SEPT 18

IS GLYPHOSATE SAFE FOR HEALTH AND THE ENVIRONMENT?

2 PM - 4 PM

European Parliament
Brussels
SPAAK 7C50

A PAN Europe event co-organised by
Christophe Clergeau and Jutta Paulus

S&D

LES VERTS/ALE au Parlement européen

Pesticide Action Network Europe

European Citizens call for a ban

- **2017- European Citizens' Initiative:** over 1 million citizens calling to ban glyphosate

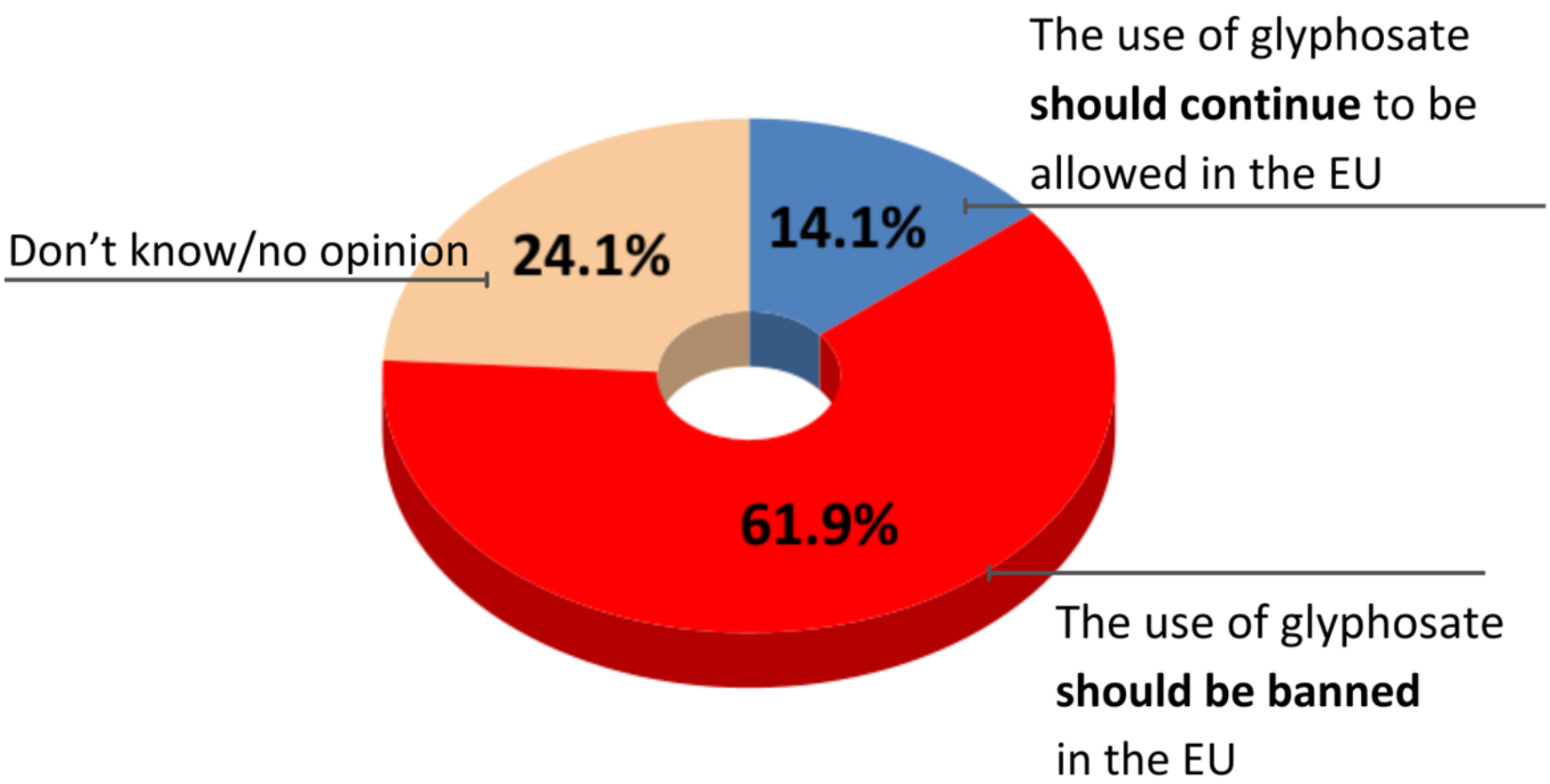
2023 question (IPSOS poll – 6 countries)

One of the most commonly-used pesticides in the EU is called glyphosate (e.g. Roundup). Experts currently disagree on the health risks associated with glyphosate. One public authority has classified glyphosate as a "probably carcinogenic" (i.e. that it may cause cancer in humans). Another public authority has classified glyphosate as "probably not carcinogenic". Given these different opinions, which of the following comes closest to your own view?

- *The use of glyphosate should continue to be allowed in the EU*
- *The use of glyphosate should be banned in the EU*

European Citizens calling for a ban

Denmark, France, Germany, Poland, Romania and Spain



Source: https://www.pan-europe.info/press-releases/2023/09/european-citizens-support-eu-ban-glyphosate

Is glyphosate safe for health & the environment?

A civil society perspective

Pesticide Action Network (PAN) Europe
Dr. Angeliki Lyssimachou
Head of Science and Policy

18th September 2023, European Parliament

The EU law

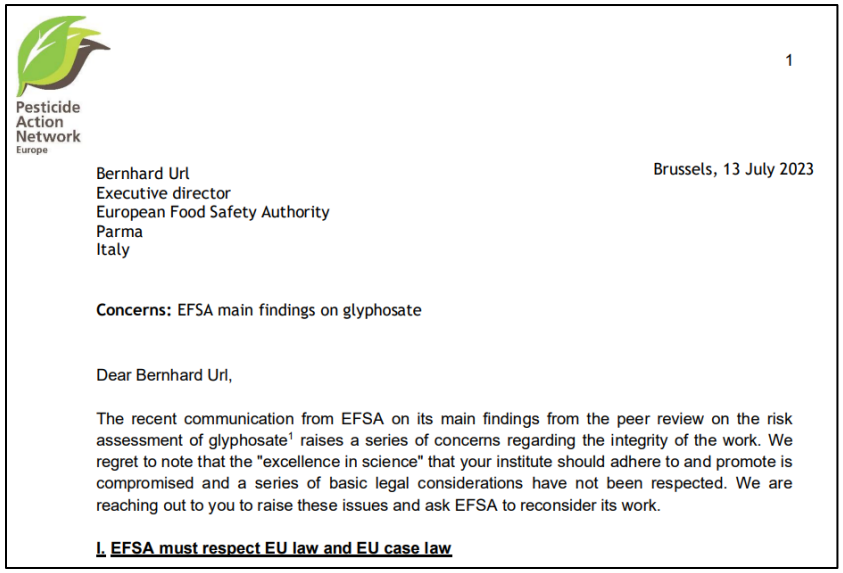
Regulation (EC) 1107/2009 (on plant protection products):

- To ensure a high level of **protection of human and animal health, and the environment** (hazard cut-off criteria: CMRs, EDC, PBT etc)
- Pay attention to the **protection of vulnerable groups** (children) & impact on **biodiversity and ecosystems**
- Industry must demonstrate that **substances or products (or residues)** cause no adverse effects
- Assessment must be **independent, objective and transparent** in the light of **current, scientific and technical knowledge**.
- Apply the **precautionary principle**

efsa
European Food Safety Authority

ECHA
EUROPEAN CHEMICALS AGENCY

Peer review of the pesticide risk assessment of the active substance glyphosate



Pesticide Action Network Europe

1

Bernhard Url
Executive director
European Food Safety Authority
Parma
Italy

Brussels, 13 July 2023

Concerns: EFSA main findings on glyphosate

Dear Bernhard Url,

The recent communication from EFSA on its main findings from the peer review on the risk assessment of glyphosate[1] raises a series of concerns regarding the integrity of the work. We regret to note that the "excellence in science" that your institute should adhere to and promote is compromised and a series of basic legal considerations have not been respected. We are reaching out to you to raise these issues and ask EFSA to reconsider its work.

I. EFSA must respect EU law and EU case law

Main findings (part of):

- Carcinogenic potential & long-term toxicity data gaps for co-formulant &/or impurities
- Impacts on microbiome
- Neurotoxicity potential
- Impacts on biodiversity

No critical areas of concern?

CAoC ***"when the approval criteria laid down in Reg. 1107/2009 (Art 4) are not met"***

Case C-616/17 - Blaise ruling

- A product can be authorised only if it has no immediate or delayed harmful effect on human health
  - *Should exhibit no long-term carcinogenicity and toxicity*

- The authorisation procedure must necessarily include an assessment of :
  - *The effects of the active substance & cumulative effects of those substances*
  - *The combined effects with other constituents of that product.*

- The burden of proof lies on the applicant:
  - *tests, analyses and studies of the product must exclude, in the light of current scientific and technical knowledge, the risk that that product exhibits such carcinogenicity or toxicity*

- The Regulation -does not exempt- the applicant from submitting tests of long-term carcinogenicity and toxicity relating to the plant protection product

Mammalian toxicology active substance Vs product - RAR

		Glyphosate	MON 52276
Acute toxicity			
Oral		39	1
Dermal		27	1
inhalation		22	1
skin irritation		24	1
eye irritation		26	1
skin sensitization		23	2
Short-term toxicity (28 or 90 days)		41	0
Genotoxicity	in vitro	44	3
	in vivo (cells)	20	0
Long-term toxicity & carcinogenicity		16	0
Reproductive toxicity	Generational	11	0
	Developmental	20	0
Neurotoxicity	Acute	2	0
	short-term	4	0
	DNT (trimesium salt)	1	0
Endocrine disruption	in vitro	4	0
	in vivo (tier 3)	4	0

Reality check

The EU assessment has concluded there is no indication of long-term toxicity of the representative formulation (carcinogenicity, genotoxicity, developmental neurotoxicity, microbiome disruption etc):

- *by disregarding all the evidence from scientific literature, and*
- *without long-term toxicity tests for the whole product nor for all its ingredients individually*

Case C-616/17 Blaise ruling

The precautionary principle *"…entails that,* ***where there is uncertainty*** *as to the existence or extent of risks to human health****, protective measures*** *may be taken* ***without having to wait until the reality and seriousness of those risks become fully apparent****.*

…because the results of studies conducted ***are inconclusive***

… the risks to health resulting from the use of those ***active substances*** *and* ***those plant protection products****.*

…the precautionary principle justifies the adoption of restrictive measures"

Pesticide Action Network Europe

Conclusion:

Based on the different evidence on the impact of glyphosate & glyphosate-based products on human health and the environment & according to EU pesticide law and case law, glyphosate should not be approved for use in agriculture.

Thank you

The contents of this publication are the sole responsibility of PAN Europe and do not necessarily reflect the opinion of the European Union.

Assessment of active substance Vs products

Active substance	Product
Data requirements AS	A range of long-term toxicity tests
Data requirements PPPs	In-vitro
Ingredients (co-formulants, impurities)	Often no data or very limited

Animal cancer studies

"The observed increases in tumour incidences were all non-significant in pairwise comparisons with control groups by the Fisher's exact test (2-sided). However, ***several of the findings were positive when tested using the Cochran-Armitage trend test****. In two of the studies (CA 5.5/016, 2001; CA 5.5/018-019, 1997), tumours were observed at multiple sites in males in the top dose groups*."

ECHA opinion 2022, p. 72

comparison test such as the Fisher exact test (Fisher, 1950) asks whether an incidence in one dose group is increased over the control group. By convention, for both tests a statistically significant comparison is one for which p is less than 0.05 that the increased incidence is due to chance. Significance in either kind of test is sufficient to reject the hypothesis that chance accounts for the result. A statistically significant response may or may not be biologically significant and vice versa. The selection of a significance level is a policy choice based on a trade-off between the risks of false positives and false negatives. A significance level of greater or less than 5% (the most common

OECD Guidance document 116

Glyphosate & carcinogenicity

- ✓ Evidence from epidemiology studies
- ✓ Evidence from cancer studies
- ✓ Evidence on the potential underlying mechanism & genotoxicity

Evidence on genotoxicity

Prof. Knasmüller (Centre of Cancer Research, Vienna):
ECHA's conclusions "…*are based on (applicants') old tests; scientific findings from literature indicate that glyphosate causes DNA damage in organs other than bone marrow**. Two validated OECD guideline-based tests** that could confirm this evidence **are missing** from the applicant's dossier*."

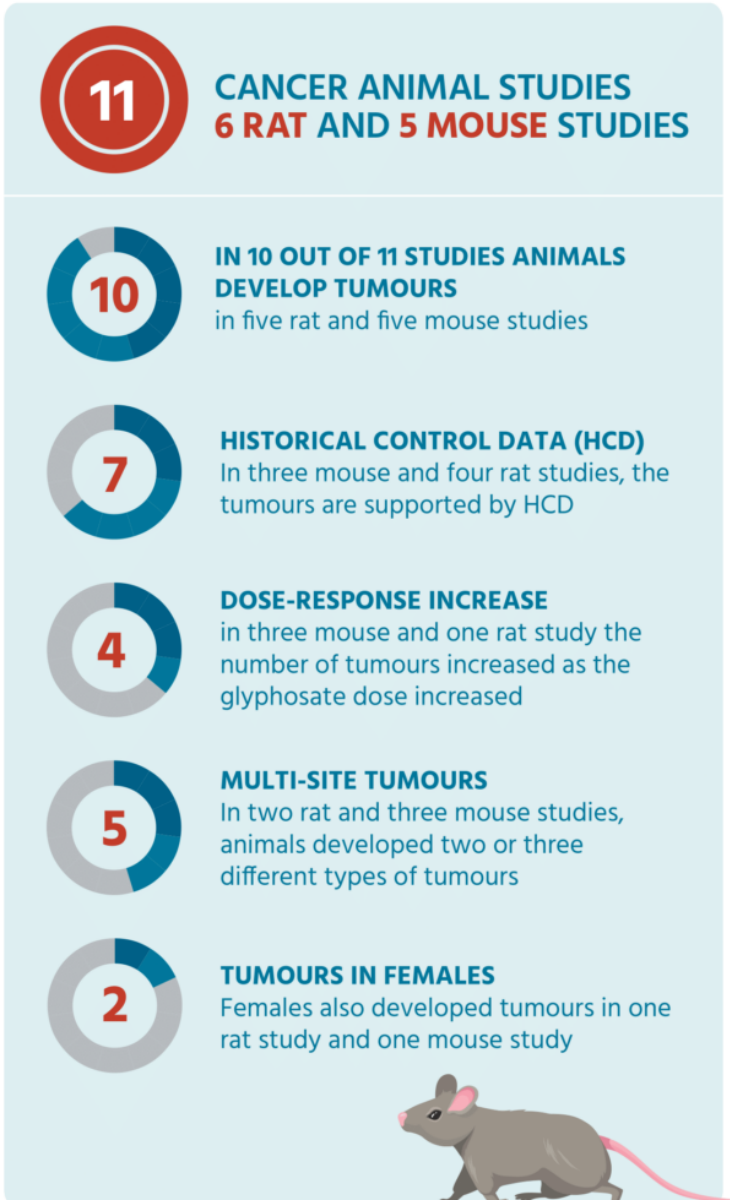
ECHA opinion 2022, p. 48

- the genotoxicity observed for glyphosate in some studies is likely to be caused by indirect mechanisms.
- Glyphosate appears to induce transient DNA strand breaks as observed in the in vitro and in vivo Comet assays … however, no reliable in vivo Comet assays were included in the CLH dossier in relevant target organs
- There is also some evidence that glyphosate may induce oxidative stress in certain cells and tissues with the potential to induce oxidative DNA-lesions that may lead to mutations if not repaired….
- **Noting the absence** of a Comet assay conducted according to OECD TG 489 in relevant tissues as well as a TGR somatic and germ cell gene mutation assay (OECD TG 488), the biological importance of such DNA lesions in relation to mutagenicity **is equivocal**.."

Glyphosate & cancer studies

OECD: The trend test is preferred

- ✓ Evidence from cancer studies
- ✓ Evidence from epidemiology studies
- ✓ Potential underlying mechanism & genotoxicity



Source: Health and Environment Alliance, 2022

EU law

Regulation (EC) 1272/2008 (CLP- hazard assessment):

"*This Regulation should ensure* ***a high level of protection of human health and the environment*** *as well as the free movement of chemical substances, mixtures and certain specific articles, while enhancing competitiveness and innovation*."

Regulation (EC) 178/2002 (General Food Law):

EFSA's missions: *"The Authority (EFSA) shall contribute to* ***a high level of protection of human life and health****, and in this respect take account* ***of animal health and welfare, plant health and the environment****, in the context of the operation of the internal market."*

Is the carcinogenicity of glyphosate (active substance) only the tip of the iceberg?