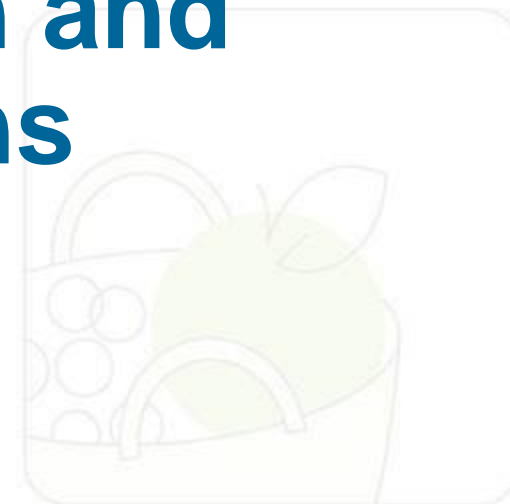
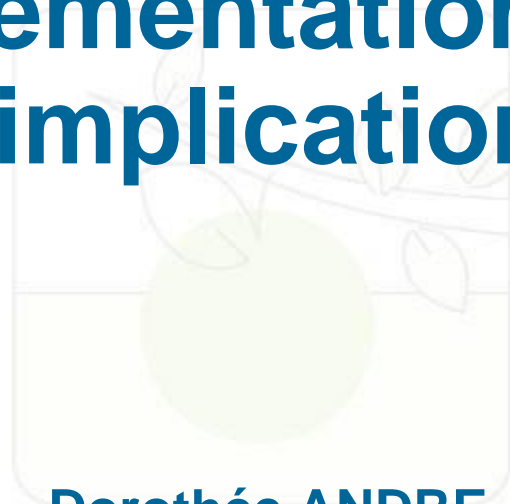


LLP Policy in the EU

Implementation and implications



Dorothee ANDRE

European Commission - DG Health and Consumers

**FAO Technical Consultation on Low Levels of Genetically Modified
(GM) Crops in International Food and Feed Trade**

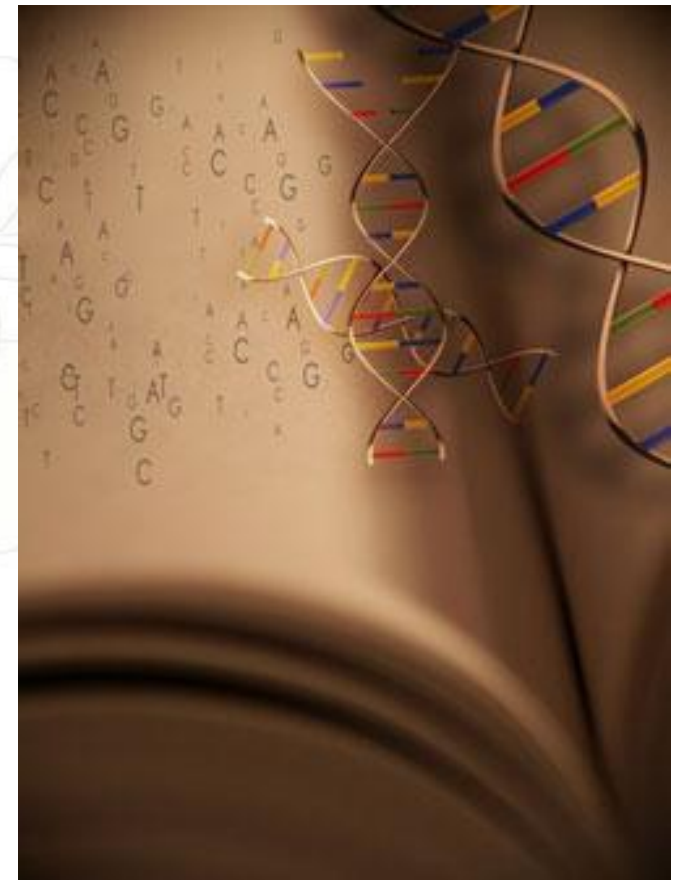
Rome, 20-21 March 2014

- **Safety**

- Each GMO MUST be authorised : zero-tolerance policy

- **Information Labelling**

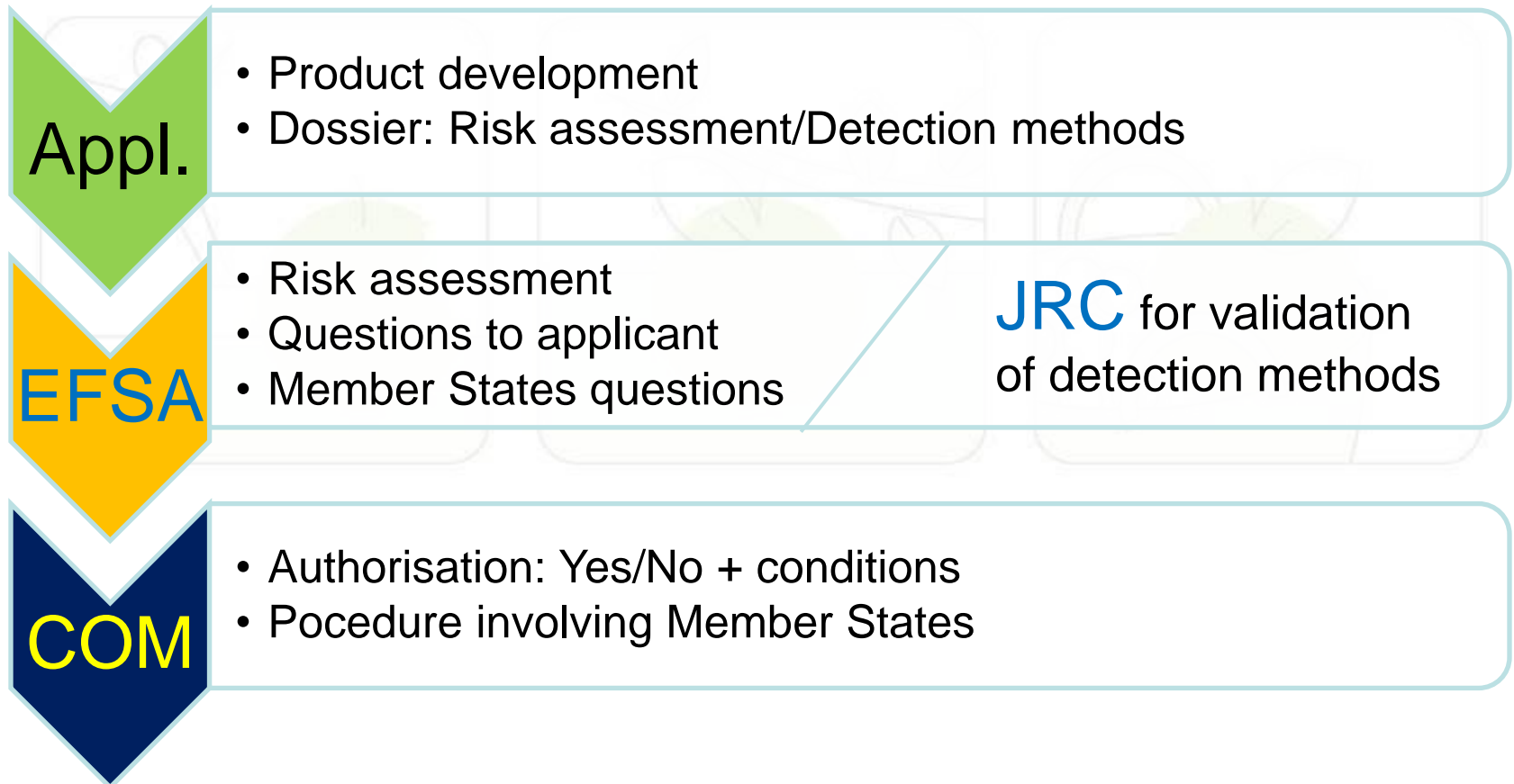
All GM food and feed containing or produced from GMOs (e.g. oil, sugar)



2 main pieces of legislation

- **Directive 2001/18/EC**
on the deliberate release of GMOs in the environment
- **Regulation (EC) No 1829/2003**
on GM food and feed

Regulation 1829/2003 Authorisation procedure



Current status of authorisations

- 57 GMOs authorised for food/feed use
 - 36 maize
 - 7 soybean
 - 8 cotton
 - 1 sugar beet
 - 3 oilseed rape
 - 2 microorganisms
- 1 GMOs authorised for cultivation and for food/feed use:
 - MON810 maize

4 types of non-authorized GMOs: current experience (I)

1. Not authorised in any country for commercial use at the time of finding

(only field trials)

- Bt 10 maize: US 2005 - emergency measure
- LLRice 601: US 2006 - emergency measures
- Rice Bt 63, Kefeng6 & KDM1: China 2010 - emergency measures
- GM papaya: Thailand 2012 – FVO inspection 2014
- GM wheat MON71800: USA 2013

2. Asymmetric for the EU

(authorised in third country but no application in EU)

- Linseed FP967 - Protocol for canadian flaxseed exported to EU

4 types of non-authorized GMOs: current experience (II)

3. **Asynchronous for the EU**

(authorised in third countries and in the pipeline for authorisation in EU)

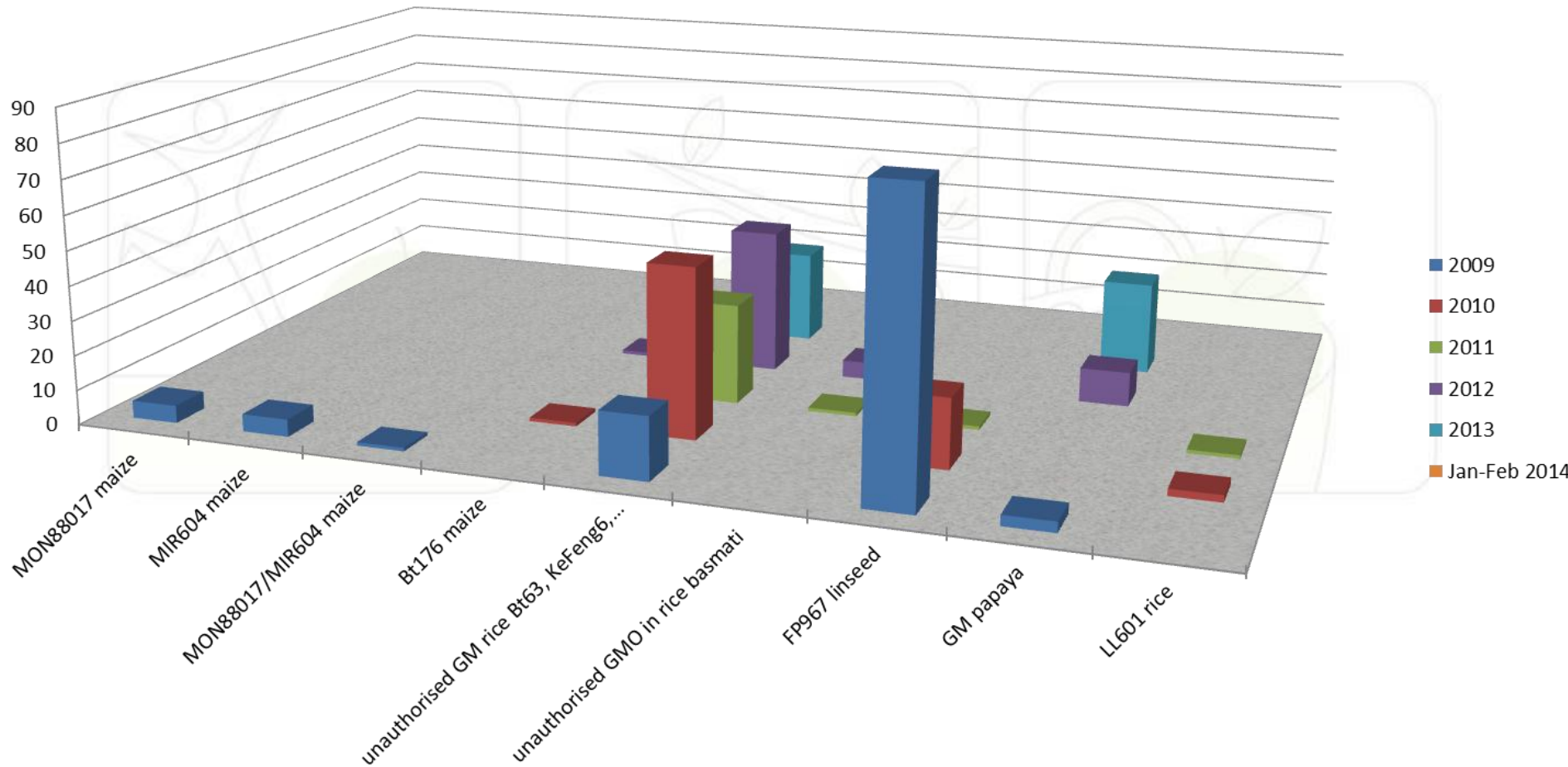
- Maize 59122, GA21, MIR604, MON88017: Now authorised

4. **Obsolete for the EU**

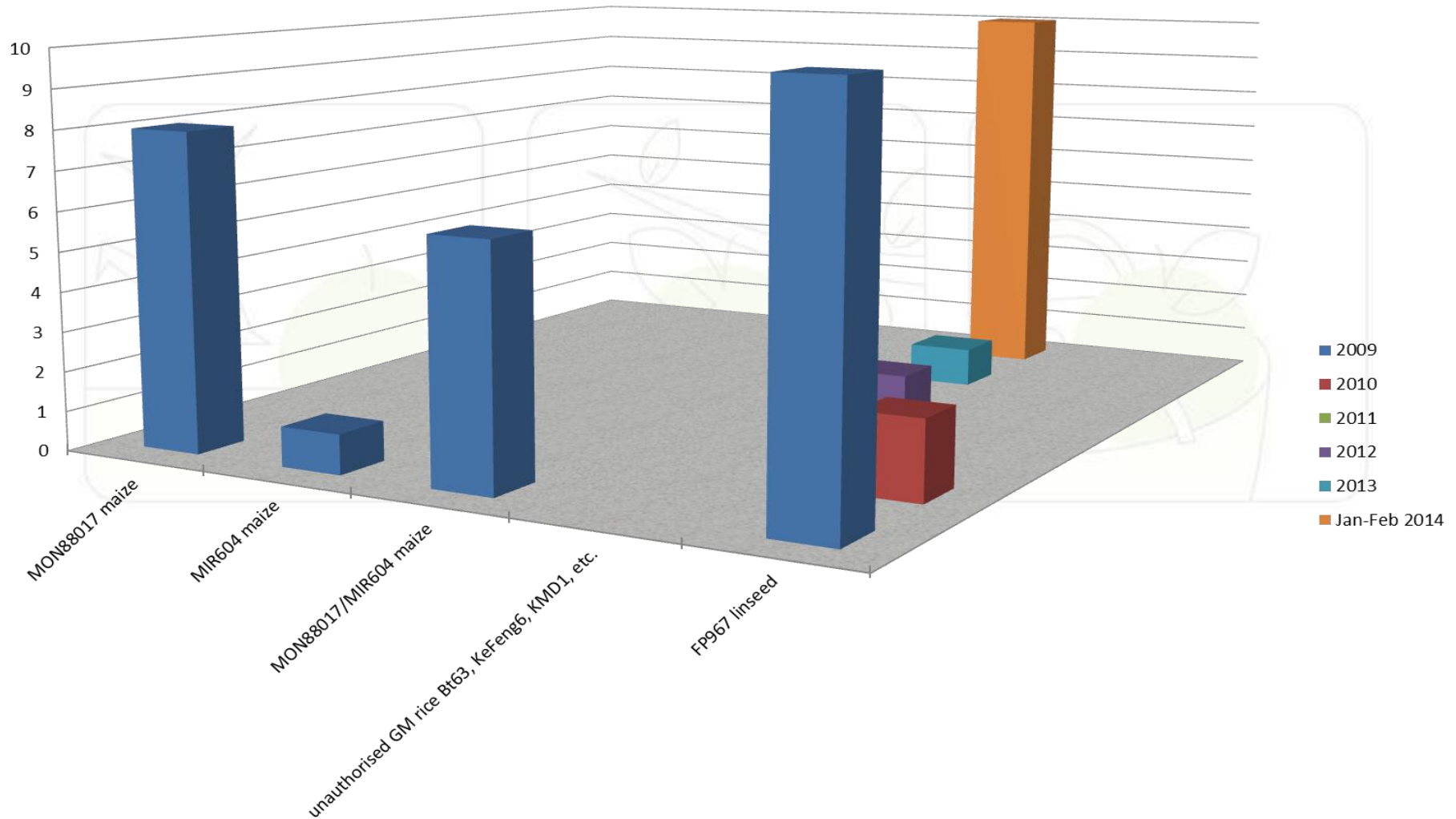
(authorisation has been cancelled or has expired)

- Maize Bt176

RASFF notifications 2009-2014 in Food



RASFF notifications 2009-2014 in Feed



Within the EU

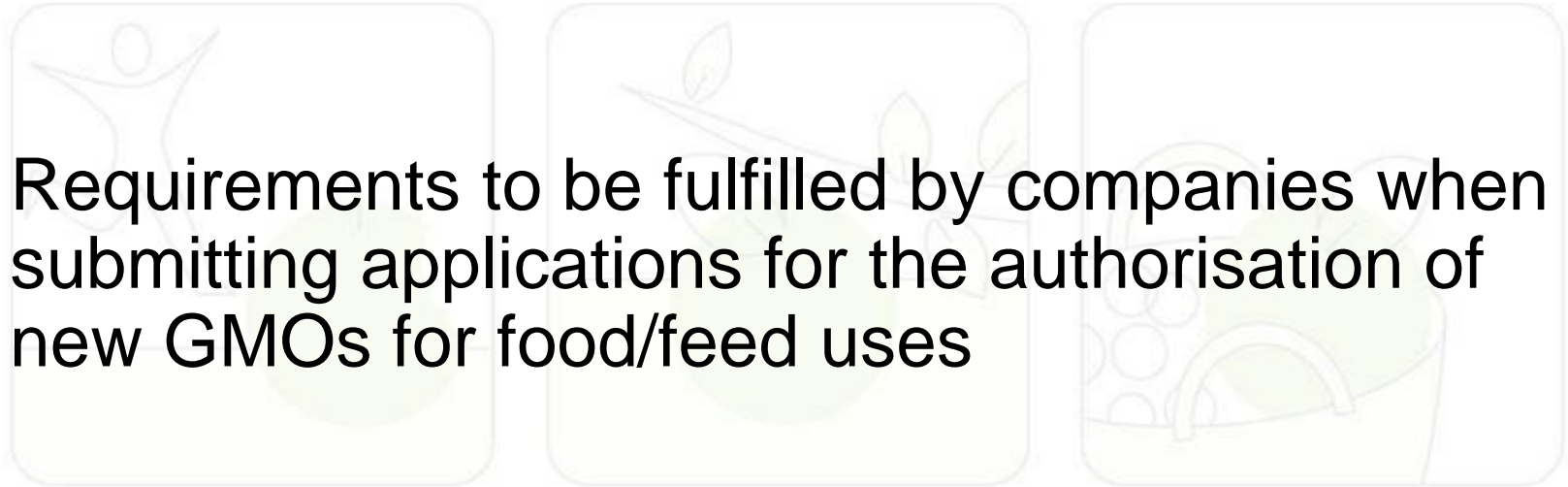
- ✓ Request to applicant to make submissions in the EU sooner than in third countries
- ✓ Streamlining the authorisation procedure: Implementing Regulation 503/2013
- ✓ Official Controls Regulation (EC) No 882/2004
- ✓ Harmonisation of controls and testing: Commission Regulation 619/2011

At International level

- ✓ Participation in CODEX, FAO GM Foods Platform, observer at the Global Low level Presence Initiative

Streamlining the authorisation process

- ✓ Requirements to be fulfilled by companies when submitting applications for the authorisation of new GMOs for food/feed uses



Technical zero for LLP in Feed

- ✓ Harmonisation of controls for GMOs in case of asynchronous authorisations
- ✓ Technical zero level for detected presence in Feed: 0.1%
 - ✓ the lowest level of GM material which is considered by the EU Reference Laboratory for the **validation of quantitative methods**
 - ✓ the lowest amount or concentration of analyte in a sample that has to be **reliably** detected and confirmed by official laboratories (=Minimum Required Performance Limit (MRPL))
 - ✓ the lowest level where results are satisfactorily **reproducible** between official laboratories

Technical zero for LLP in Feed

✓ Prerequisites

- ✓ Authorised for commercialisation in a non-EU country
- ✓ Authorisation procedure is pending for more than 3 months and it has not been identified by EU as susceptible to have adverse effects on health or the environment
- ✓ A quantitative method has been validated and published by the EU Reference Laboratory
- ✓ Certified Reference Material available

16 events currently covered

Status : Pending / Expired

Table listing GM material, which currently fulfils the requirements of Regulation (EC) No. 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 is expired.

Name of the product	Unique identifier	EFSA Application Number	Date of valid EFSA application or opinion published	Date European Union Reference Laboratory method published	Location Certified Reference Material	Authorisation in a third country
T304-40 cotton Bayer CropScience AG	BCS-GH004-7	EFSA-GMO-NL-2011-97	Valid EFSA application 24/10/2011	21/12/2012	IRMM	Link
MON 87708 soybean Monsanto	MON-87708-9	EFSA-GMO-NL-2011-93	Valid EFSA application 13/05/2011	06/05/2013	AOCS	Link
...

Looking ahead

- ✓ EU study to analyse experience and views as regards LLP food.
- ✓ This study will feed an Impact Assessment assessing whether and how LLP food would need to be specifically addressed at EU level.



Thank you !