

16<sup>th</sup> March 2022

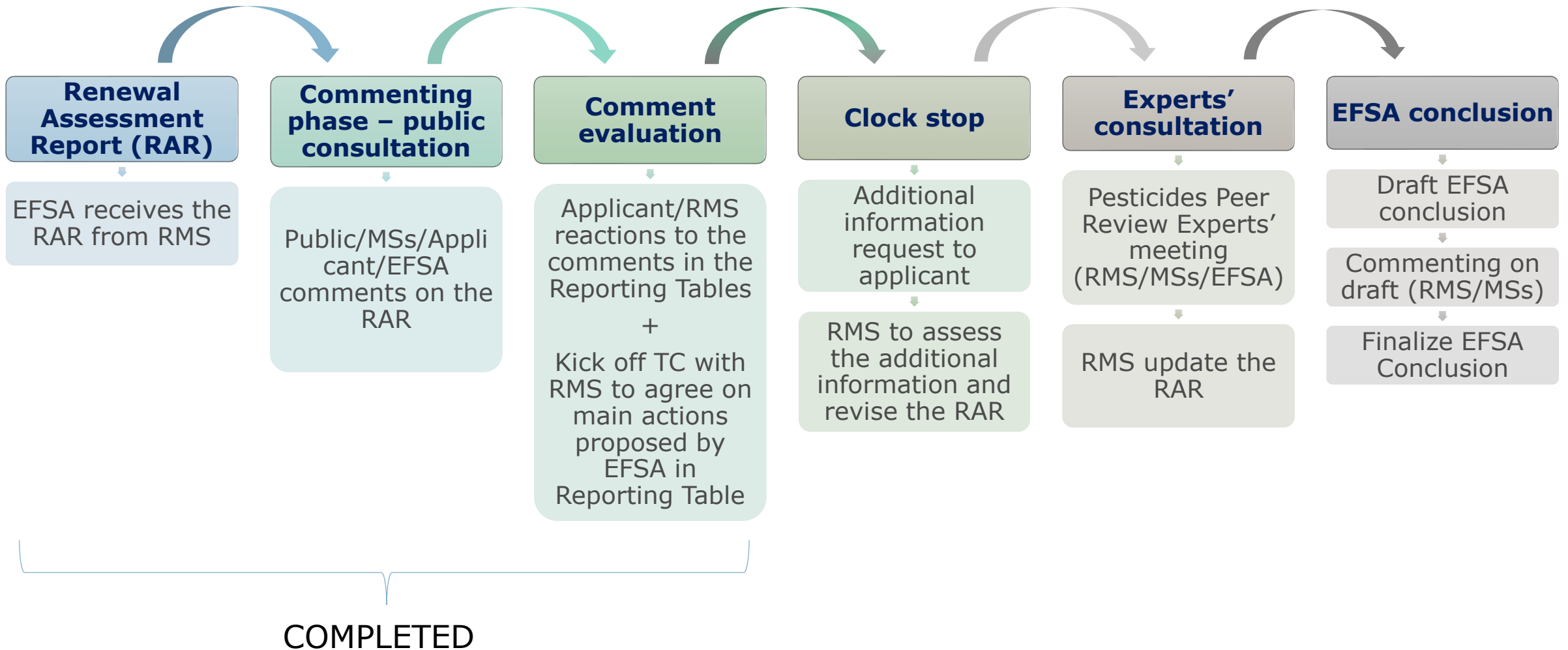


# Glyphosate renewal assessment

Martina Panzarea  
*Mammalian Toxicology Team*  
Pesticide Peer Review Unit

Trusted science for safe food

# RENEWAL OF APPROVAL OF ACTIVE SUBSTANCES

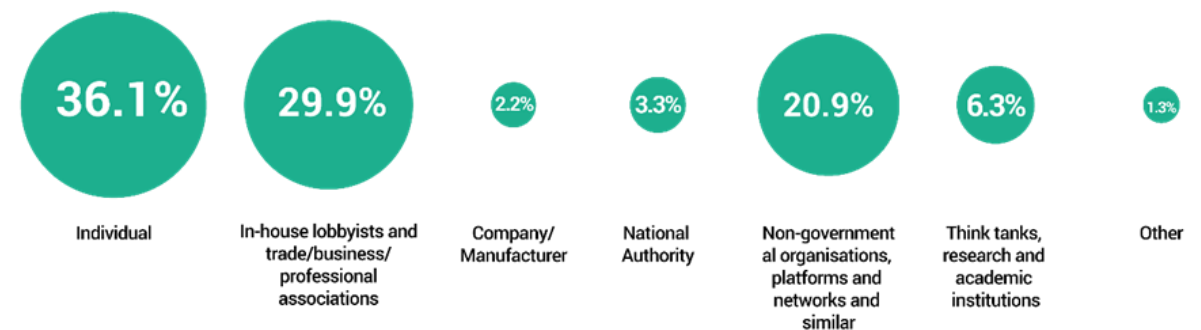


- **EFSA/ECHA parallel public consultation : 23 September – 22 November 2021**
- **368** total comments received from during the **public consultation**
- **2447** total comments from MSs (i.e. AT, IT, DE, DK, BE, IE, FI, LT, PL, SI), EURLs, Applicant, EFSA during the EFSA **peer review process**

Number of comments per section		
Sections	No. comments	Percentage
Physico-chemical properties	126	34.2%
Mammalian toxicology	203	55.2%
Residues	3	0.8%
Environmental fate and behaviour	15	4.1%
Ecotoxicology	21	5.7%
<b>Grand total</b>	<b>368</b>	<b>100%</b>

Number of comments per section		
Sections	No. comments	Percentage
General	7	0.3%
Physico-chemical properties	316	15.3%
Mammalian toxicology	704	34.1%
Residues	170	8.2%
Environmental fate and behaviour	392	19.0%
Ecotoxicology	474	22.9%
Confidential Volumes 4	384	15.7%
<b>Grand total</b>	<b>2447</b>	<b>100%</b>

EFSA: Type of submitters



- **Comments received** covering all the 5 main sections:
- **2858 pages** including comments from all actors (MS, EFSA, Applicant and public) as well as the EFSA considerations for further actions included in the column 4
- **388 data requirements** for Applicant –of which **86** in **mammalian toxicology section**
  - Applicant was asked to submit all the additional information requested during the clock stop that are relevant for the classification **also to ECHA** for consideration during the opinion development
- **86 points** to be discussed at the experts' meetings
  - **43** experts' consultation points will be on mammalian toxicology area, including **genotoxicity, carcinogenicity, developmental and reproductive toxicity** endpoints.

## Long-term toxicity and Carcinogenicity

- Relevance of **salivary glands findings** observed in various studies
- **Weight of evidence (WoE)** on relationship between glyphosate exposure and risk of **non-Hodgkin lymphoma (NHL)** from epidemiological studies
- Relevance of effects observed in **carcinogenicity studies, statistical analysis approach, use of HCD, appropriateness of the doses tested**
- Potential for induction of **oxidative stress**

## Genotoxicity

- Reliability and relevance of the studies (e.g. Ames test, in vitro CA, in vitro MN)
- **WoE** for genotoxicity (gene mutation, clastogenicity and aneugenicity, DNA damage)

## Reproductive and developmental toxicity

- **Human relevance** of rabbits in the developmental toxicity assessment
- **NOAEL/LOAEL reproductive tox** studies (parental, offspring, reproductive); **NOAEL/LOAEL developmental toxicity studies** (developmental and maternal)
- relevance and reliability of HCD for **developmental toxicity parameters**
- Non monotonic dose-response (NMDR) effect, **retroesophageal right subclavian artery** (dev tox)
- **Epidemiological data** on relationship between exposure to glyphosate and reproductive toxicity

**THANK YOU FOR YOUR ATTENTION**



## Subscribe to

[efsa.europa.eu/en/news/newsletters](https://efsa.europa.eu/en/news/newsletters)  
[efsa.europa.eu/en/rss](https://efsa.europa.eu/en/rss)



## Receive job alerts

[careers.efsa.europa.eu](https://careers.efsa.europa.eu) – job alerts



## Follow us on Twitter

[@efsa\\_eu](https://twitter.com/efsa_eu)  
[@plants\\_efsa](https://twitter.com/plants_efsa)  
[@methods\\_efsa](https://twitter.com/methods_efsa)  
[@animals\\_efsa](https://twitter.com/animals_efsa)



## Follow us Linked in

[Linkedin.com/company/efsa](https://linkedin.com/company/efsa)



## Contact us

[efsa.europa.eu/en/contact/askefsa](https://efsa.europa.eu/en/contact/askefsa)



SAVE  
THE  
DATE!

HEALTH • ENVIRONMENT • SOCIETY

**21-24 JUNE 2022** - Brussels and online

[One2022.eu](https://www.one2022.eu)

[#OneEU2022](https://twitter.com/OneEU2022)