



MEACB 2019  
Berlin 6-7 November 2019

# Report on EFSA's stakeholder workshop "Problem formulation for the ERA of gene drive modified insects"

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Gene Drive Modified Insects

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Trusted science for safe food

  
European Food Safety Authority

- Is current EFSA guidance related to Genetically Modified Insects fit for purpose for Gene Drive Modified Insects?

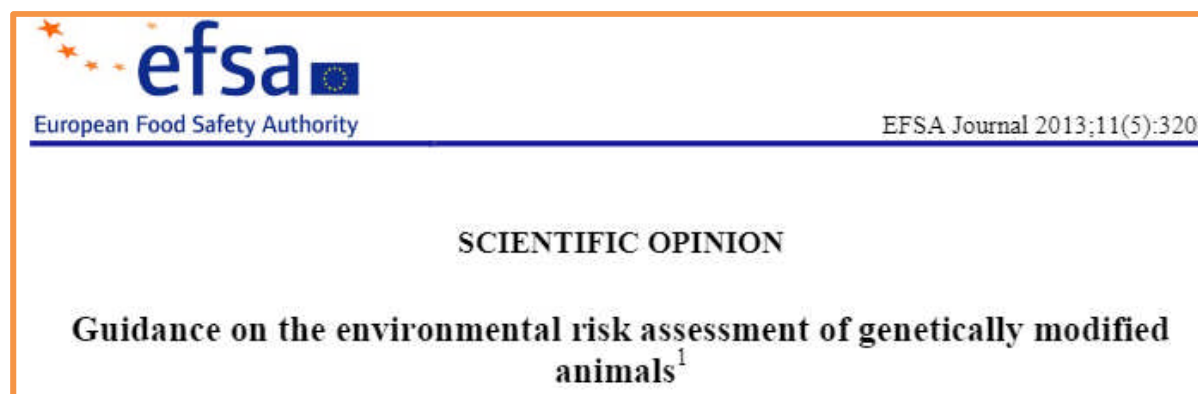
- Requestor
  - European Commission
- Date
  - June 2018 (accepted: August 2018)
- Output type
  - GMO Panel Scientific Opinion
- Timeline
  - Draft output March 2020
  - Public consultation
  - Publication by the end of 2020
  - ***Too early to give even draft findings***

- To **identify potential risks** in terms of impact on human and animal health and the environment that gene drive modified organisms (GDMOs) could pose
- To **identify potential novel hazards** of GDMOs, considering relevant comparators, where appropriate

- To determine whether existing risk assessment (RA) guidance documents (GD) are adequate and sufficient for GDMOs, or whether there is a need for updated GD
- To identify specific areas where such updated GD is needed

- This advice will support the EU in its work under the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, which addresses the transboundary movement of GMOs

- 2012 EFSA GMO Panel GD for food/feed RA of GM animals (GMAs)



- 2013 EFSA GMO Panel GD for ERA of GMAs



- Directive 2001/18/EC

**DIRECTIVE 2001/18/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of 12 March 2001**

**on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC**

- Directive (EU) 2018/350

**COMMISSION DIRECTIVE (EU) 2018/350**

**of 8 March 2018**

**amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms**



- Creation of *ad hoc* Gene Drive ERA WG

Experts		
Name	Role	Declaration of Interest
BONSALL Michael	Member	Dol 
CRISANTI Andrea	Member	Dol 
FIRBANK Leslie George	Chair	Dol 
MUMFORD John	Member	Dol 
NOGUE Fabien	Member	Dol 
WIMMER Ernst A.	Member	Dol 

Other invitees		
Name	Role	Declaration of Interest
FRIESS Johannes	Hearing Expert	Dol 
GIESE Bernd	Hearing Expert	Dol 

- Series of Gene Drive ERA WG meetings
  - <http://www.efsa.europa.eu/sites/default/files/wgs/gmo/wg-gene-drive-era.pdf>
- Close liaison with GMO Panel

- Two approaches
  - 1-day stakeholder workshop (15 May; Brussels)
    - At the beginning of the process
    - Aim – To collect input from stakeholders and EU Member States on potential environmental risks and means to assess them through a problem formulation exercise
  - Online public consultation
    - At the end of the process
    - Aim – To collect input from the public at large on the draft GMO Panel output

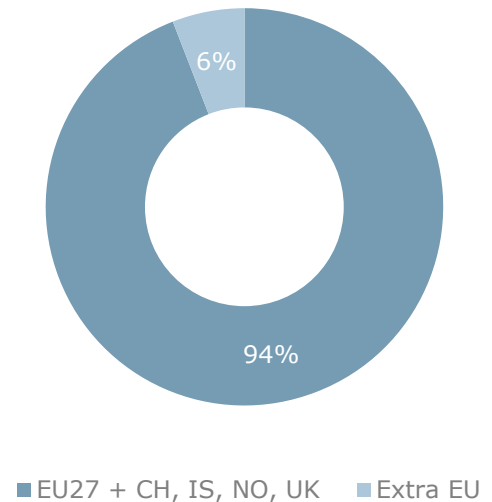
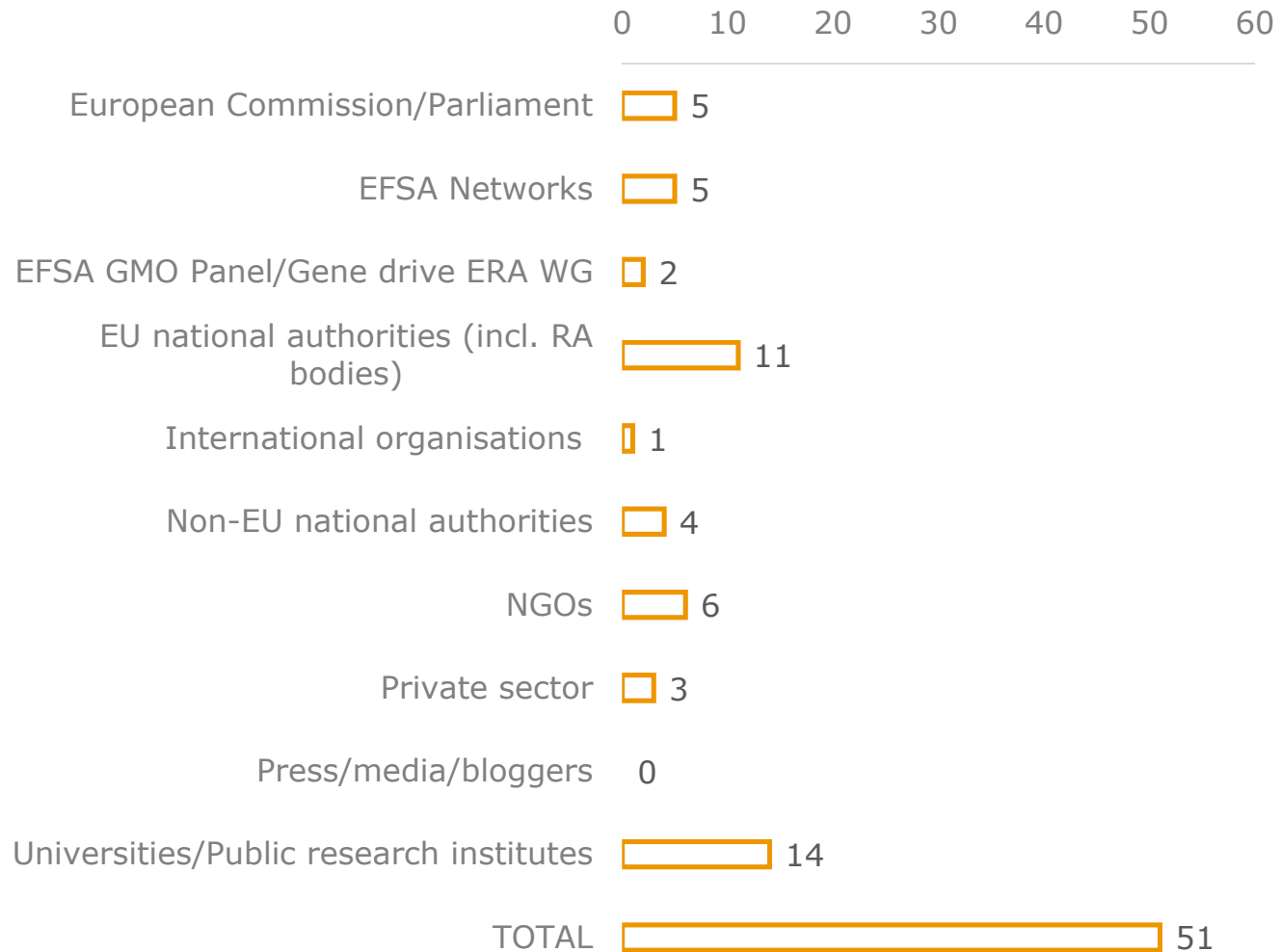
# Stakeholder workshop, Brussels May 2019



The screenshot shows the EFSA website page for an event. The URL is <https://www.efsa.europa.eu/en/events/event/190515>. The page title is "Workshop on the problem formulation for the environmental risk assessment of gene drive modified insects". The event is scheduled for Brussels, Belgium, on 15 May 2019. The main text describes the workshop's purpose: "On 15 May, EFSA met stakeholders and EU Member States to discuss plausible environmental risks associated with the release of gene drive modified insects into the environment. Gene drives consist of genetic elements that can pass traits among sexually reproducing individuals with higher efficiency than expected under Mendelian inheritance." A summary paragraph follows: "This emerging technology has sparked both enthusiasm and concerns. While gene drives could be used to control agricultural pests and invasive species, rescue". On the left, there are social media sharing options for Twitter, LinkedIn, and Facebook, along with a print icon. On the right, under "Subject area", there are two categories: "Environmental risk assessment" and "GMO", both with right-pointing arrows.

- Documents available online
  - Agenda and briefing notes (including abstracts)
  - List of participating stakeholders
  - Presentations

## ■ Audience mix (excluding speakers/chairs/moderators/rapporteurs)



- Morning part
  - Plenary session
    - Series of technical talks to set the scene
    - Moderated panel discussion
- Afternoon part
  - Breakout sessions
    - Two discussion groups
      - Self-sustaining/unrestricted gene drives
        - Disease-spreading insect (→ *Aedes albopictus*)
        - Agricultural pest (→ *Drosophila suzukii*)
  - Plenary session
    - Reporting about breakout sessions
    - Concluding remarks

- Use problem formulation to:
  - Formally devise plausible pathways to harm that describe how a proposed activity could be harmful
  - Formulate risk hypotheses about the likelihood and severity of such events
  - Identify the information that will be useful to test the risk hypotheses
  - Develop a plan to acquire new data for hypothesis testing should tests with existing information be insufficient

# Some of the key issues raised

- Support for problem formulation approach
  - But should it be used to follow all pathways to harm, or just the most plausible?
- Balancing risk and benefit
  - Difference between “impact” and “harm” is quite a grey area
  - Concerns over “naturalness”
  - Balancing certainty and regulatory delay



## ■ Feedback survey – Key figures



New contacts  
**45% of registrants**



No-show rate  
**<10%**



Customer satisfaction  
**80%**



Informative rate  
**95%**

- Outreach was good: 45% of registrants never attended EFSA's events before
- The event was well attended (# 60 with speakers/chairs/moderators/rapporteurs). The no-show rate (<10%) is in line with the average (12%)
- 80% of participants declared that their event experience was good or excellent. The sample is representative due to the high response rate of the survey (68%). The customer satisfaction rate is positive, but lower than the average (95%). The discrepancy is mainly due to a perceived lack of time to address the questions raised during the workshop in an exhaustive manner, too large discussion groups limiting effective interaction, and the aggressive approach of two NGOs
- Despite the short time for a proper discussion, the workshop was effective in enhancing the understanding of the topics discussed. 95% of participants declared that their knowledge increased to good or excellent after the event

## 4. Stakeholder workshop

- Professionally prepared event
  - Helpful briefing notes
  - Participation of relevant experts in the field, including new ones that never engaged with EFSA before
  - Knowledge sharing about gene drive
  - Exposure to problem formulation concept
  - Active participation of stakeholders during the event
  - Networking options
  - Outreach
  - Valuable engagement format
- Heterogeneous audience resulting in various levels of familiarity with the topic and diverse contributions during discussions
  - Better alignment of expectations needed
    - Duration of event
    - Size of discussion groups
    - Moderation role of breakout group discussions



- Support for the approach, as long as the event is used and not just whitewashed over
- Any points raised would have been raised later anyway
- Approach consistent with new legislation on transparency and sustainability of EU risk assessment model in the food chain
- I really enjoyed it

- Next steps
  - Reporting
    - Online
    - Appendix to GMO Panel scientific opinion
      - Points raised by stakeholders
  - In-house discussion
    - Lessons learnt for future (early in the process) stakeholder engagements
      - Format
      - Return on investment ratio
      - Criteria triggering the need for such events

# Thanks to ...

- Scientific project coordinator and main contact point
  - **Yann Devos (EFSA, GMO)**
- Scientific project contributors
  - Ana Martin Camargo (EFSA, GMO)
  - Konstantinos Paraskevopoulos (EFSA, GMO)
  - EFSA's Gene Drive ERA Working Group experts
- Organisational project coordinator
  - Cinzia Percivaldi (EFSA, CORSER)

Stay connected!

Thank you for your attention



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