

European Commission DG ENLARGEMENT - TAIEX
Libyan National Center for Standardization and Metrology
and Secretariat of Agriculture

*Workshop on Genetically Modified Organisms
and Food Additives*

AGR 41349

Tripoli, Libya

24 - 25 May 2010

ILARIA
CIABATTI

Overview of the EU legislation on GMOs



Centro di Referenza Nazionale per la ricerca di OGM

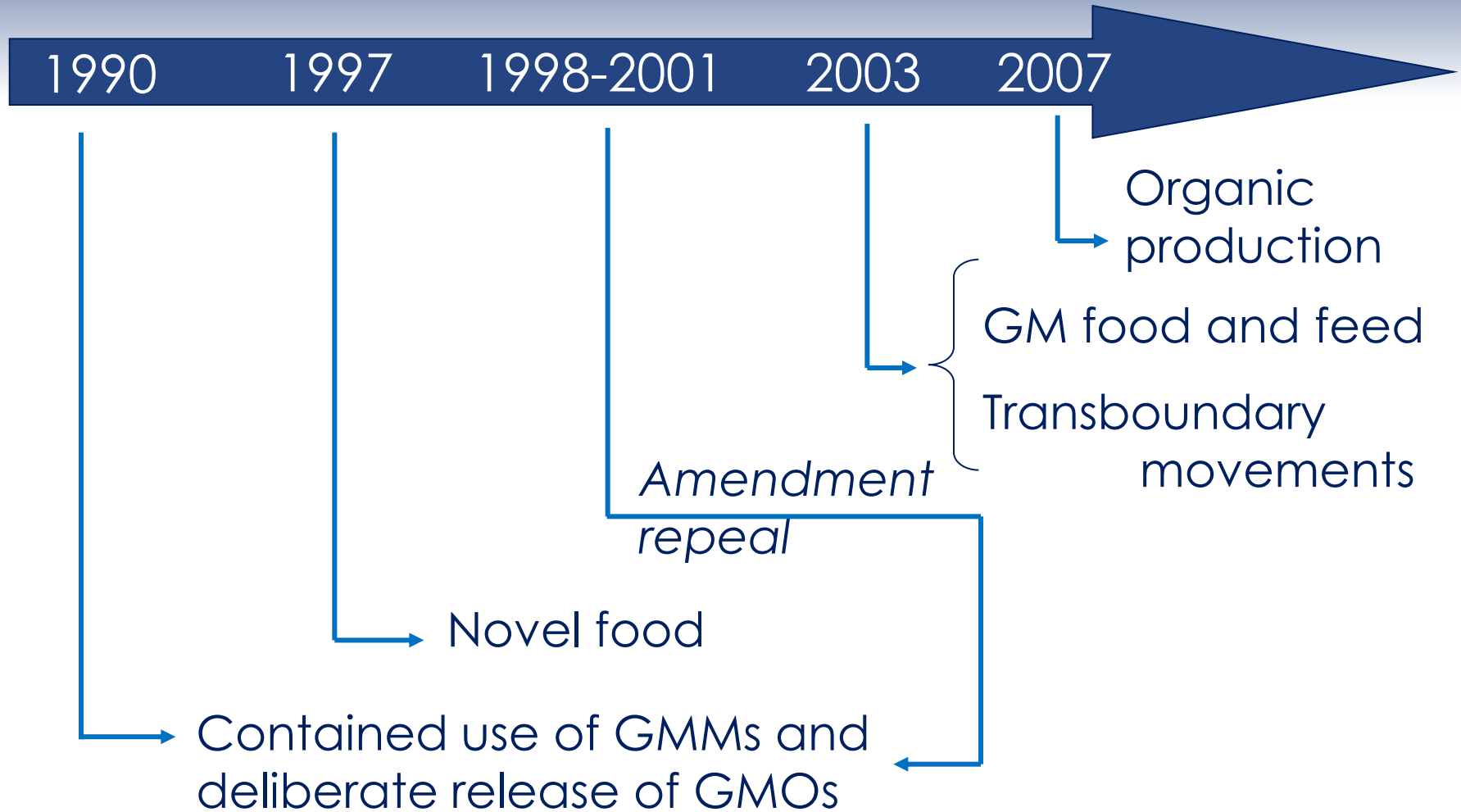
National Reference Laboratory for GMO analysis, Italy



Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscana



Historical evolution





O v e r v i e w



- ❑ Directive 2001/18 on the deliberate release into the environment of GMOs
- ❑ Regulation (EC) No 1829/2003 of the European Parliament and of the Council on GM food and feed
- ❑ Regulation (EC) No 1830/2003 of the European Parliament and of the Council 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) No 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) No 65/2004 establishing a system for the development and assignment of unique identifiers for GMOs
- ❑ Regulation (EC) 1946/2003 on transboundary movements of 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
- ❑ Recommendation 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the coexistence of GM crops with conventional and organic farming

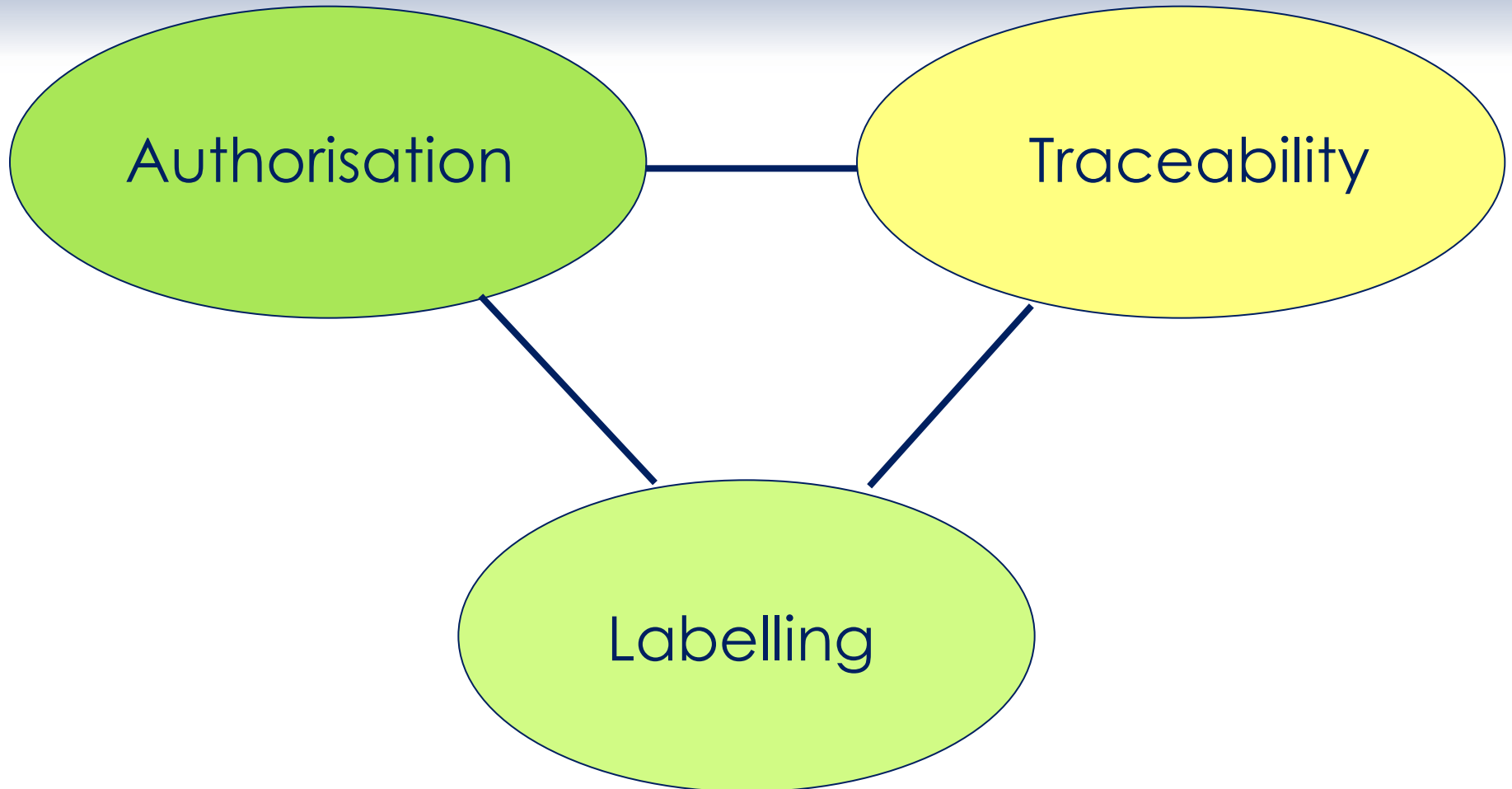
Main objective of EU legislation on GMOs



- ⊙ protection of human life and health, animal health and welfare, environment and consumer interests in relation to GMOs
- ⊙ ensuring the effective functioning of the internal market



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)





CROGM

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
 - ⊙ Consultation of scientific committees
 - ⊙ Labelling and traceability
 - ⊙ Information and material for GMOs identification and detection
 - ⊙ Monitoring plan in order to identify effects of the GMO(s) on human health or the environment
 - ⊙ Safeguard clause
 - ⊙ Consultation of and information to the public
- Environmental
Food/feed



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



European Commission
Joint Research Centre
Institute for Health and Consumer Protection

Deliberate releases and placing on the EU market of Genetically Modified Organisms - GMO Register

The purpose of this web site, managed by the [Joint Research Centre](#) of the [European Commission](#) on behalf of the [Directorate General for the Environment](#) is to publish information and to receive comments from the public regarding notifications 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

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)

[All products](#)



In order to view and print PDF files, you need the latest version of the free Adobe Acrobat Reader. Click on the link below to download and install the version for your computer.





Deliberate releases and placing on the EU market of Genetically Modified Organisms - GMO Register



Placing on the market of GMOs as or in products

[Home](#)

Authorised **Pending**

Notifications authorized under Directive 2001/18/EC

Notification Number	Country	Name of the Institutes or Companies	Name of the product (commercial and other names)	Info according to Dir. 2001/18 Art. 24 and 31 More info..
C/NL/06/01	Netherlands	Florigene Limited	Genetically modified carnation Moon aqua 123.8.12 with a modified colour (Unique Identifier FLO-40689-6)	24/10/2006 Summary notification file Public comments file 28/03/2007 Assessment report file Public comments to the risk assessment file 10/01/2008 CRL Method 12/03/2008 EFSA Opinion 16/03/2009 EC Decision



Information on authorised GM food and feed: the Community Register of GM food

EUROPA - Food Safety - Biotechnology - GM Food & Feed - Introduction - Windows Internet Explorer

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

community register gm food

Community register of genetically modified food and feed.

Genetically modified cotton

Transformation event/ Unique ID/ Company	Genes Introduced / Characteristics	Authorized use	Authorization Expiration Date	Details
Cotton (MON1445) <u>MON-Ø1445-2</u> Monsanto	Genetically modified cotton that contains: cp4 epsps gene inserted to confer tolerance to the herbicide glyphosate	Food produced from MON1445 cotton (cottonseed oil)	18/12/2011	
		Food additives produced from MON1445 cotton	Renewal of authorisation ongoing	
		Feed produced from MON1445 cotton (feed materials and feed additives)	Renewal of authorisation ongoing	
Cotton (MON15985) <u>MON-15985-7</u> Monsanto	Genetically modified cotton that contains: cry1Ac and cry2Ab2 genes inserted to confer insect-resistance highly selective in controlling Lepidopteran insects	Food additives produced from MON-15985-7 cotton	Renewal of authorisation ongoing	
		Feed produced from MON 15985 cotton (feed materials and feed additives)	Renewal of authorisation ongoing	
Cotton (MON15985 x MON1445)	Genetically modified cotton that contains: cry1Ac and cry2Ab2 genes inserted to confer	Food additives produced from	Renewal of	

Enlargement Agreements
EU - Russia: SPS issues

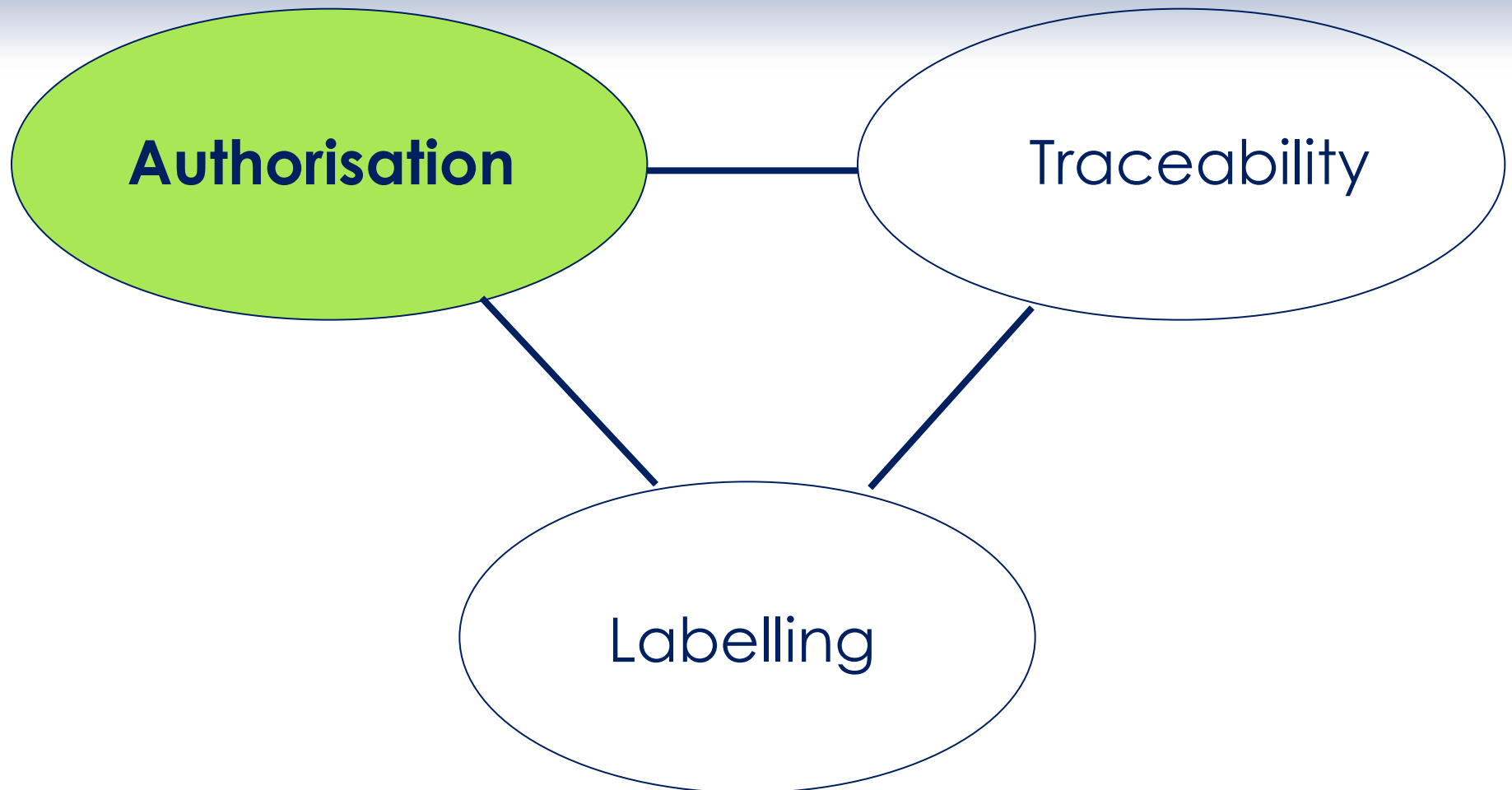
Menu
GM Register Introduction
Authorised products
Cotton (MON1445)
Cotton (MON15985)
Cotton (MON15985 x MON1445)
Cotton (MON531)
Cotton (MON531 x MON1445)
Cotton (LLCotton25)
Maize (Bt11)
Maize (DA S1507)
Maize (GA21)
Maize (MON810)
Maize (MON863)
Maize (MON863 x NK603)
Maize (MON863 x MON810)

Internet 100%

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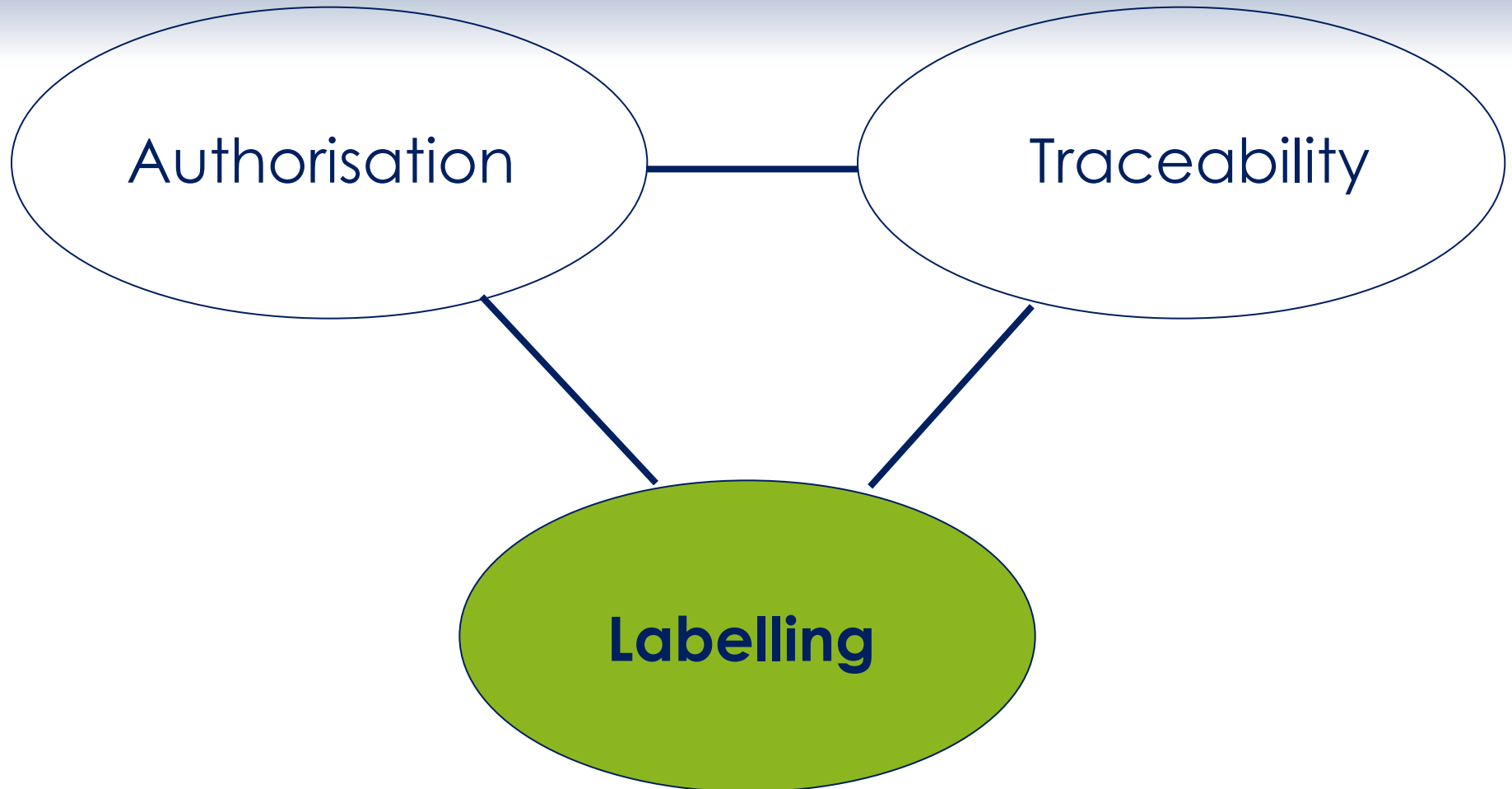


EU legislation on GMOs





EU legislation on GMOs





EU legislation on GMOs

Labelling

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

Labelling

~~CONTAINS GMO~~

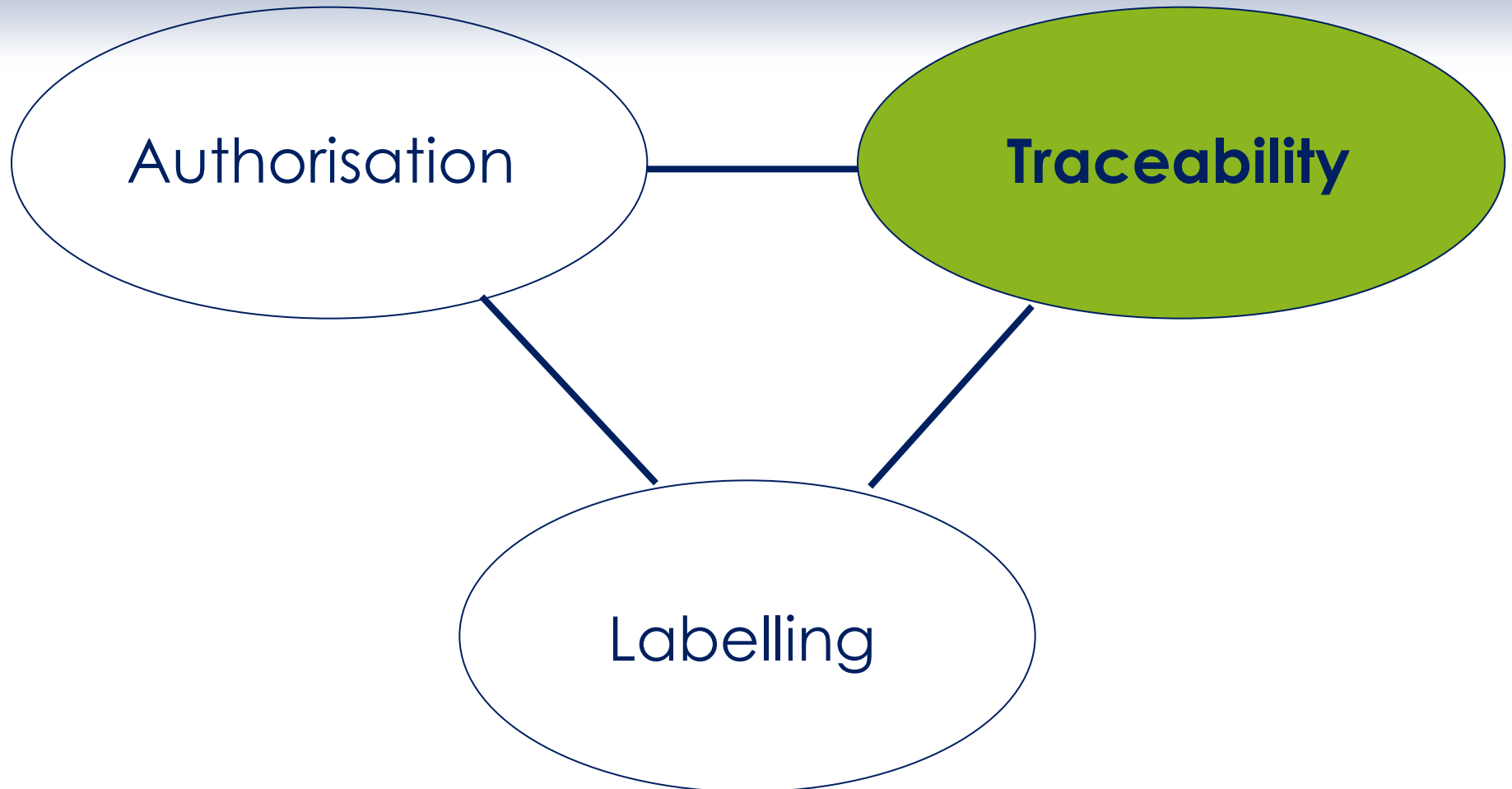
CONTAINS
GM "NAME OF THE INGREDIENT"

e.g.

CONTAINS GM MAIZE FLOUR



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





Reg. (EC) No 1831/2003

Traceability



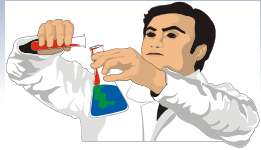
WHAT information shall be transmitted:

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



TO WHOM information shall be transmitted:

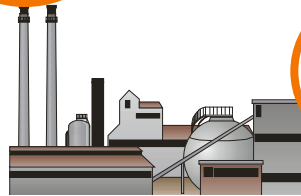


**Biotech & Breeding
(Institutions/Companies)**

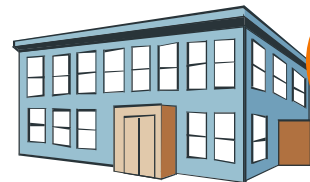
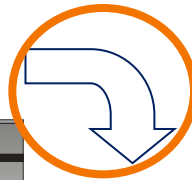
At all subsequent stages of the placing on the market, information received is transmitted to the operators receiving the products



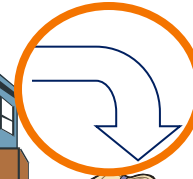
Agriculture



Food Processors



Food Retailers



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



Consumer

Traceability

- © Operators shall have in place systems and standardised procedures to allow:
 - ✓ the holding of information
 - ✓ the identification, for a period of five years from each transaction of the operator by whom and the operator to whom the products have been made available

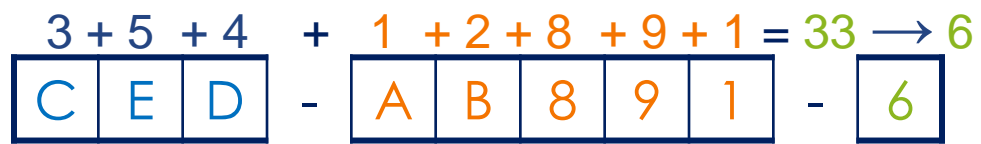


Unique identifier Reg. (EC) n° 65/2004

establishing a system for the development and assignment of unique identifiers for GMOs

Format established by the OECD: 3 components

1. applicant/consent holder (2 or 3 alphanumeric digits)
2. transformation event (5 or 6 alphanumeric digits)
3. a means for verification (1 alphanumeric digits)



an example: MON-Ø4Ø32-6



Traceability and labelling requirements do not apply to:

- © GM processing aids used only during the production process
- © animals fed with GM feed



Reg. (EC) 834/2007 on organic production and labelling of organic products (repealing Regulation (EEC) 2092/91)



- © Prohibition of use of GMOs and products produced from or by GMOs
- © 0.9% - tolerance threshold



Regulation (EC) 1946/2003 on transboundary movements of GMOs

Objectives

- ⊙ Regulating the intentional and unintentional movements of GMOs between EU Member States and third countries
- ⊙ establishing a common system of notification and information for transboundary movements of GMOs
- ⊙ ensuring coherent implementation of the provisions of the Cartagena Protocol on Biosafety
- ⊙ Ensuring an adequate level of protection in the safe transfer, handling and use of GMOs.



Commission Recommendation 2004/787/EC

on technical guidance for
sampling and detection of
GMOs and material
produced from GMOs

Consideranda

- ❑ ...
- ❑ facilitating a coordinated approach for inspections and control measures
- ❑ sampling and detection should be carried out using sound scientific and statistical protocols in order to achieve an appropriate level of confidence for detection of GMOs or material produced from GMOs
- ❑ ...

General principles

...

- ❑ Official controls should be carried out at any stage of the production, processing, and storage, distribution of products that contain or may contain GMOs or food and feed produced from GMOs, including at the point of import
- ❑ Alternative sampling and testing strategies to those recommended in this guidance may be applied

provided such methods are approved by the EURL

Sampling protocols

- ❑ Sampling seed and other plant propagating material lots
 - ✓ in accordance with current international methods and with the International Seed Testing Association (ISTA) rules
- ❑ Sampling bulk agricultural commodities
 - ✓ two-step procedure that allows to obtain estimates of GMO presence levels, together with their associated uncertainty , without imposing any assumption on the possible heterogeneity of the GMOs



Thank you

