Workshop on allergenicity assessment of GM plants

European Food Safety Authority

17 June 2015 (Brussels)

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European Food Safety Authority

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MANDATE ON ALLERGENICITY ASSESSMENT OF GMOS

OUTLINE

- Background information
- Topics requiring supplementary guidance
- Summary

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BACKGROUND

- **Self-task activity (accepted in July 2014):**

  - EFSA WG to be created with the following tasks

- **Terms of reference of the WG:**

  - to develop supplementary guidance on allergenicity assessment of GM plants (3 topics)

  - to participate in a workshop with stakeholders organised by EFSA

  - to consult the public on the draft scientific opinion

  - to review the draft scientific opinion accordingly

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BACKGROUND

- **Timelines:**
  - Workshop in June 2015
  - Public consultation in the second quarter of 2016
  - Adoption of the guidance document by the end 2016

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TOPICS REQUIRING SUPPLEMENTARY GUIDANCE

- Non-IgE-mediated immune adverse reactions to foods
- *In vitro* digestibility test for allergenicity assessment
- Endogenous allergenicity

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TOPICS REQUIRING SUPPLEMENTARY GUIDANCE

- **Non-IgE-mediated immune adverse reactions to foods**

- Allergenicity assessment of GMOs mainly focuses on IgE-mediated food allergy (well described weight-of-evidence approach in place)

- Assessment of non-IgE-mediated immune adverse reactions, when required (but no details on how and in which cases this assessment should be performed)

- Background information obtained from EFSA external scientific report (Mills et al 2013)

- EFSA GMO Panel considered that relevant methodology (*in silico*/*in vitro*) could be applied in the allergenicity assessment

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TOPICS REQUIRING SUPPLEMENTARY GUIDANCE

- ***In vitro* protein digestibility test for allergenicity assessment**

- Digestibility of novel proteins may be assessed employing *in vitro* digestibility tests using different conditions

- Impact of the matrix as well as the effects of the processing to be taken into account in *in vitro* digestibility tests

- Background information obtained from EFSA external scientific report (Mills et al 2013)

- EFSA GMO Panel considered a potential need for better standardisation and harmonisation of the conditions used when performing *in vitro* digestibility studies

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TOPICS REQUIRING SUPPLEMENTARY GUIDANCE

- **Endogenous allergenicity**

- General requirement embedded in various international documents: FAO/WHO (2001), Codex (2003, 2009), EFSA (2006, 2011)

- Implementing Regulation (EC, 2013) requires the inclusion of certain allergens (as defined in OECD Consensus documents) in the compositional analysis and consequently the quantitative measurement of individual allergens

-EFSA GMO Panel considered that supplementary guidance would be very useful to assist both applicants and risk assessors in the practical implementation of the requirement

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SUMMARY

- Self-task activity of EFSA to consider latest scientific developments
- EFSA Working Group is composed by leading scientist in the different areas covering the topics of the mandate
- Main objective is to develop supplementary guidance
- EFSA guidance will better assist applicants and risk assessors
- Guidance relevant not only for GMO

Focus group

1. Background
   - EFSA aims at exploring new ways to enhance participation of stakeholders
   - EFSA has launched a pilot project establishing a stakeholder focus group to contribute to the development of the guidance document on allergenicity
2. Objectives
   - Enhance the quality, clarity and usability of GD developed by EFSA
   - Draw lessons for future engagement with stakeholders

Focus group

3. Terms of reference

Members of the pilot Focus group shall:

- provide timely feedback on the scientific content of the GD
- attend specific meetings (EFSA workshop and a meeting of the WG after the public consultation)
- produce a report on lessons learnt

Composition of the group:

- Up to 4 representatives from EFSA stakeholder platform
- Up to 4 representatives from the Member States

Focus group

4. Expected deliverables and timelines

- Comment on briefing notes and participate to EFSA workshop
- Comment on draft GD before its endorsement
- Comment during public consultation
- Attend to a meeting of the allergenicity WG after the public consultation to discuss all comments received during the public consultation
- Provide feedback on the experience gained with this initiative

Thank you for your attention