



Robust and objective scientific dialogue between government and stakeholder experts - an Authority perspective

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BMEL/BfR Workshop, Berlin, 23-24 November 2017

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Stakeholder dialogue – the EFSA approach

Where EFSA has come from...

- Stakeholder Consultative Platform (24 members)
- Yearly meetings with industry and NGOs
- Public consultations

...what prompted us to change...

- Evolving societal demands regarding accountability and engagement with public organisations

- Need for:
 - More meaningful, agile interactions
 - Stakeholder expertise and data
 - Broader representation and more inclusivity

What does stakeholder dialogue mean to EFSA?



- Prioritise public and stakeholder engagement in the process of scientific assessment
- Widen EFSA's evidence base and optimise access to its data
- Build the EU's scientific assessment capacity and knowledge community
- Prepare for future risk assessment challenges
- Create an environment and culture that reflects EFSA's values

...where EFSA is now...

Stakeholder Engagement Approach – July 2016

- **List of registered stakeholders**
 - More than 100 across 7 categories
- **Permanent Engagement Mechanisms**
 - Stakeholder Forum and Bureau
- **Targeted Engagement Mechanisms**
 - Discussion, consultation, and focus groups (GMOs, feed additives, emerging risks, endocrine disruptors, bee health)
 - Roundtables with industry and NGOs
 - Communicators lab
 - Public consultations

EFSA engagement in action – recent examples

Guidance Document on allergenicity assessment of GMOs

Focus group with stakeholders

Objectives:

- Enhance quality, clarity and usability of GD
- Offer transparency in the process

Terms of reference:

- Provide feedback on scientific content of the GD
- Attend specific meetings

Guidance on allergenicity assessment of genetically modified plants

EFSA Panel on Genetically Modified Organisms (GMO),
Hanspeter Naegeli, Andrew Nicholas Birch, Josep Casacuberta, Adinda De Schrijver,
Mikolaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan,
Elsa Ebbesen Nielsen, Fabien Nogué, Christophe Robaglia, Nils Rostoks, Jeremy Sweet,
Christoph Tebbe, Francesco Visioli, Jean-Michel Wal, Philippe Eigenmann, Michelle Epstein,
Karin Hoffmann-Sommergruber, Frits Koning, Martinus Lovik, Clare Mills,
Francisco Javier Moreno, Henk van Loveren, Regina Selb and Antonio Fernandez Dumont

Abstract

This document provides supplementary guidance on specific topics for the allergenicity risk assessment of genetically modified plants. In particular, it supplements general recommendations outlined in previous EFSA GMO Panel guidelines and Implementing Regulation (EU) No 503/2013. The topics addressed are non-IgE-mediated adverse immune reactions to foods, *in vitro* protein digestibility tests and endogenous allergenicity. New scientific and regulatory developments regarding these three topics are described in this document. Considerations on the practical implementation of those developments in the risk assessment of genetically modified plants are discussed and recommended, where appropriate.

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Keywords: guidance, allergenicity assessment, newly expressed proteins, endogenous allergenicity, GMO

Guidance Document on allergenicity assesment of GMOs

Composition:

- 4 stakeholders - European Federation of the Associations of the Dietitians, EuropaBio, German Allergy and Asthma Association, FoodDrinkEurope
- 4 Member State experts - Austria, France, Italy, The Netherlands

Outcome:

- Knowledge and data exchange between stakeholders and Panel members
- Strengthened stakeholder confidence in the final output
- Better quality GD

Guidance document on endocrine disruptors

- Joint EFSA/ECHA consultation group
- Stakeholders and MS experts invited to contribute to draft versions of the Guidance
- Open call and selection – broad mix of stakeholders
- 2 rounds of consultation: 1300 + 1800 comments
- Significant redrafting required
- All comments to be published



EU Partnership on bee health

Scientific Symposium and Discussion Group (DG)

- European Parliament tasked EFSA to organise bee health symposium for Bee Week 2017
- Objectives: convene relevant stakeholders to build support for EU Bee Partnership - addressing absence of harmonised data on bee health
- Approach: facilitation/scientific support
- Outcome: general stakeholder agreement to work towards Partnership

EU Partnership on bee health

- EFSA is supporting establishment of the Partnership through the SEA DG
- Call for DG members launched in September; first meeting in December
- Good balance across stakeholder groups
- Run by stakeholders for the benefit of stakeholders

Reflections and lessons learnt

Stakeholder dialogue - reflections and lessons learnt

1. Targeted, early engagement works best

- Best suited to answer specific scientific questions
- Quality not quantity – expertise may rest with a limited number of stakeholders
- Involving stakeholders at first stages of risk assessment helps to generate confidence and increase buy-in

Stakeholder dialogue - reflections and lessons learnt

2. Limits to what engagement can achieve

- Engagement is not the panacea for resolving all stakeholder concerns
- e.g. Glyphosate – reliance on industry studies, public access to data, pesticide formulations – issues that need to be addressed at societal/political level
- Stakeholder dialogue has to take place on agreed terms

Stakeholder dialogue - reflections and lessons learnt

3. Engagement comes at a cost and return on investment is hard to measure

- What price on stakeholder engagement?
- How do you measure it?
- Culture is as important as resources

Stakeholder dialogue - reflections and lessons learnt

4. Transparency is key, but it has to be smart

- The process is just as important as the outcome
- Balanced representation and equal opportunity is fundamental
- Not enough just to put something on your website



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