How to maintain a robust and objective scientific dialogue between government and stakeholder experts?

An NGO Perspective

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Workshop: "*What does the future hold for harmonised human health risk assessment of plant protection products*?"

Berlin, BfR premises, 20th November 2017

EU Law

Lisbon Treaty (2009)

- Open decision making
- Citizens participation
- Transparency
- Good administration

Survey – Questionnaire

PAN EUROPE SURVEY – DIALOGUE IN PESTICIDES RISK ASSESSMENT

Pesticide Action Network Europe

NGO Survey – PAN Europe

Name of NGO:

Person to contact and position:

Deadline: As soon as possible and *no later than 15th of November*

Background:

PAN Europe has been invited at a workshop to give a presentation, on behalf of civil society, concerning governments' dialogue with stakeholders during the risk assessment procedure of pesticides (plant protection products).

The workshop is called "What does the future hold for harmonised human health risk assessment of plant protection products?". It is organised by the European Commission, the German Federal Ministry of Food and Agriculture, and the German Federal Institute for Risk Assessment (BfR) on 23-24th of November 2017 and will take place at BfR's premises in Berlin.

In order to give a presentation that reflects the position of all NGOs active in this field, we have prepared a questionnaire for you to fill in, as your opinion is **VERY important.**

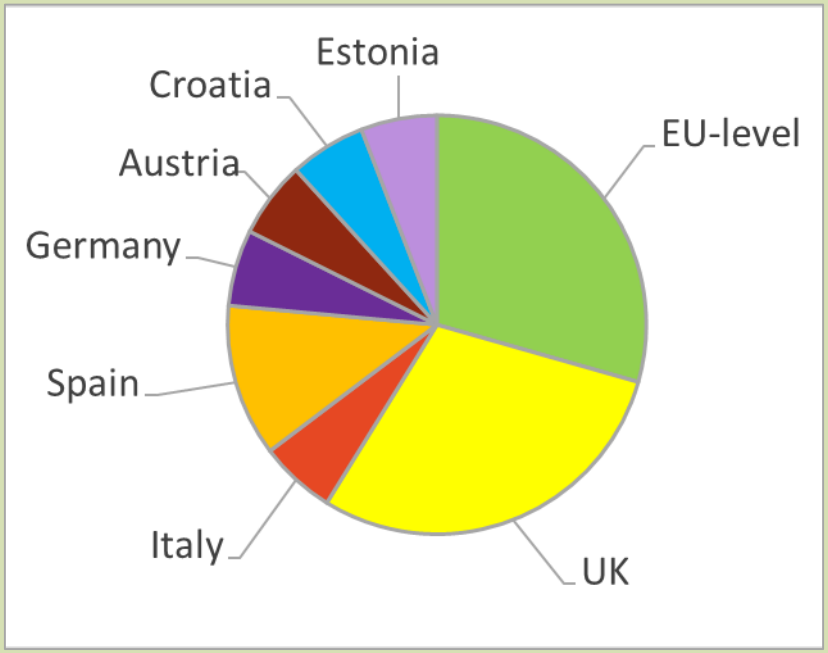
The presentation is under session: **Enhancement of the scientific dialogue between the experts**

The title of the presentation is:

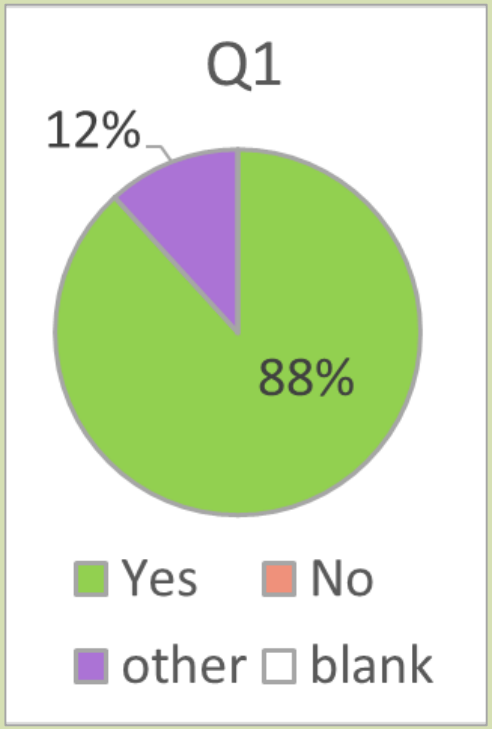
"How to maintain a robust and objective scientific dialogue between government and stakeholder experts (during the risk assessment procedure of pesticides)? - An NGO perspective".

By 'government' they are referring to Member State Authorities but this is also applicable for members of the European Commission and European Food Safety Authority (EFSA) to some extent.

- 10 Questions
- 17 NGO replies

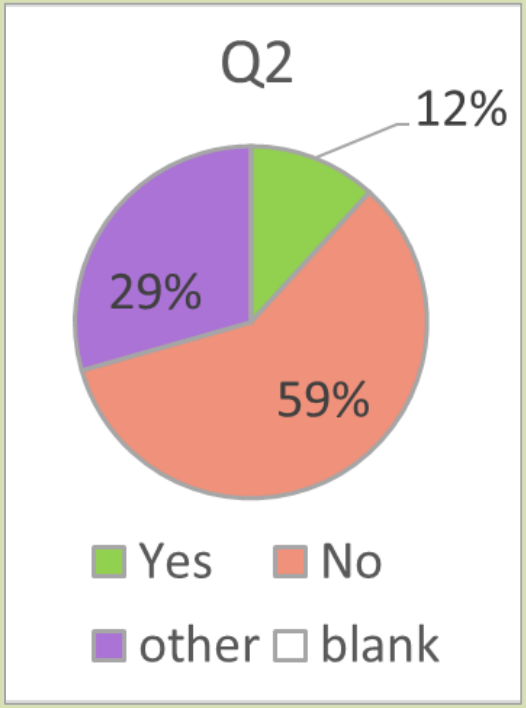


Survey – Question 1



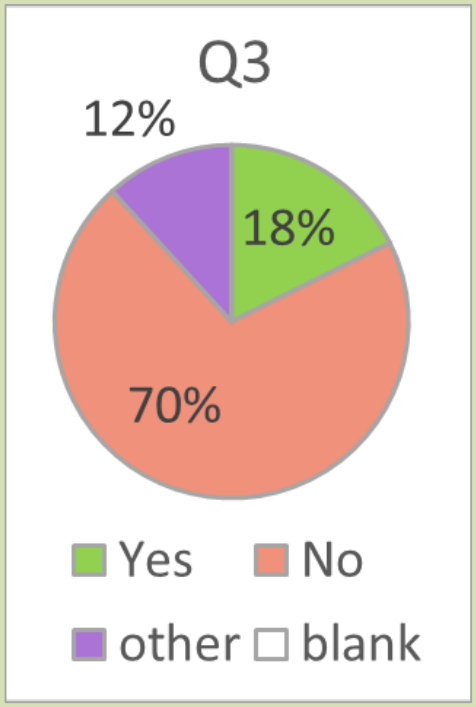
"Do you agree that governments should consult with stakeholders (industry and NGOs) during the risk assessment procedure of plant protection products (PPPs)?"

Survey – Question 2



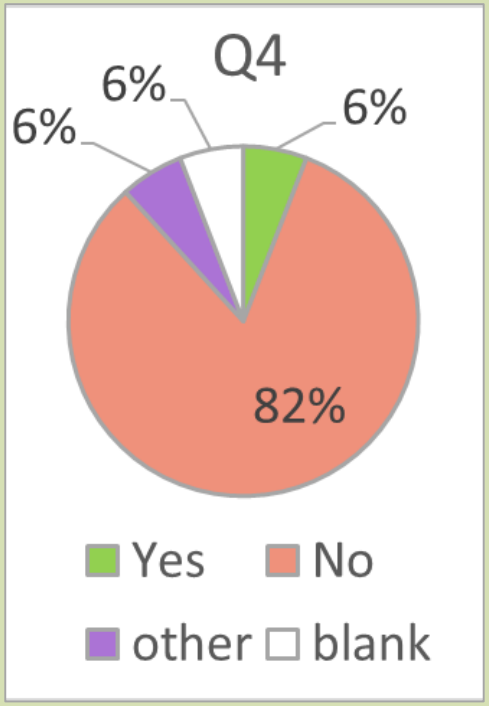
"In your opinion, do you consider that there is currently a scientific dialogue between governments and NGOs during the risk assessment procedure of PPPs?"

Survey – Question 3



"Do you consider that your NGO is engaged in a dialogue with government during the procedure of pesticide risk assessment?"

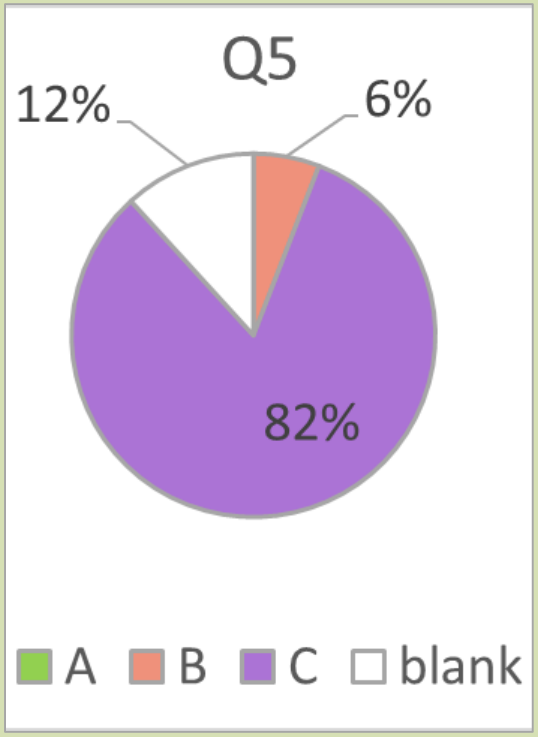
Survey – Question 4



"In your perspective is the current dialogue with government and stakeholders (industry and NGOs) transparent?"*

*Transparency: The general public can find out how many exchanges have taken place and when, the content and how the governments have responded.

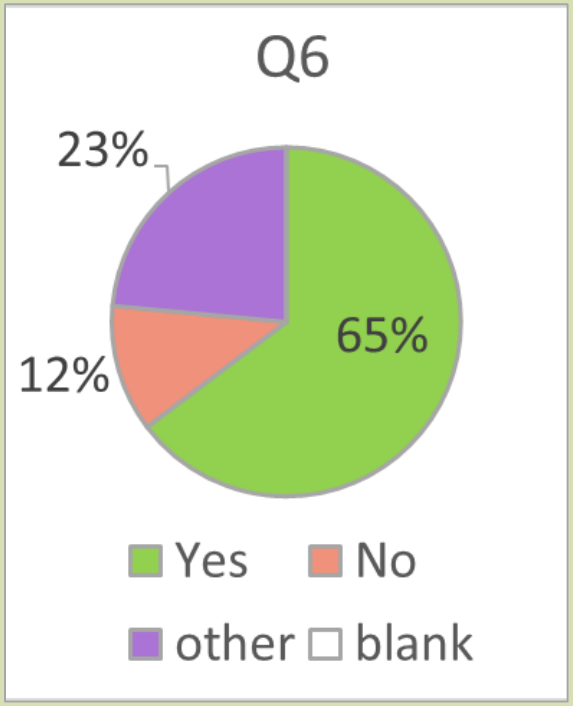
Survey – Question 5



"In your opinion, in which phase should stakeholders (industry and NGOs) participate in the risk assessment of PPPs?"

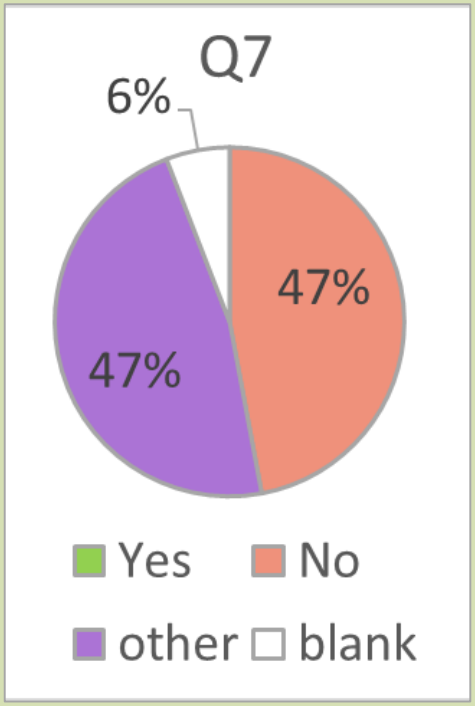
- *A: During DAR/RAR*
- *B: During EFSA peer-review*
- *C: During both phases*

Survey – Question 6



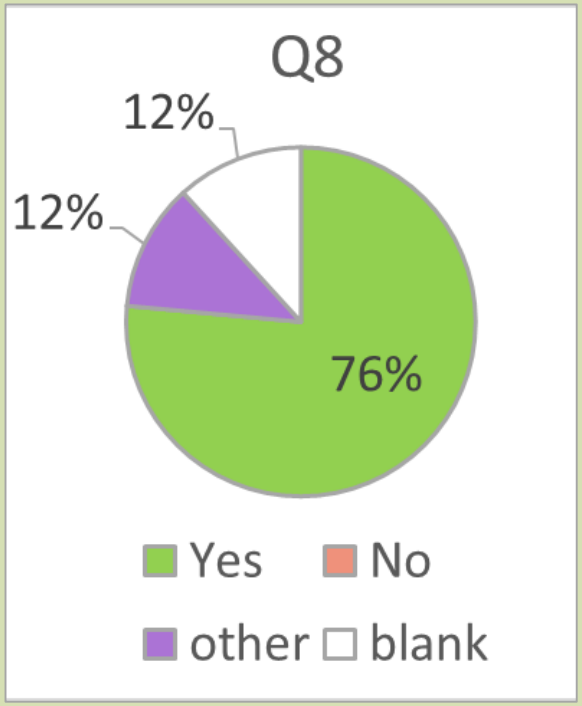
"In your perspective, should stakeholders (NGOs and industry) participate as observers in SCoPAFF, where the pesticide dossiers are discussed with Member States and decisions are taken?

Survey – Question 7



*"In your experience, do you feel that governments take into account **your opinion (NGO)**, during the pesticide risk assessment procedure?*

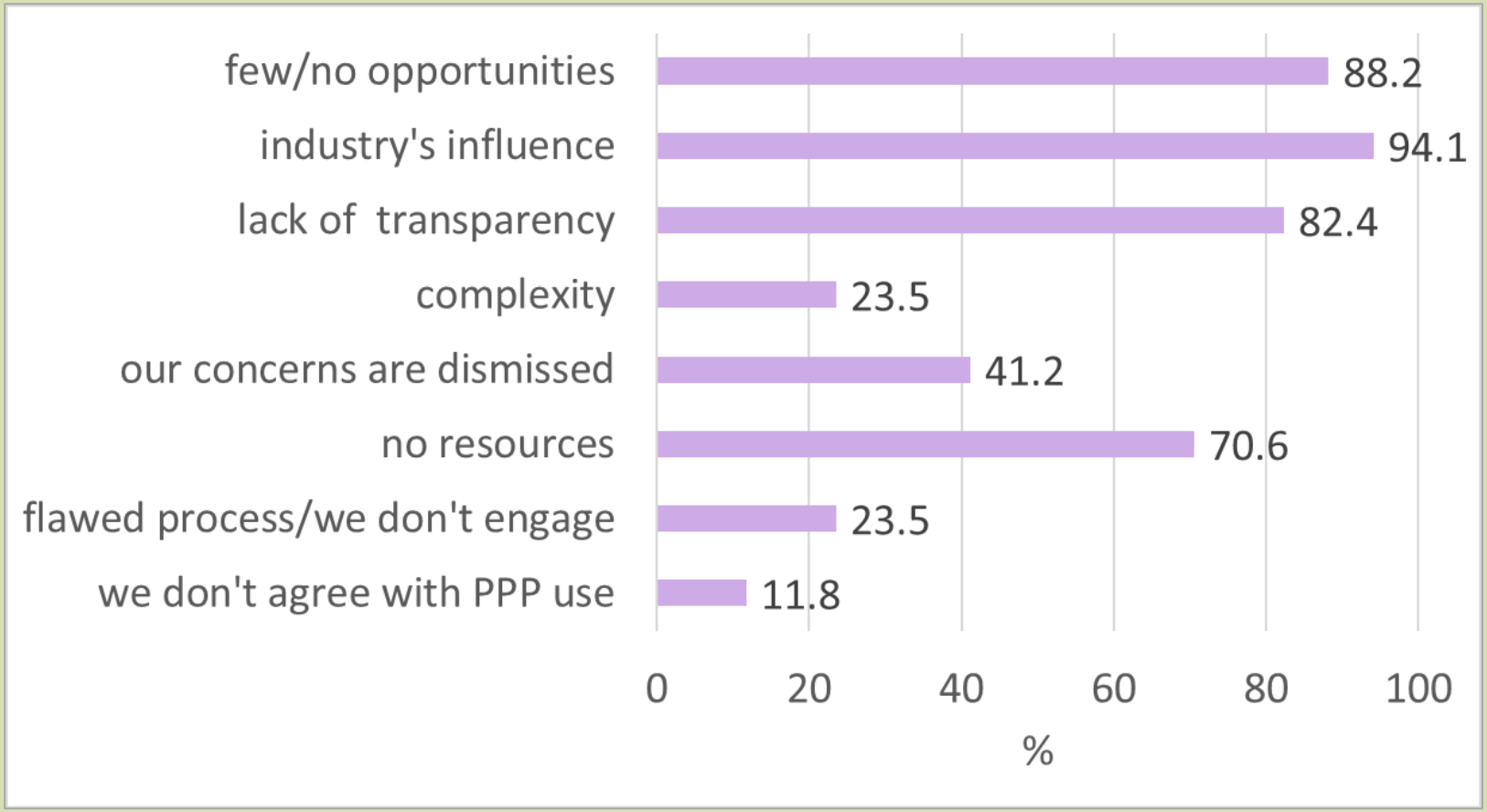
Survey – Question 8



*"In your experience, do you feel that governments take into account the opinion of **industry stakeholders**, during the pesticide risk assessment procedure?"*

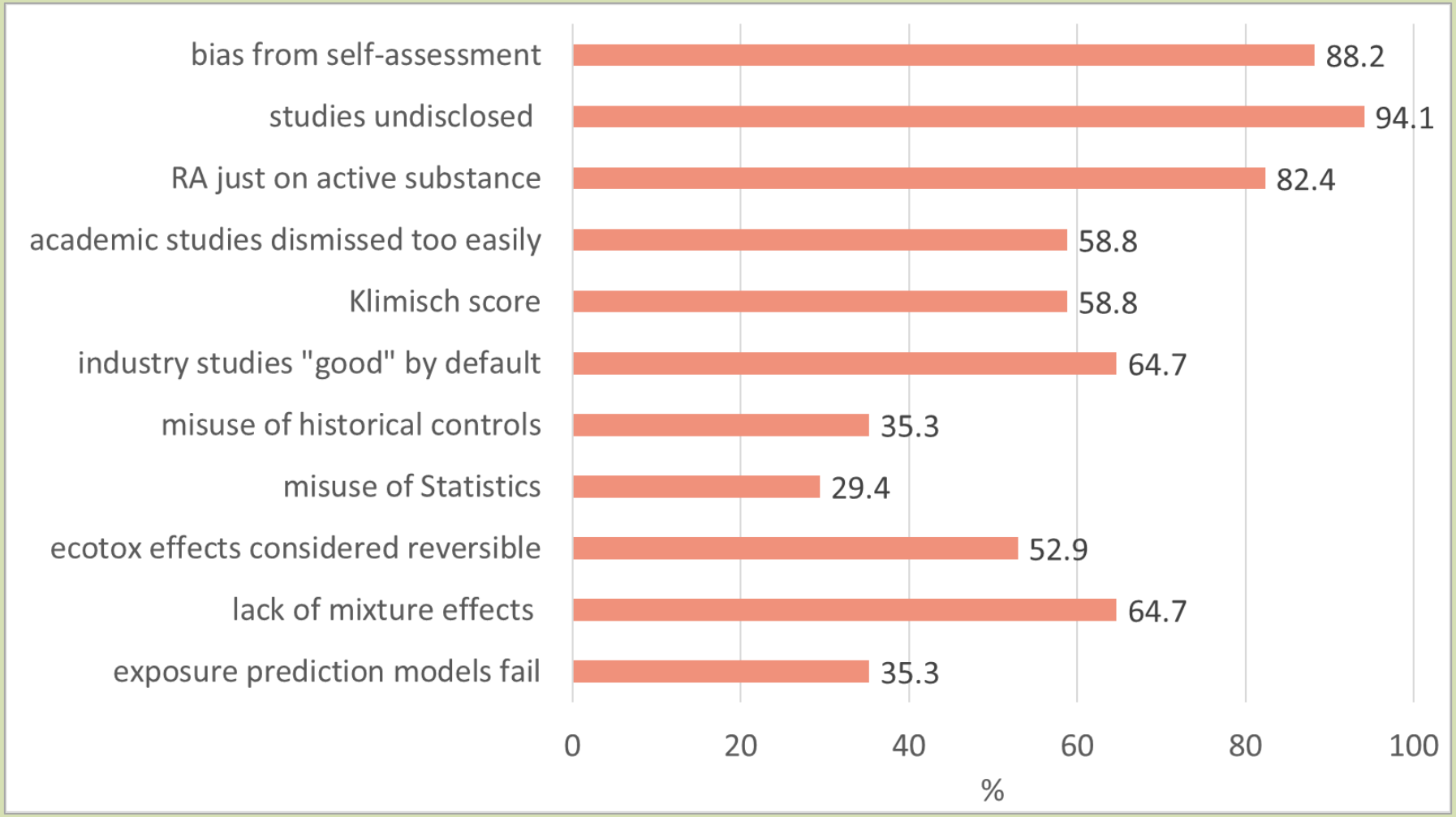
Survey – Question 9

"In your perspective what are the main limitations (or flaws) for a robust and objective dialogue between government and NGOs during the process of pesticide risk assessment?"



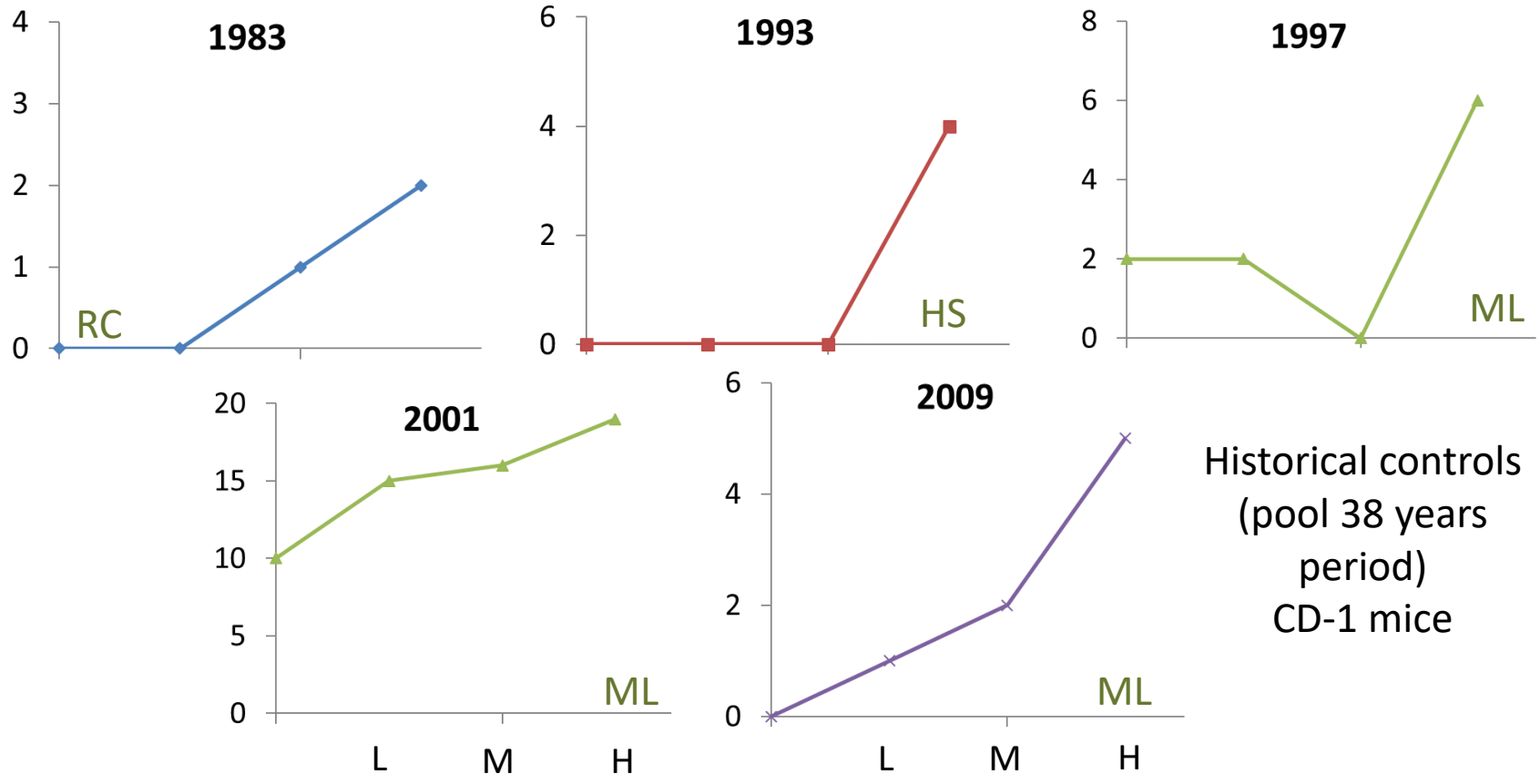
Survey – Question 10

"What do you think are the main limitations (or flaws) currently in the pesticide risk assessment?



An example - Glyphosate

- Carcinogenicity
  - OECD TGs, adult animals, high dose range (810 – 4841 mg/kg)
  - Tumours in 5 mice studies – after revision significant



Survey Highlights - proposals

- Increase transparency throughout the process and reduce complexity
  - Clear reporting & scientific justification with proof, publish industry-sponsored studies, use independent scientific literature, eliminate data gaps, use systematic review, apply the precautionary principle
- Involve experts from the civil society and academia:
  - Workshops, trainings, regular meetings, briefings
  - Consider the limited resources
- Reduce the involvement of industry in the assessment of its own products
  - RA should be based on the work of independent experts

Is RA missing the forest for the trees?

- EU Regulation 1107/2009

*"The purpose of this Regulation is to ensure **a high level of protection of both human and animal health and the environment** and at the same time to safeguard the competitiveness of Community agriculture. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The **precautionary principle** should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market **do not have any harmful effect** on human or animal health or any unacceptable effects on the environment."*

Relevance

Reliability

- Reliability
  - “Free from bias”
  - “Risk of bias” at all levels including financial bias
    - Design (housing, controls), performance, analysis, modifications, reporting, statistics
  - GLP does not guarantee scientific quality

Future of Risk Assessment

- Systematic review
- Integration of all lines of evidence (Weight of Evidence):
  - In silico, in vivo, in vitro, epidemiology
  - Studies on products, other adverse effects than data requirements (obesity, diabetes, brain function), data gaps
  - Include several independent reviewers
  - Highlight uncertainties for further research and regulatory actions

Integration of data – WoE example

Industry-sponsored studies
(OECD TG protocol)

Non-sensitive for low doses and latent effects, limited endpoints,
high risk of bias due to conflict of interest

Peer-reviewed literature studies
(non OECD TG protocols)

Low-dose exposures, non-monotonic, real-life exposures, additional endpoints, effects of mixtures, latent effects, mechanistic data

Thank you!

Pesticide Action Network Europe