GMO Network meeting
(18-19 June 2019; Parma)

Update on EFSA's gene drive activities

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Trusted science for safe food

European Food Safety Authority

TOC

1. Mandate

- 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

1. Terms of reference

- 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

1. Terms of reference

- 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

1. Scope

- Clarifications
  - Scoping approach (→ future complementary mandates)
    - Focus on most likely cases moving to practical applications
      - Various gene drives, technical approaches and strategies in insects
        - Desired outcome: suppression vs. replacement
        - Ability of trait to establish/spread: self-sustaining vs. self-limiting drives
    - Focus on molecular characterisation (MC) and environmental risk assessment (ERA)

1. Scope

- Clarifications
  - Do not develop new RA GD for GDMOs at present
  - Use problem formulation to frame the work
  - Consider relevant comparators

1. Reference documents

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

- 2013 EFSA GMO Panel GD for ERA of GMAs

1. Reference documents

- 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

2. Working group

- Creation of *ad hoc* Gene Drive ERA WG

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

- 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

3. Consultations

- 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

4. Stakeholder workshop

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

4. Stakeholder workshop

- 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

Gene drive modified insects: hopes, fears, gene drive systems and the problem formulation concept

Fred Gould
North Carolina State University

Problem formulation consultations for gene drive modified mosquitoes designed to reduce malaria transmission in Africa

Stephanie James

EFSA, Brussels
May 15 2019

FNIH
Foundation for the National Institutes of Health

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Economic Affairs,
Education and Research EAER

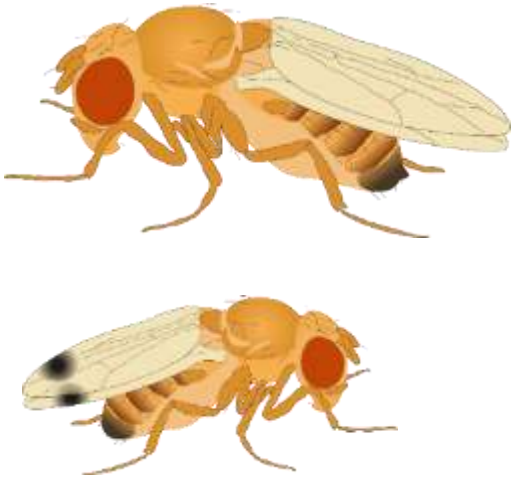
Agroscope

Problem formulation for the environmental risk assessment of gene drive modified *Drosophila suzukii*

Jörg Romeis, Jana Collatz
Agroscope, Zurich, Switzerland

Debora CM Glandorf
National Institute of Health and the Environment
The Netherlands

Michael B Bonsall
Oxford University, UK



Agroscope

perseus

Experiences with gene drives and risk assessment implications Opinion of the Netherlands Commission on Genetic Modification (COGEM)

EFSA Workshop

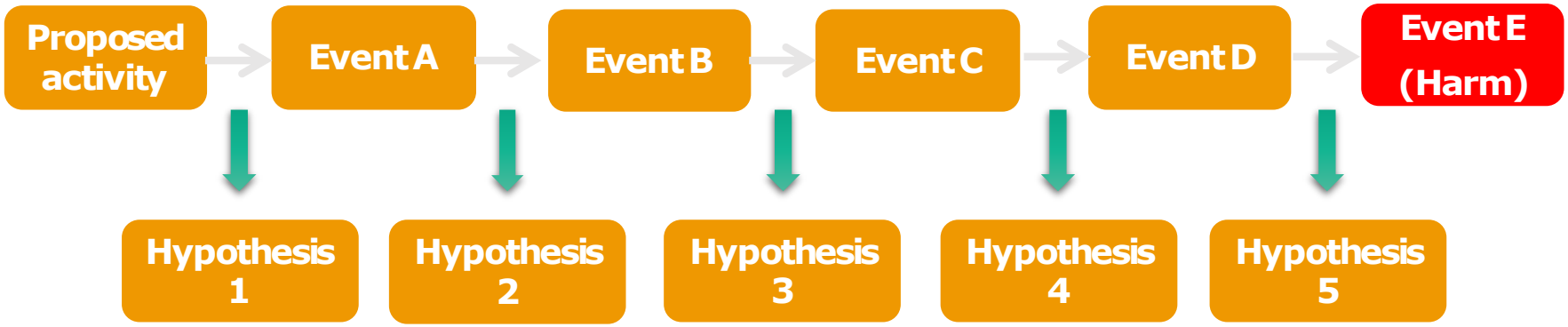
Brussels, Belgium – 15 May 2019

Marjan Bovers, Greet Smets & Patrick Rüdelsheim

4. Stakeholder workshop

- Discussion groups
  - 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

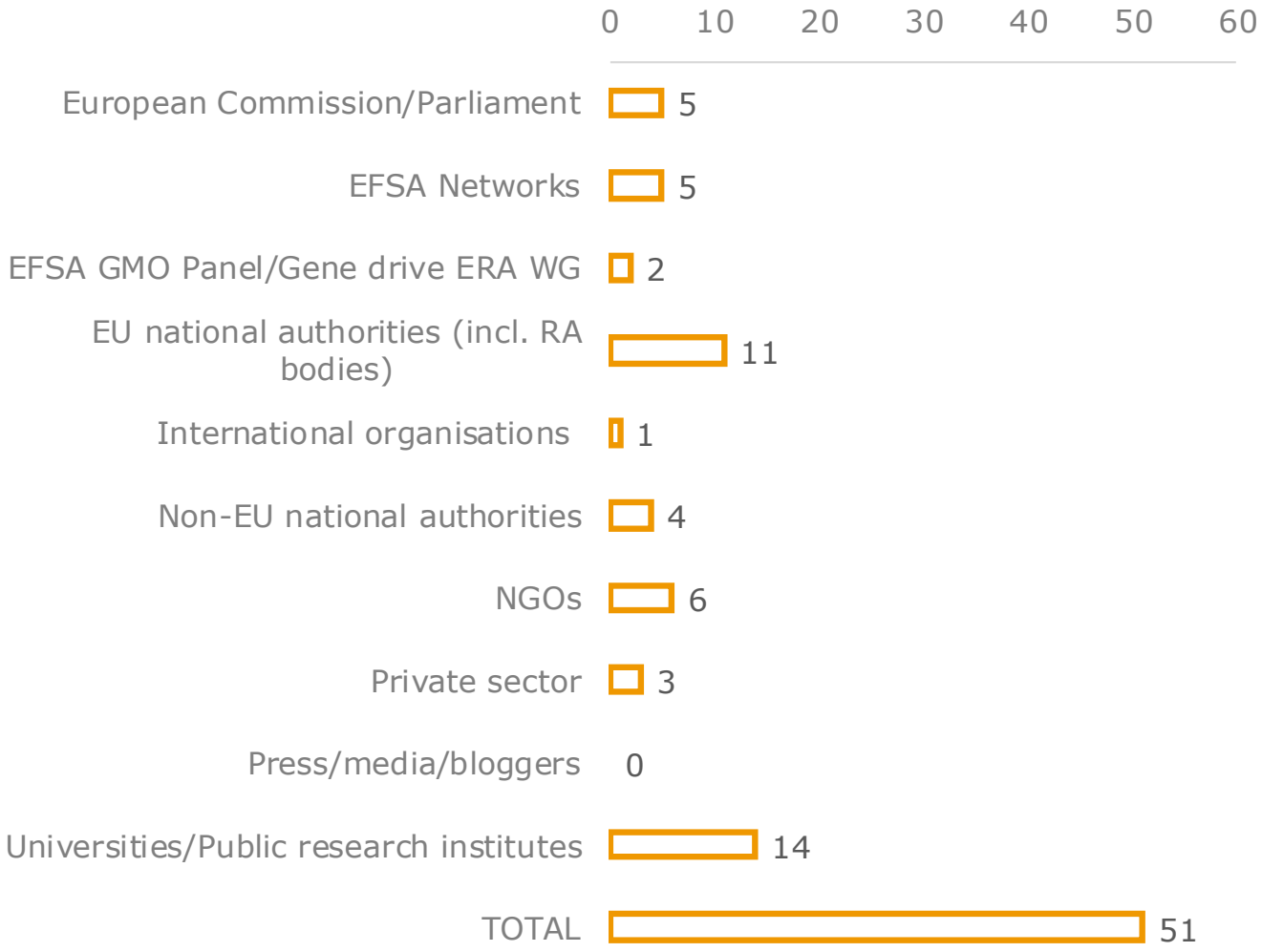
4. Stakeholder workshop

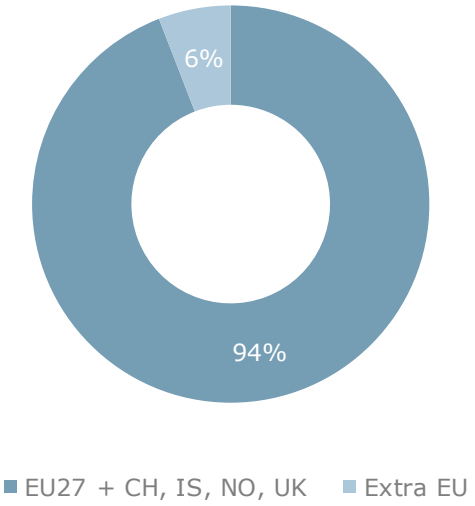


Plausible pathway to harm	Testable risk hypotheses (compared with GM insects)	Relevant information to test risk hypotheses	Means to gather relevant information (and feasibility)
Protection goal: …			
Step1			
Step2			
Step3			
Step4			
Step5			
Step6			
Step7			
Step8			
Step9			
Harm: …			

4. Stakeholder workshop

- Audience mix (excluding speakers/chairs/moderators/rapporteurs)





4. Stakeholder workshop

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
- Duration of event too short for set goals
- Discussion groups perhaps too large
- Stronger moderation of breakout group discussions needed
- Better alignment of expectations needed
- …

4. Stakeholder workshop

- Next steps
  - Reporting
    - Online
      - Already published
    - Appendix to GMO Panel scientific opinion
      - Points raised by stakeholders (tabular format)
  - 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

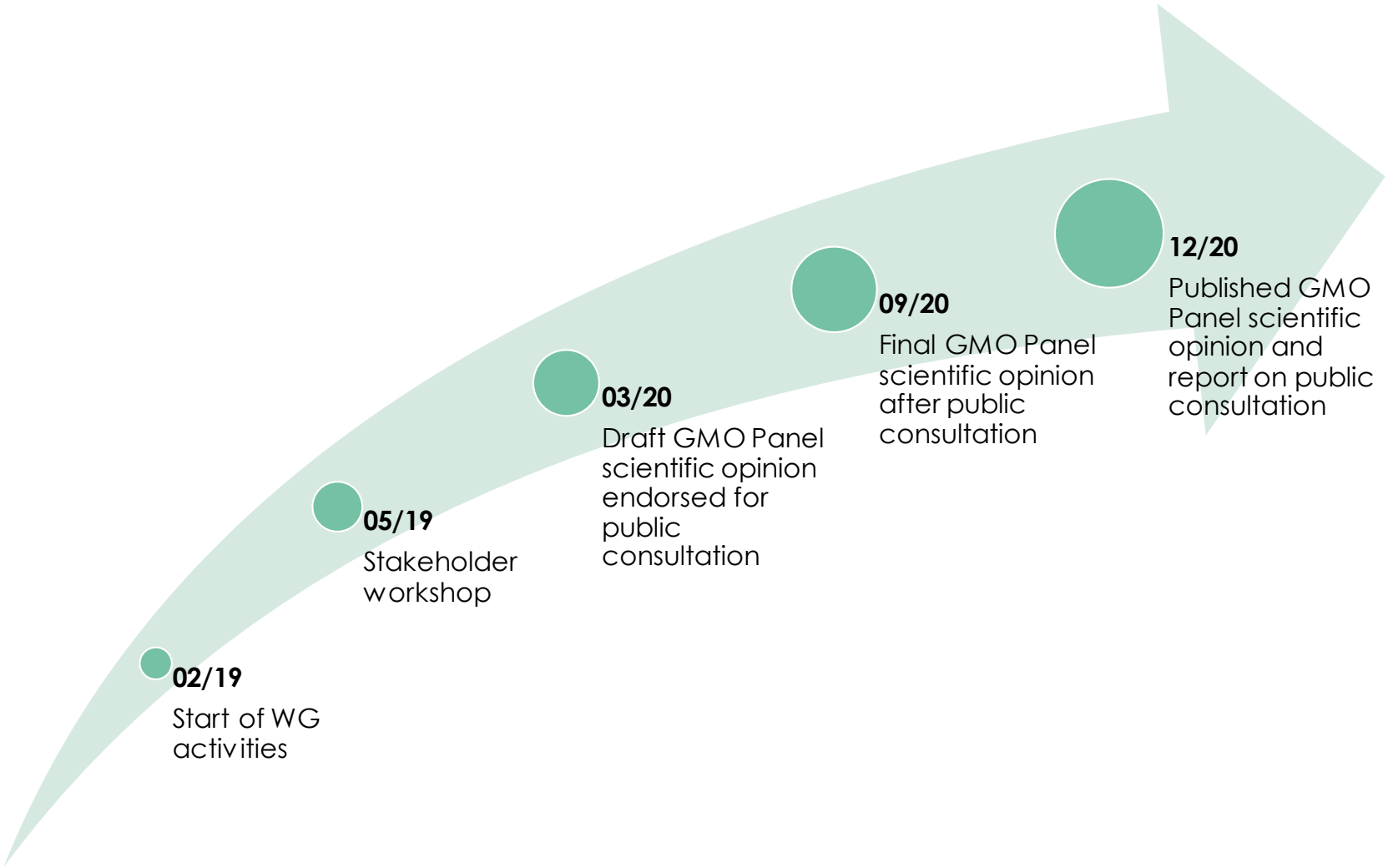
4. Stakeholder workshop

- Acknowledgements
  - Organisational project coordinator
    - Cinzia Percivaldi (EFSA, CORSER)
  - Scientific project coordinator
    - Yann Devos (EFSA, GMO)
  - Scientific project contributors
    - Ana Martin Camargo (EFSA, GMO)
    - EFSA's Gene Drive ERA Working Group experts

5. Contact points

- Project coordinator
  - Yann Devos (EFSA, GMO)
- Project contributors
  - MC
    - Konstantinos Paraskevopoulos (EFSA, GMO)
  - ERA
    - Ana Martin Camargo (EFSA, GMO)
    - Fernando Álvarez (EFSA, GMO)

6. Conclusion



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