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

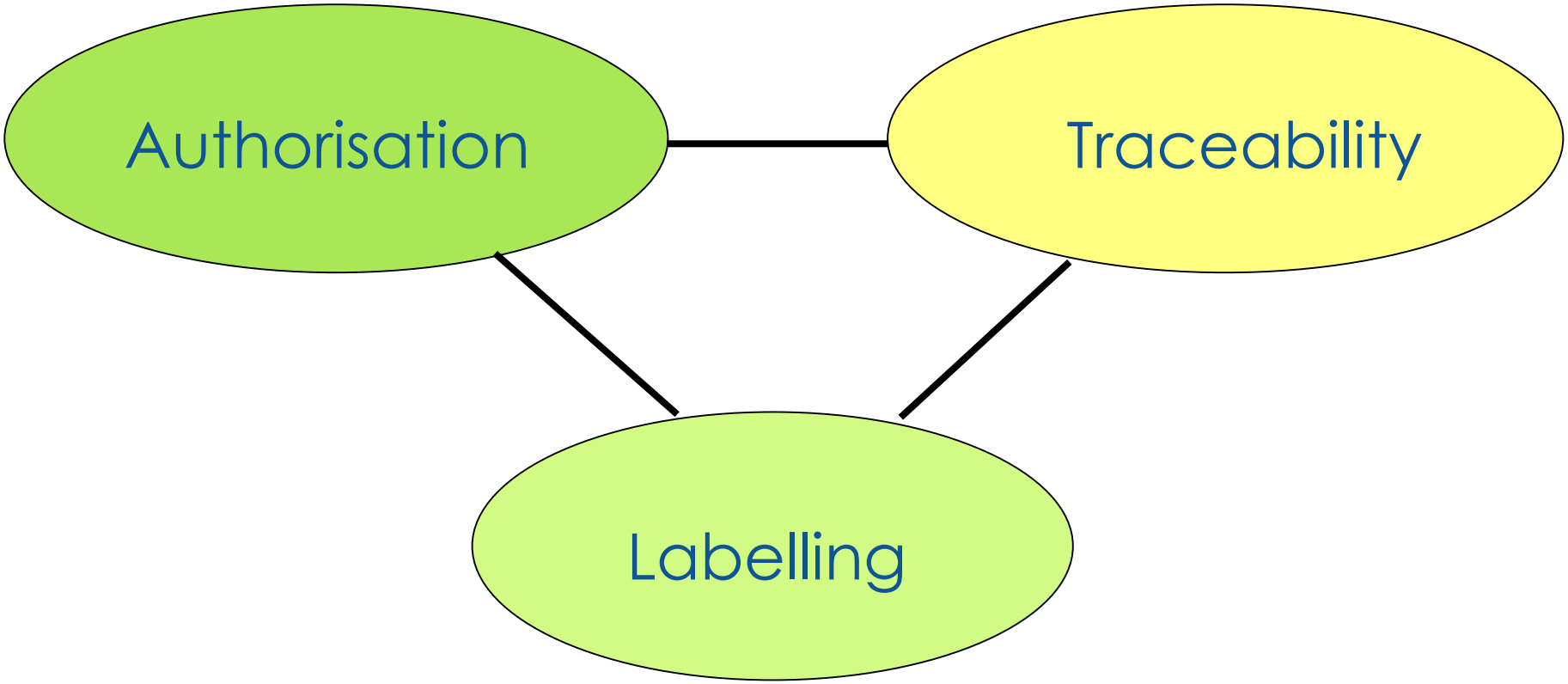
Protection of consumer interests in relation to GMOs

Ensuring the effective functioning of the internal market

Overview

- **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

Principles

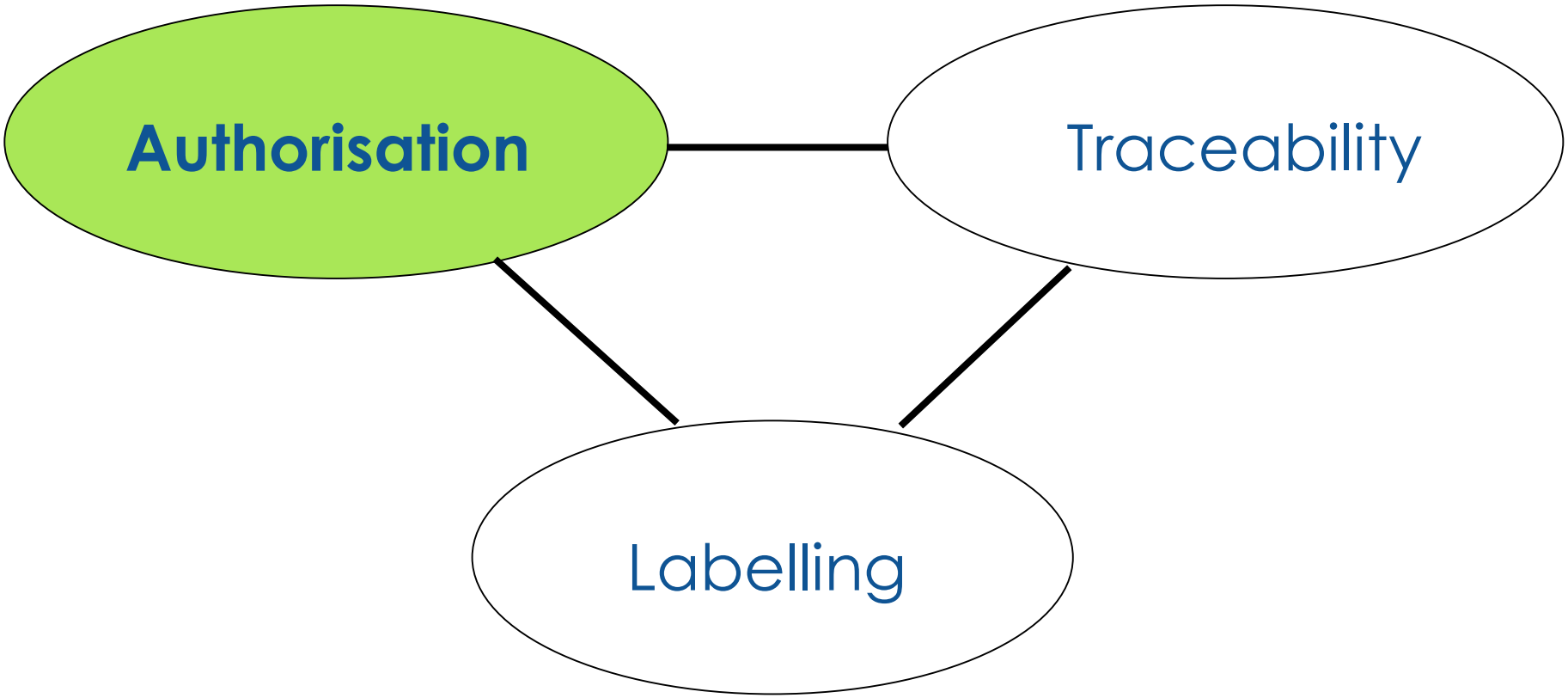
- *Authorisation (10-year validity)*
- *Risk assessment* — Environmental; Food/feed
- *Labelling and traceability*
- *Monitoring plan in order to identify potential effects of the GMO(s) on human health or the environment*
- *Consultation of and information to the public*
- *Information and material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

Information to the public
http://gmoinfo.jrc.ec.europa.eu

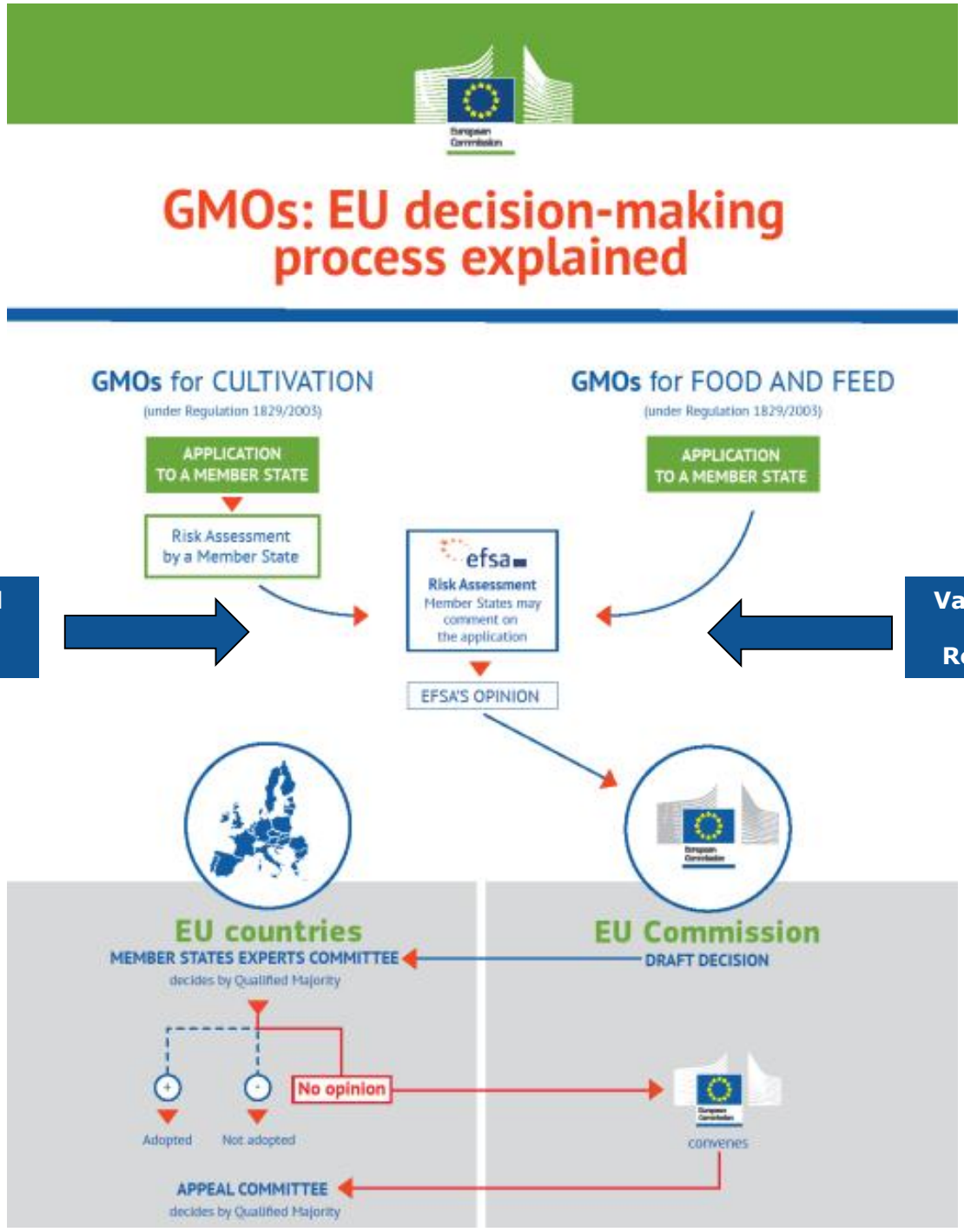
The EU Register of authorised GMOs

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

EU legislation on GMOs



Validation of analytical method by the EU Reference Laboratory



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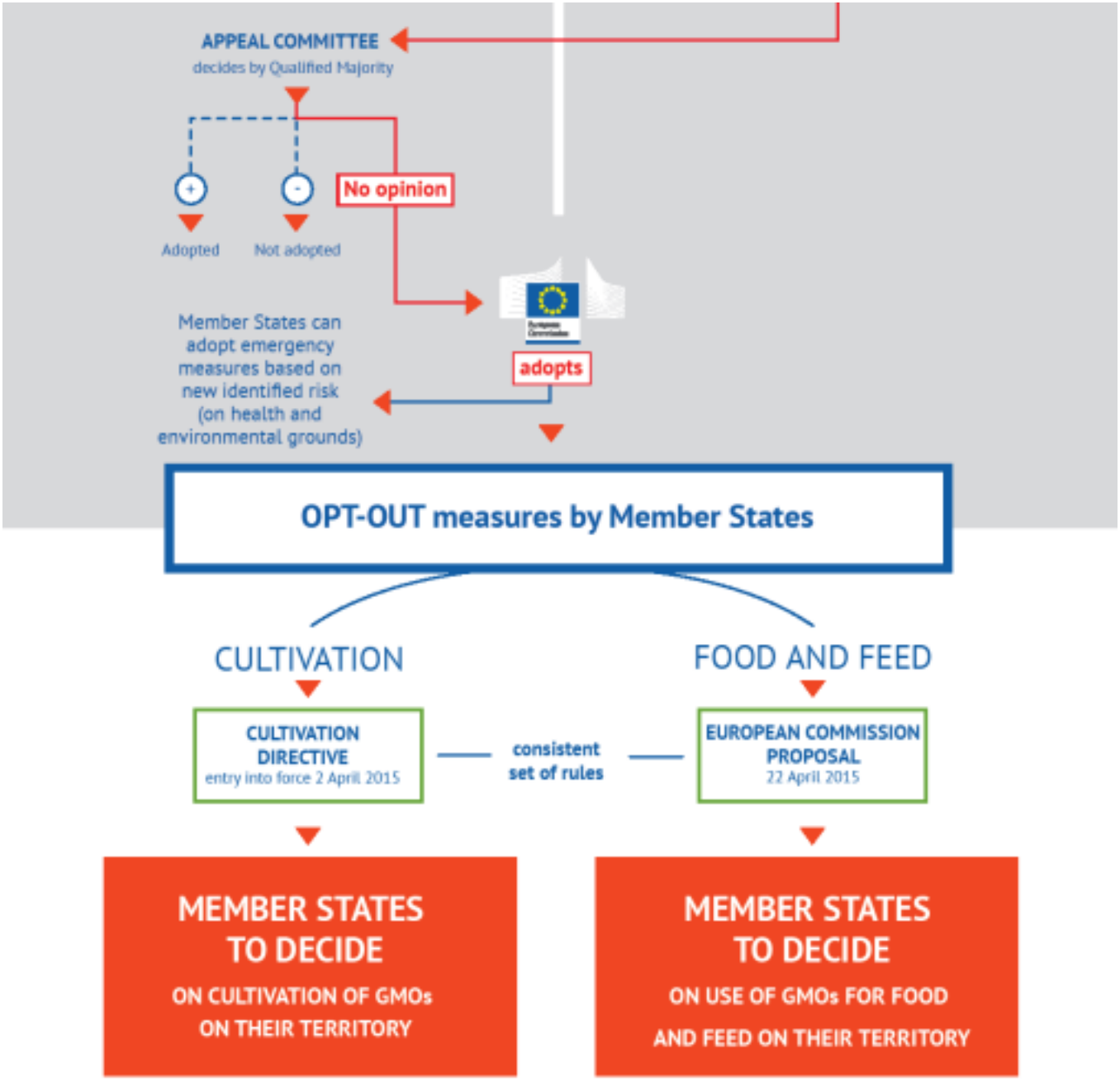
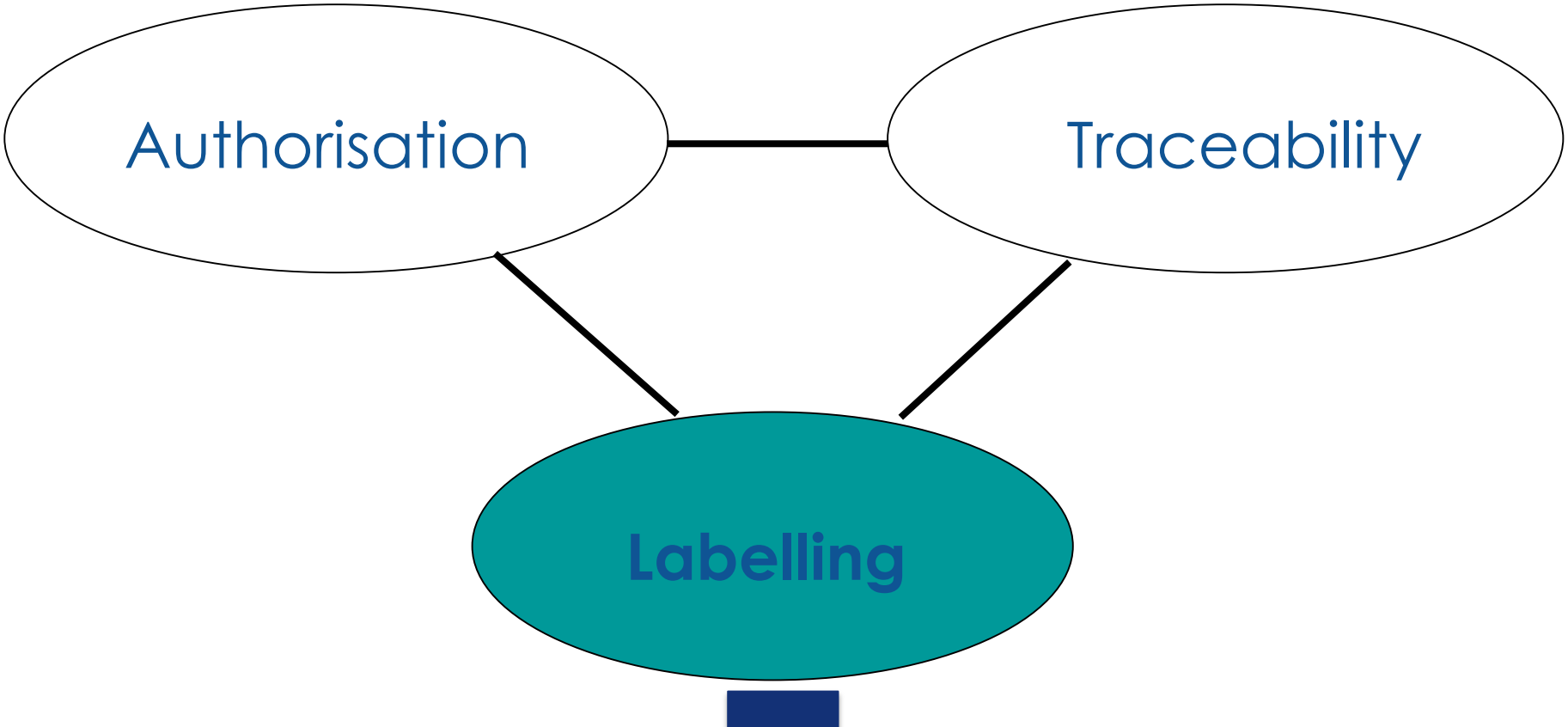

APPEAL COMMITTEE
decides by Qualified Majority
+
-
No opinion
Adopted
Not adopted
Member States can adopt emergency measures based on new identified risk (on health and environmental grounds)
adopts
OPT-OUT measures by Member States
CULTIVATION
FOOD AND FEED
CULTIVATION DIRECTIVE
entry into force 2 April 2015
consistent set of rules
EUROPEAN COMMISSION PROPOSAL
22 April 2015
MEMBER STATES TO DECIDE
ON CULTIVATION OF GMOs ON THEIR TERRITORY
MEMBER STATES TO DECIDE
ON USE OF GMOs FOR FOOD AND FEED ON THEIR TERRITORY

EU legislation on GMOs



EU legislation on GMOs

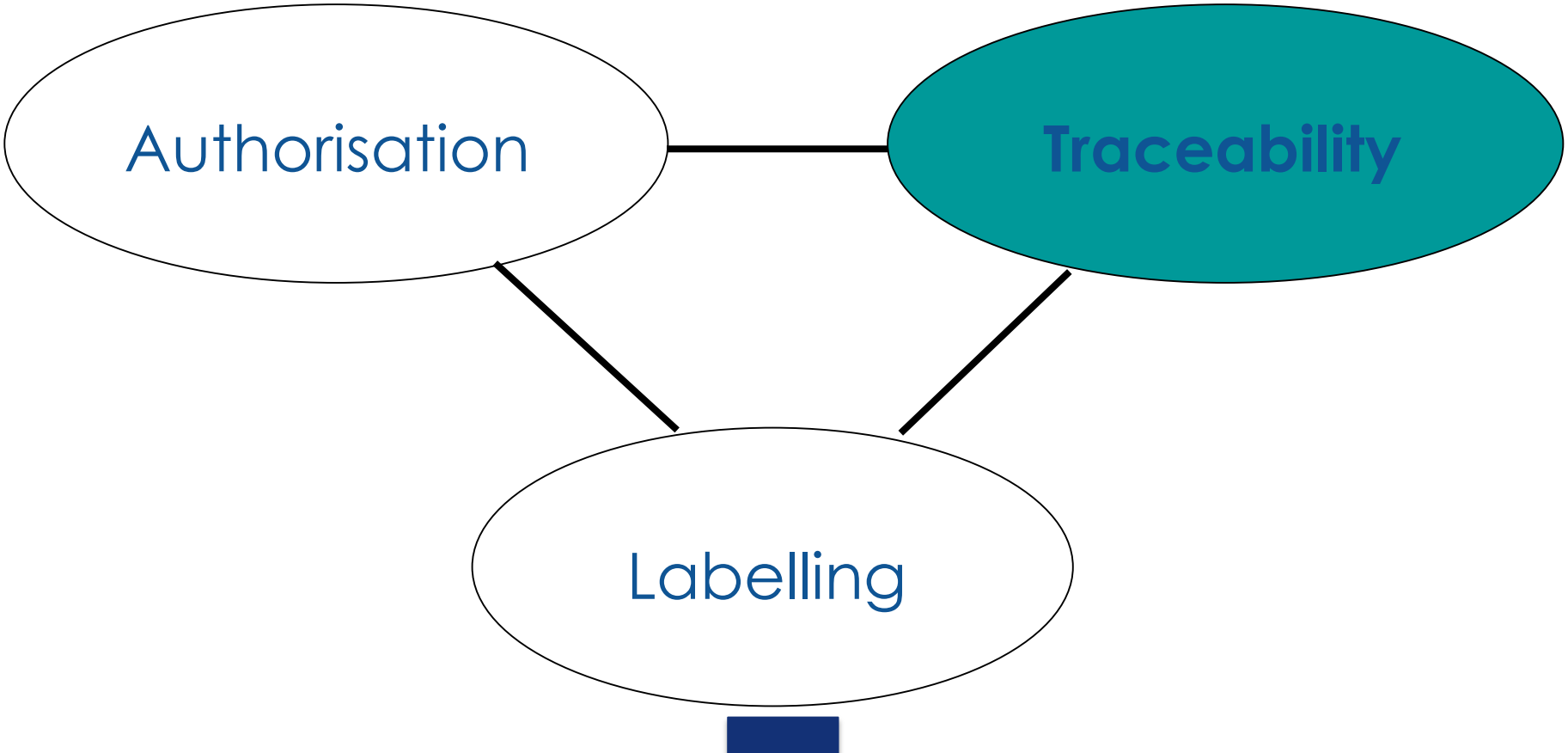
Labelling

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

Labelling not compulsory when GM material ≤ 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

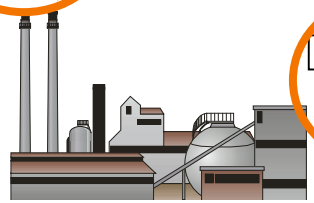
traceability of GMOs

traceability of food and feed products produced from GMOs

TO WHOM information shall be transmitted:

Biotech & Breeding (Institutions/Companies)

Agriculture



Food Processors

Food Retailers

Consumer

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

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*

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

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 ≥ 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

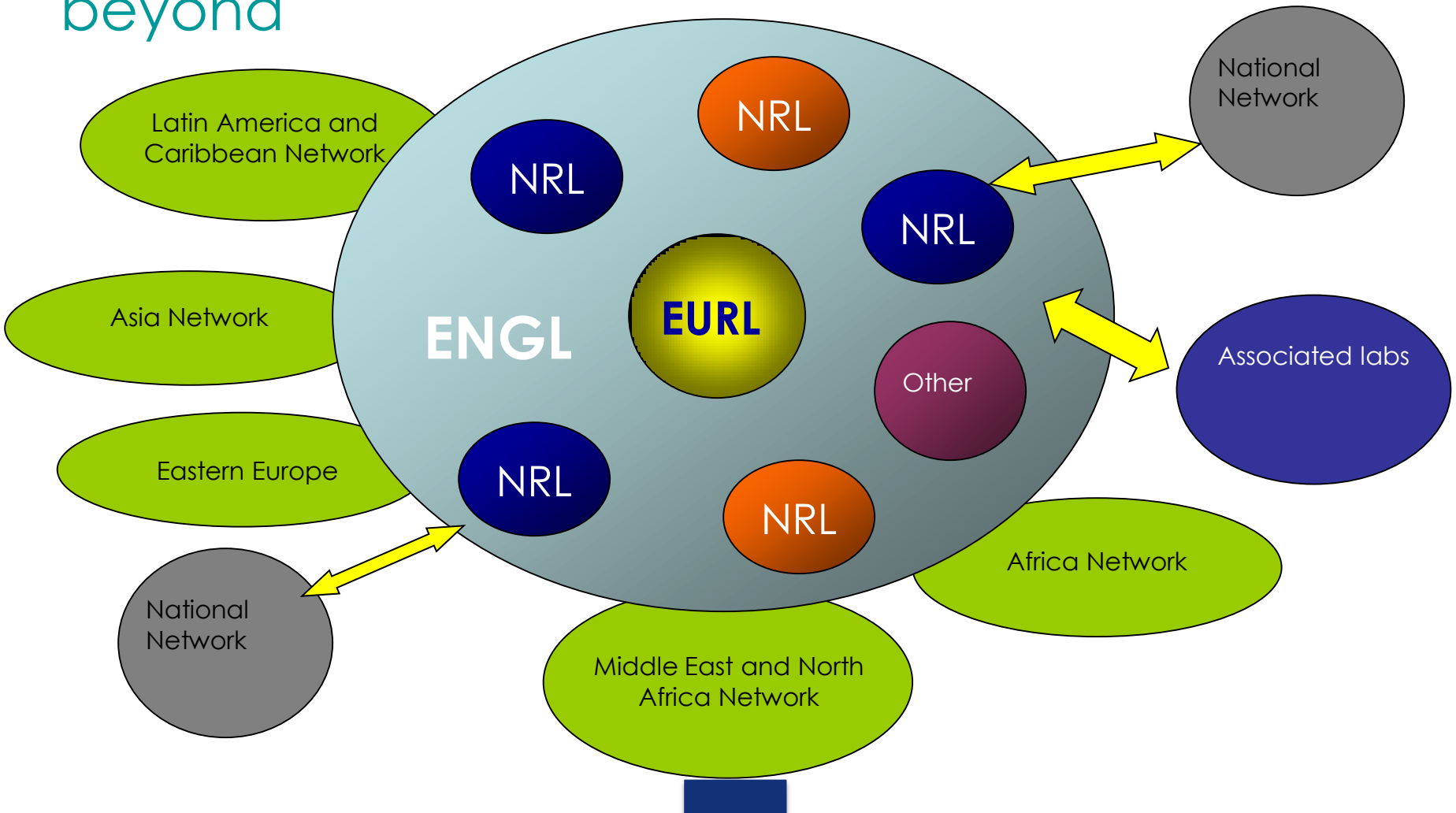
GM events to be detected

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

Need to detect and quantify

Need to detect

The GMO analytical galaxy in the EU… and beyond



Thank you