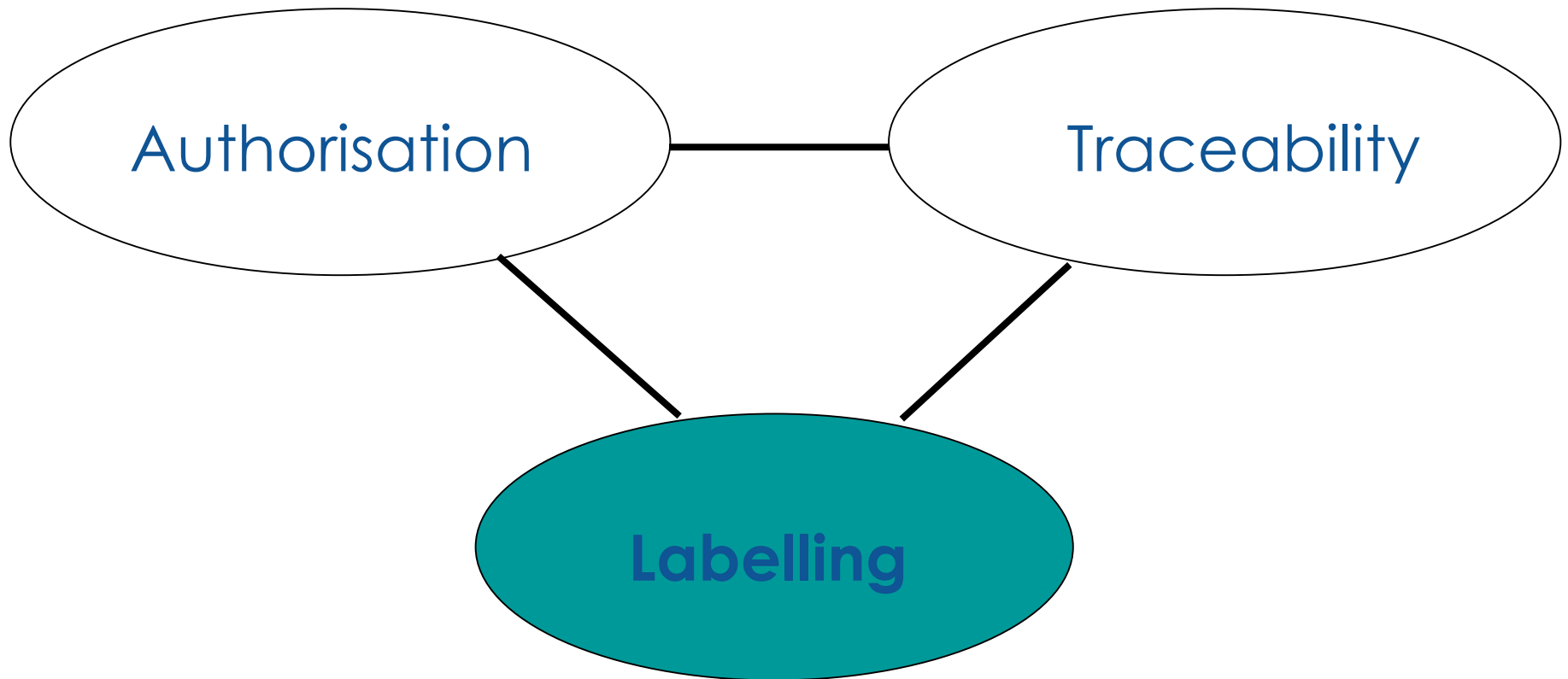
convenes

APPEAL COMMITTEE

decides by Qualified Majority



EU legislation on GMOs



EU legislation on GMOs

Labelling

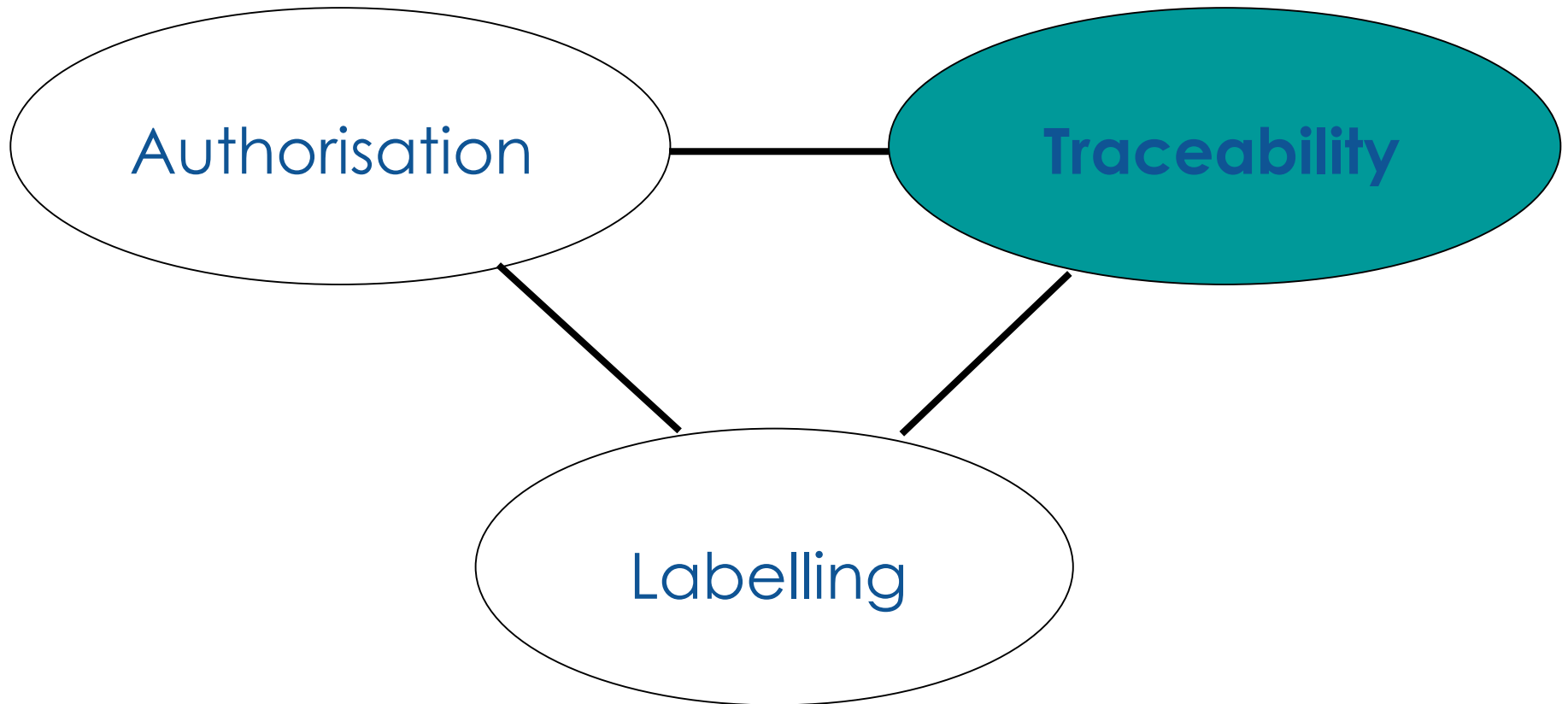
Specific labelling requirements when GM material > 0.9% of the food ingredient/feed material

Labelling not compulsory when GM material \leq 0.9%, provided that this presence is adventitious or technically unavoidable

⇒ operators must be in a position to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material



EU legislation on GMOs



EU legislation on GMOs

Traceability

ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains

traceability of GMOs

traceability of food and feed products produced from GMOs

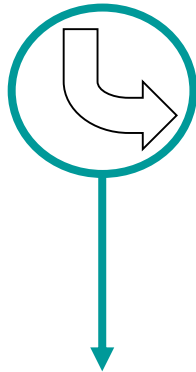


TO WHOM information shall be transmitted:



**Biotech & Breeding
(Institutions/Companies)**

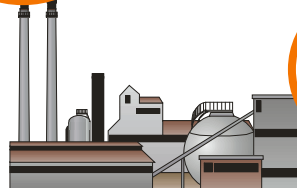
**At all subsequent stages of the placing on the market,
information received is transmitted to the operators
receiving the products**



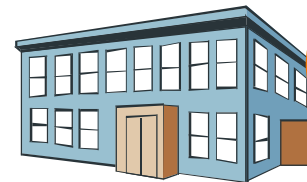
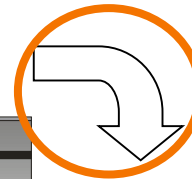
At the first stage of the placing on the market, information is transmitted to the operator receiving the product



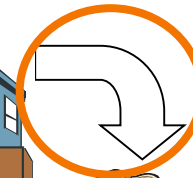
Agriculture



Food Processors



Food Retailers



Consumer

Reg. (EC) No 1830/2003

Traceability



WHAT information shall be transmitted:

above the
0.9%
threshold

- That the product/ingredient consists of or contains or is produced from GMOs**
- For products containing or consisting of GMOs, the **Unique Identifier** shall be provided**

GM food and feed legislation

Penalties

*Laid down by each Member State
individually*

Reg. (EC) 834/2007

and subsequent amendments

on organic production and labelling of organic products



Prohibition of use of GMOs and products produced from or by GMOs

0.9% - tolerance threshold

Reg. (EU) 619/2011

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



Reg. (EU) 619/2011

Scope

- ✓ *GM material authorised in a third country and for which a valid application has been submitted and for which the authorisation procedure has been pending for more than 3 months provided that:*
 - **it has not been identified by EFSA as susceptible to have adverse effects on health or the environment**
 - **the quantitative method has been validated and published by the European Union Reference Laboratory**
 - **the certified reference material is available**
- ✓ *GM material for which the authorisation has expired*

Reg. (EU) 619/2011

- ❑ *Methods of Sampling*
- ❑ *Criteria for sample preparation and methods of analysis*
- ❑ *'Minimum Required Performance Limit (MRPL)': the lowest amount or concentration of analyte in a sample that has to be reliably detected and confirmed by official laboratories*

⇒ **MRPL = 0.1%**

Analytical result - $U < 0.1\%$ ⇒ **compliant**

Analytical result - $U \geq 0.1\%$ ⇒ **non compliant**

- ❑ *Measures in case of detection of GM material*

The analytical control to enforce the GMO legislation

Official control

Aim:

Verify the compliance to EU legislation on
GMOs and GM food and feed within the
European market

Compliance to
authorisation
provisions

Compliance to labelling
and traceability
provisions

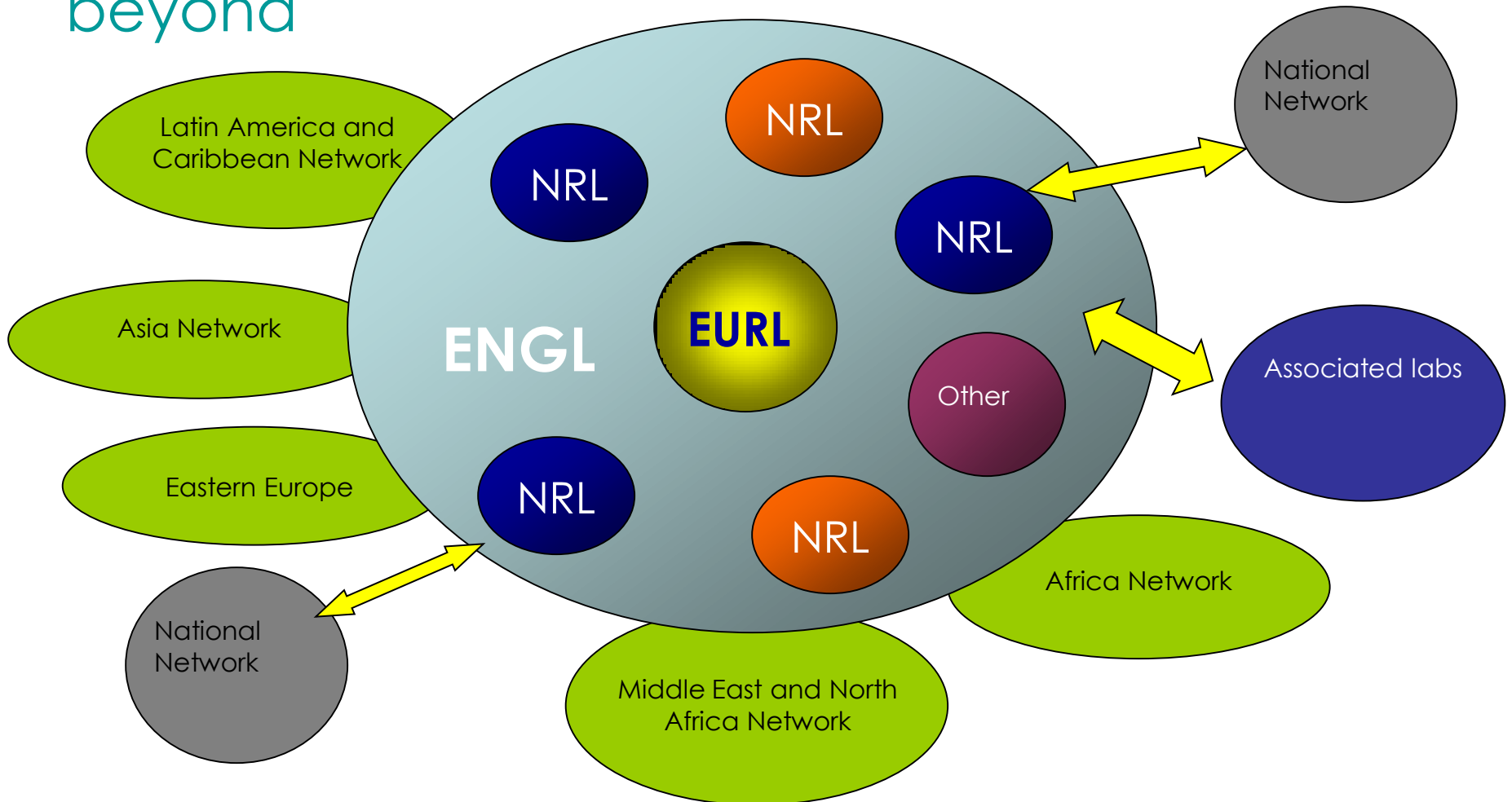
GM events to be detected

Need to detect
and quantify

- Authorised events
- Pending or expired authorisation (in feed)
- Unauthorised events (e.g. LL Rice 601, Bt63, KMD1, Kefeng6 rice, FP967 linseed)

Need to detect

The GMO analytical galaxy in the EU... and beyond





European
Commission

Thank you