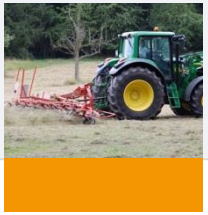
GRACE

GMO Risk Assessment and Communication of Evidence

Human Health | Environment | Socio-Economy





Implementing Open Science in GMO Risk Research Experiences and Challenges from a Practioner's Perspective

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4S/EASST Conference
31 Aug - 3 Sept 2016, Barcelona
Session "Open Science in Practice", 1 Sept 2016, 9:00 am - 10:30 am

SEVENTH FRAMEWORK PROGRAMME

Context

- **Long standing controversy** in the EU on animal feeding studies with GM food/feed for safety assessment on
  - Conduct
  - Interpret
  - Value and mandatory requirement
- EU-funded project GRACE (2012-2015)
  - *Conducted model-type animal studies and* ***tested designs and analyses*** for certain types of animal feeding studies
  - ***Explored the use*** of other laboratory studies not requiring animals
  - ***Developed guidance and advice to the European Commission***
    - for conducting and analysing these studies
    - on the value of these studies for GM food/feed risk assessment

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Study says genetically modified corn causes tumors, but other scientists skeptical about research

This image from a study in a Seralini et al study in the journal, Food and Chemical Toxicology, shows female rats with mammary tumors that purportedly grew after being fed genetically modified food with and without Roundup herbicide. / FOOD AND CHEMICAL TOXICOLOGY

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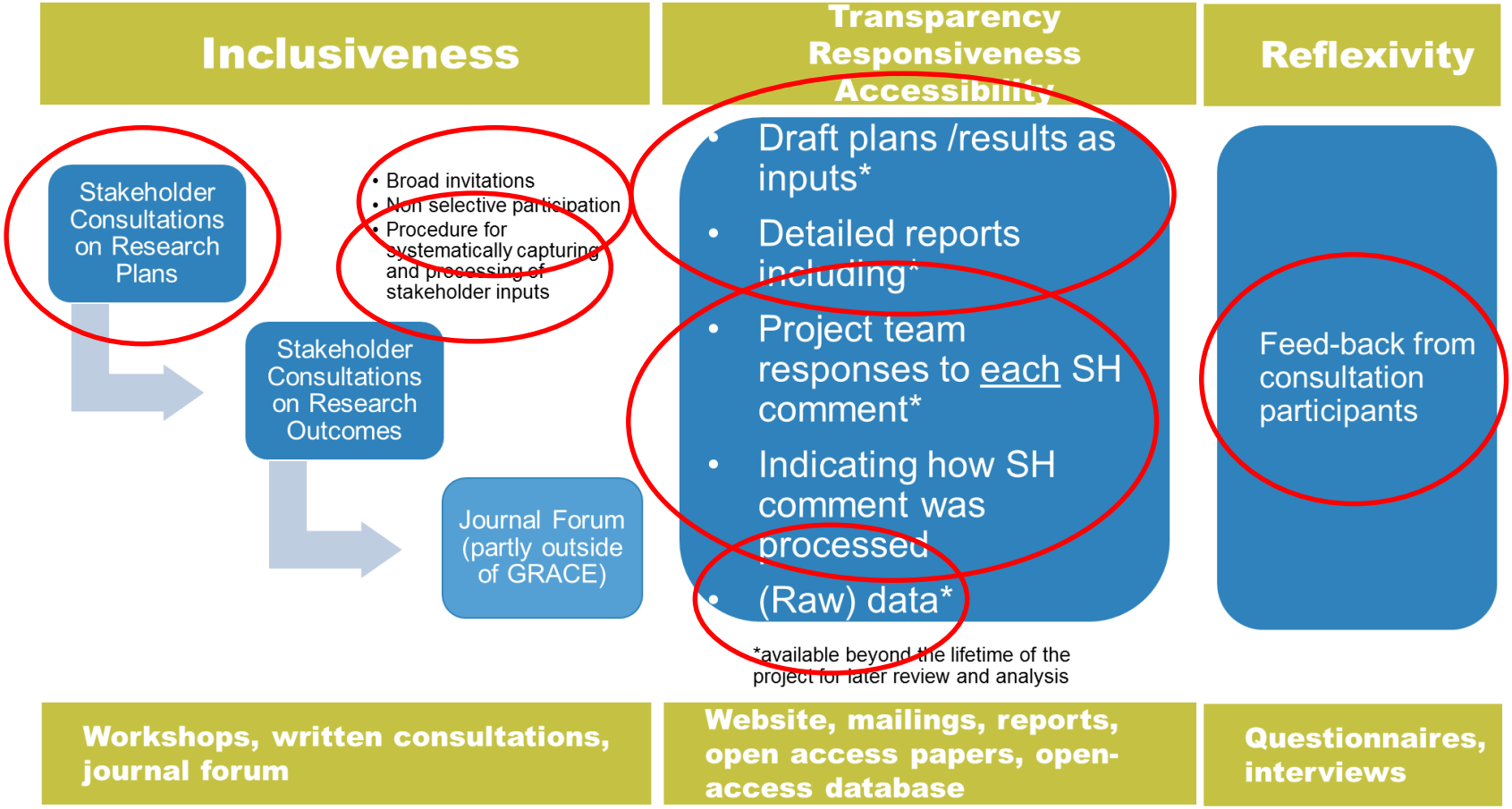
(CBS News) A French study that supposedly shows that mice who ate genetically modified corn sprayed with weed killer were more likely to develop tumors, organ damage and die early is becoming a polarizing debate among researchers.

The two-year study, which was published on Sept. 19 in Food and Chemical Toxicology, revealed that mice who were fed either a diet of Monsanto's genetically modified maize sprayed with Roundup - the company's brand of weed killer - or drank water with levels of Roundup similar to what is found in U.S. tap water were much more likely to die and at an earlier age, in addition to other health problems.

Open Science Approach of GRACE



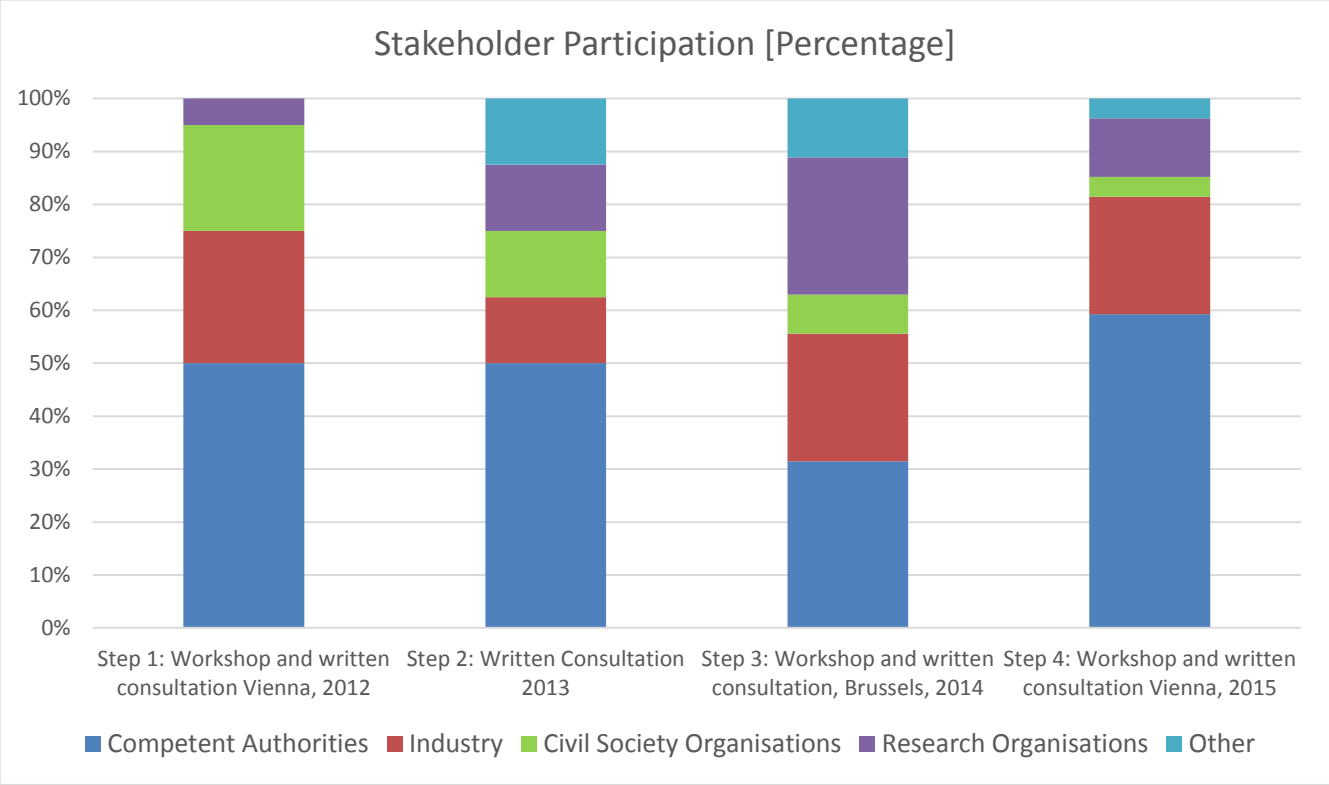
EXPERIENCES

Participation & Responses

Consultation Subject	External Stakeholder Participants	Written Comments (Total)	Comments Adopted[e]	Comments Not Adopted[f]	Other[g]
Planning[a]	40	147	62	82	3
Planning[b]	8	240	88	118	34
Outcome[c]	54	86	26	17	43
Outcome[d]	27	103	22	14	67
Total		576	198	231	147

a) Workshop and written consultation on 90-day subchronic study with animals and on alternative studies
b) Written consultation on 1-year and 90-day longitudinal study with animals
c) Workshop and written consultation on the outcome of the 90-day feeding study
d) Workshop and written consultation on 1-year and 90-day longitudinal study with animals as well as on overall conclusions and recommendations
e) Adopted/not adopted in study plan or considered/not considered in interpreting, concluding and recommendation drawing.
f) Includes comments indicated as general comments not needing a response, comments where the processing status remained unclear and comments that were not responded to. The number of general comments not needing a response increased considerable in later stages of the project.
g) 23 responses were processed by the project team by adding explanations to the final study plans.

Stakeholder Participation



Stakeholder participation over time in number of participants and percentage. Only main steps are considered. The category "other" includes international organisations, and EC or national governmental organisations other than CAs etc.

OBSERVATIONS AND RECOMENDATIONS

Participant's Perceptions

- **Transparency and Accessibility**
  - Information and data accessible and clear
  - Documentation of stakeholder inputs and team responses
- **Inclusiveness**
  - Upstream engagement
  - Stakeholder did shape the research process – but limitations perceived by SH participants
- **Responsiveness**
  - Positively perceived but documentations only checked by a small participant group – indication for transparency overload?
- **Other**
  - Indications for improving trust and mutual learnings

Open Science Challenges Identified

- For research funders and managers
  - **Too little flexibility** and high organizational hurdles for changes in research projects in terms of tasks, timelines, budget, process
  - **IPR and CBI** can hamper publicly funded research, e.g.
    - Impedes access to research material (plant seeds) and knowledge generated by companies (animal feeding study data)
- For scientists
  - Could **discourage scientists** by
    - interfering with standard scientific practice, e.g. jeopardize publications in scientific journals
    - making them vulnerable to criticism when exposing preliminary plans and results to an extended peer review
  - **High workload** with **no/unclear scientific credentials**
- For stakeholders
  - **Information /consultation overload**
  - **Workload** and **resource needs**

Observations related to Open Science in Controversial Topics

- Openness and dialog seems to work if a 'protected space' and is provided…
  - By limiting openness (no journalists)
- and if scope is confined to "more technical and scientific" aspects
  - Contextual factors could not be (properly) addressed, e.g.
    - Independence of project scientists
      - Resulted in an exchange of press releases and open letters
    - Fundamental differences in interpreting GMO risk assessment needs

Recommendations

- Open science and public engagement on GMO/ controversial topics would benefit from
  - More flexibility in research plans, timeline, and (ideally also) budgets
  - Paying more attention to expectation management - being proportionate to the flexibility to accommodate inputs
  - Establishing rules and procedures to alleviate discomfort of scientists in disclosing preliminary results
  - (More) resource allocation to stakeholders
  - Complementary fora and processes to address contextual factors

Thank You

For more details on GRACE: http://www.grace-fp7.eu/

Follow-up project: https://www.g-twyst.eu/

Acknowledgment

Stakeholder Engagement Team

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Monica Racovita

Patrick Rüdelsheim

Greet Smets

Armin Spök

Stakeholders

> 95 representatives from 17 EEA Member States, the EU-level, the USA and international organisations

Wider GRACE Team

Wendy Craig
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Pablo Steinberg
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All other GRACE team members