

Presentation of the White Paper

A WHITE PAPER

ENSURING A HIGHER LEVEL OF PROTECTION FROM PESTICIDES IN EUROPE

THE PROBLEMS WITH CURRENT PESTICIDE RISK ASSESSMENT

PROCEDURES IN THE EU – AND PROPOSED SOLUTIONS

DG Sante; February 12th 2019

CITIZENS FOR SCIENCE IN PESTICIDE REGULATION - A EUROPEAN COALITION

- A. **Prioritise public health, the environment and sustainable agriculture -**
- B. **Ensure that decision makers rely on data that is complete, public, up to date and free from industrial bias**
- B. **Enable decision makers, civil society and the scientific community to scrutinise the integrity and effectiveness of European pesticide policy**



More than 130 NGOs and institutions



Session 1	Session 2	Session 3	Session 4
<p>Improving scientific assessment</p> <p>Points:</p> <p>2.1. Test methodologies are outdated and testing is incomplete</p> <p>2.5. Peer-reviewed scientific literature is used in a limited, biased, and unintegrated way</p> <p>2.6. Scientific evidence for adverse effects is frequently dismissed for unscientific and non-transparent reasons</p> <p>2.9. Weight of evidence is misused</p>	<p>Improving the implementation of legislative requirements</p> <p>Points:</p> <p>2.7. Toxicity of pesticide formulations is not addressed</p> <p>2.8. Toxicity of pesticide mixtures is not addressed</p> <p>1.9. There is no meaningful post- authorisation monitoring</p>	<p>Improving transparency and independence</p> <p>Points:</p> <p>1.1. Safety testing for risk assessment is carried out by the company that stands to profit from a favourable assessment</p> <p>1.2. Lack of transparency in reporting of animal studies</p> <p>1.3. Lack of transparency of industry studies</p> <p>1.4. Conflicts of interest in EFSA and national authorities</p> <p>1.5. Conflicts of interest in risk assessment methodology design</p> <p>1.8. Industry evaluates and prepares its own risk assessment methodologies</p> <p>1.6. There is a reported shortage of independent experts to carry out risk assessment</p>	<p>Improving risk management and endorse the precautionary principle</p> <p>Points:</p> <p>1.7. Current risk assessment policies prioritize industry interests, rather than human and animal health and the environment</p> <p>2.2. Incomplete dossiers and assessment reports are wrongly accepted</p> <p>2.3. Harmful pesticides continue to be authorised in the EU without restrictions</p> <p>2.4. In some cases, the RMS takes the applicant's assessment of the evidence at face value</p>

Violation of Article 4 of 1107/2009

- 1107/2009 – Article 4:
- only be approved, if ... in accordance with the **data requirements:**

- 283/2013 (data requirements)
- A carcinogenicity study shall be conducted using rat.
- A second carcinogenicity shall be conducted using mouse.

Phosmet „dilution“ of assessment

- Approval 30 Sept 2017, extended until 31 July 2018/ 31 July 2019

DAR (2005, p. 25):

RAT study: „... study carried out in rats **was not accepted** due to high mortality“

DAR (2005, p. 174):

RAT study: „... there was no treatment related increase in tumor incidence. However the **relevance** of this study **was limited** ...“

Mouse study: significant **↑** in tumor incidence, but dismissed with „historical control data“ (not presented)

„Based on all available information of Phosmet, **there is no evidence of carcinogenicity**“

Neglect and misuse of „Weight of evidence“ (WoE):

- **Neglect**

- Renewal of market approval without appropriate review of current scientific knowledge.

- **Misuse of the term**

- Failure to apply an **integrated** WoE (results of regulatory vs. published studies)
- „Creating“ a WoE in violation of OECD guidance (historical control data)

Long-term toxicity of formulations and pesticide mixtures

1/ The toxicity of some pesticides (e.g. glyphosate-based herbicides) is due to the co-formulants and not to their active principles.

Mesnager et al., 2018, *Front. Public Health* 5:361

Proposed solution: Improved evaluation of formulated products toxicity

2/ Mixtures of pesticides (e.g. triazole fungicides) interact to increase the toxic potential of other pesticides

In laboratory animals: Kortenkamp A, Faust M. *Science Magazine*. 2018. 361: 224- 226

In bees: Colin et al., *Pest Manag. Sci.*, 36 (1992), pp. 115-119,

Proposed solution: Prioritize the testing of mixtures / Use safety factors

3/ Residential proximity to agricultural pesticides during pregnancy is associated with neurodevelopmental disorders

Shelton et al., *Environ Health Perspect.* 2014 Oct;122(10):1103-9

Proposed solution: Implement routine pesticide exposure biomonitoring and epidemiological studies