Overview of the EU legislation on GMOs

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Outline

- How does it work in the EU?
  - **Post-market monitoring provisions in the GMO legislation**
- Example – nutritionally-altered GM soybean

GMO legislation in the EU

- **Directive 2001/18/EC** on the deliberate release of GMOs into the environment ("living" organisms)
- **Regulation (EC) No 1829/2003** on GM food and feed
- **Implementing Regulation (EU) No 503/2013** on applications for autorisation of GM food and feed in accordance with Regulation (EC) No 1829/2003

Authorisation procedure for GM food and feed

Appl.

- Product development
- Dossier/Risk assessment/Detection

Risk assessment

- Risk assessment
- Questions to applicant

COM

- Authorisation: Yes/No + conditions
- Comitology

SAFETY

- Each GMO is assessed and authorised on a case by case basis.

- Authorisation may be subject to conditions, e.g. post marketing monitoring.

Post-market monitoring
Regulation (EC) No 1829/2003

Appl.

Articles 5(3)(k) and 17(3)(k)

Application for authorisation

"3. The application shall be accompanied by the following:

...

(k) **where appropriate, a proposal for post-market monitoring regarding use of the food/feed for human/animal consumption**;

..."

Post-market monitoring
Regulation (EC) No 1829/2003

Articles 6(5)(e) and 18(5)(e)

Opinion of the Authority (EFSA)

"5. In the event of an opinion in favour of authorising the food/feed, the opinion shall also include the following particulars:

...

(e) **where applicable, specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment**..."

Post-market monitoring
Regulation (EC) No 1829/2003

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- If a post-market monitoring is recommended by EFSA and agreed by the risk managers (Member States and the Commission), it is a part of the authorisation decision.

- After an authorisation has been issued, the authorisation-holder shall comply with the conditions of the post-market monitoring and shall submit reports to the Commission in accordance with the terms of the authorisation.

Post-market monitoring

Implementing Regulation (EU) No 503/2013

Article 7 sets out the requirements applicable for **post-market monitoring of GM food or feed** for applications submitted under Regulation (EC) No 1829/2003

Post-market monitoring
Implementing Regulation (EU) No 503/2013

The applicant shall submit a proposal for post-market monitoring regarding the use of the food and feed when, in accordance with the outcome of the risk assessment, it is appropriate to confirm:

a) that specific recommendations of uses are followed;

b) the predicted consumption of the GM food or feed; or

c) the relevance and intensity of effects and unintended effects detected during the pre-market risk assessment which can only be further characterised by post-market monitoring.

Post-market monitoring
Implementing Regulation (EU) No 503/2013

The applicant shall ensure that the post-market monitoring is:

a) developed to collect reliable information (it shall allow the detection of indications on whether any (adverse) effect on health may be related to GM food or feed consumption);

b) based on strategies aiming at collecting relevant information from specific stakeholders including consumers and on a reliable and validated flow of information between the different stakeholders;

c) accompanied by adequate justification and a thorough description of the selected methodologies for the proposed post-market monitoring including aspects related to the analysis of the collected information.

Post-market monitoring
Implementing Regulation (EU) No 503/2013

- Specific attention shall be paid to those GM plants which are aimed at modifying nutritional characteristics of the food and feed.

- For those GM products, the requirement for post-market monitoring shall be discussed as a mechanism for determining actual changes to overall dietary intake patterns of the GM food/feed, to what extent this has occurred and whether or not the product induces known or unexpected side effects.

- If the performance of post-market monitoring is deemed necessary, the reliability, sensitivity and specificity of the proposed methods shall be provided.

Example

- 67 GMOs authorised for food/feed uses.
- 3 nutritionally-altered GM soybeans where a post-market monitoring is requested.

- Plenish soybean
  - High in monounsaturated fatty acids and low in polyunsaturated fatty acids;
  - Oil for human consumption;
  - EFSA recommendation: The PMM should focus on the collection of consumption data for the European population.

Plenish soybean
Commission Decision COM/698/2015

1. The authorisation holder shall collect the following information:

(i) quantities of Plenish soybean oil and Plenish soybeans for oil extraction, imported into the European Union for the placing on the market as or in products for food;

(ii) in case of import of products mentioned under (i), results of database searches in FAOSTAT database on the quantities of vegetable oil consumption by Member State, including shifts in quantities between the different types of oils consumed.

2. The authorisation holder shall, based on the information collected and reported, review the nutritional assessment conducted as part of the risk assessment.

Summary

- Regulation (EC) No 1829/2003 provides that a proposal for post-market monitoring of the use of the GM food or feed shall only be submitted by the applicant where it is appropriate.

- Implementing Regulation (EU) No 503/2013 sets out the conditions under which such a proposal should be made, according to the outcome of the risk assessment.

- Post-market monitoring should only be considered in cases where it is appropriate to confirm the expected consumption, the application of conditions of uses or identified effects.

Thank you for your attention!