LLP Policy in the EU
Implementation and implications

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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

**Appl.**
- Product development
- Dossier: Risk assessment/Detection methods

**EFSA**
- Risk assessment
- Questions to applicant
- Member States questions

**COM**
- Authorisation: Yes/No + conditions
- Procedure involving Member States

**JRC for validation of detection methods**
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-authorised 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-authorised 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
LLP/AP Incidents

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

Regulation (EC) 619/2011
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.

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

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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 !